

Technological University Dublin  
College of Business  
3S Group

The 2P-K Framework  
**A Personal Knowledge Measurement  
Framework for the Pharmaceutical  
Industry**

By

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A thesis submitted in fulfilment of the requirements for the award of Doctor of  
Philosophy (PhD)

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## **Abstract**

Knowledge is a dynamic human process to justify our personal belief in pursuit of the truth. The intellectual output of any organisation is reliant upon the individual people within that organisation. Despite the eminent role of personal knowledge in organisations, personal knowledge management and measurement have received little attention, particularly in pharmaceutical manufacturing. The pharmaceutical industry is one of the pillars of the global economy and a knowledge-intensive sector where knowledge is described as the second product after medicines. The need of measurement to achieve effective management is not a new concept in management literature. This study offers an explanatory framework for personal knowledge, its underlying constructs and observed measures in the pharmaceutical manufacturing context.

Following a sequential mixed method research (MMR) design, the researcher developed a measurement framework based on the thematic analysis of fifteen semi-structured interviews with industry experts and considering the extant academic and regulatory literature. A survey of 190 practitioners from the pharmaceutical manufacturing sector enabled quantitative testing and validation of the proposed models utilising confirmatory factor analysis. The pharmaceutical personal knowledge framework was the fruit of a comprehensive study to explain and measure the manifestations of personal knowledge in pharmaceutical organisations.

The proposed framework identifies 41 personal knowledge measures reflecting six latent factors and the underlying personal knowledge. The hypothesised factors include: regulatory awareness, performance, wisdom, organisational understanding, mastership of product and process besides communication and networking skills. In order to enhance the applicability and flexibility of the measurement framework, an abbreviated 15-item form of the original framework was developed. The abbreviated pharmaceutical personal knowledge (2P-K) framework demonstrated superior model fit, better accuracy and reliability.

The research results reveal that over 80% of the participant pharmaceutical organisations had a form of structured KM system. However, less than 30% integrated KM with corporate strategies suggesting that KM is still in the early stages of development in the pharmaceutical industry. Also, personal knowledge measurement is still a subjective practice and predominately an informal process. The 2P-K framework offers researchers and scholars a theoretically grounded original model for measuring personal knowledge. Also, it offers a basis for a personal knowledge measurement scale (2P-K-S) in the pharmaceutical manufacturing context.

Finally, the study had some limitations. The framework survey relied on self-ratings. This might pose a risk of social desirability bias and Dunning–Kruger effect. Consequently, a 360-degree survey was suggested to achieve accurate assessments. Also, the model was developed and tested in an industry-specific context. A comparative study in similar manufacturing industries (e.g. chemical industries) is recommended to assess the validity of the current model or a modified version of it in other industries.


## Declaration

I certify that this thesis which I now submit for examination for the award of Doctor of Philosophy, is entirely my own work and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

This thesis was prepared according to the regulations for postgraduate study by research of the Technological University Dublin and has not been submitted in whole or in part for an award in any other Institute or University.

The work reported on in this thesis conforms to the principles and requirements of the Institute's guidelines for ethics in research.

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## Publications

### Journal Articles:

- Ramy, A., Floody, J., Ragab, M. A., & Arisha, A. (2018). A scientometric analysis of Knowledge Management Research and Practice literature: 2003–2015. *Knowledge Management Research & Practice*, 16(1), 66–77.  
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### Conference Papers:

- Ramy, A., Floody, J., Ragab, M. A. F., Arisha, A., & Schiuma, G. (2017). Scientometric Analysis of Knowledge Management Research and Practice (KMRP): 2003 -2015. In *12th International Forum on Knowledge Asset Dynamics* (pp. 1–24).
- Abohamad, W., Ramy, A., & Arisha, A. (2017). A Hybrid Process-Mining Approach for Simulation Modelling of Hospitals. In *Winter simulation conference 2017*.



*To my granny, my mum, my sister and my beloved wife*



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## Glossary of Terms and list of Abbreviation

<b>APQC</b>	American Productivity & Quality Center
<b>CAQDAS</b>	Computer Assisted Qualitative Data Analysis Software
<b>CFA</b>	Confirmatory Factor Analysis
<b>CFI</b>	Comparative Fit index
<b>COP</b>	Communities of Practice
<b>CR</b>	Critical Realism
<b>DIT</b>	Dublin Institute of Technology
<b>EFPIA</b>	The European Federation of Pharmaceutical Industries and Associations
<b>EVA</b>	Economic Value Added
<b>FDA</b>	Food and Drug Administration
<b>GXP/GMP</b>	Good Practice/ Good Manufacturing Practice
<b>HC</b>	Human Capital
<b>HCVM</b>	Human Capital Value Metric
<b>HRCA</b>	Human resource costing & accounting
<b>HRM</b>	Human Resource Management
<b>IAM</b>	Intangible Asset Monitor
<b>ICH</b>	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
<b>ICMRA</b>	International Coalition of Medicine Regulatory Authorities
<b>IMID</b>	International Medicinal Inspectorate Database
<b>IMPACT</b>	The International Medical Products Anti-Counterfeiting Taskforce
<b>MMR</b>	Mixed Method Research
<b>MTB ratio</b>	Market to Book Ratio
<b>MVA</b>	Market Value Added
<b>NFI</b>	Normed Fit Index
<b>OKM</b>	Organisation Knowledge Management
<b>PIC/S</b>	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
<b>PKM</b>	Personal Knowledge Management
<b>PRISMA</b>	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
<b>QRM</b>	Quality Risk Management
<b>RC</b>	Relational Capital
<b>RMSEA</b>	The Root Mean Square Error of Approximation
<b>ROA</b>	Return on Assets
<b>ROE</b>	Return on Equity
<b>ROI</b>	Return on Investment
<b>ROS</b>	Return on Sales
<b>SC</b>	Structural Capital
<b>SEM</b>	Structural Equation Modelling
<b>SJT</b>	Situational Judgement Test
<b>SNA</b>	Social Network Analysis
<b>TU Dublin</b>	Technological University Dublin
<b>UNICEF</b>	The United Nations Children's Fund
<b>VAIC</b>	Value added intellectual coefficient
<b>WHO</b>	World Health Organisation



## **Chapter 1 : Introduction**

### 1.1 *Background*

By the end of the twentieth century, the notion of managing knowledge had evolved at the corporate level as organisations acknowledged the need to leverage and exploit their knowledge resources (Carmeli & Tishler, 2004). Knowledge Management (KM) is considered a vital organisational function and a key source of sustainable competitive advantage (Anatolievna Molodchik et al., 2014). While KM is concerned with the use of technology and management processes for effective management of organisational knowledge, personal knowledge management (PKM) helps the individual be more effective in the personal, organisational and social environment (Pauleen & Gorman, 2010). PKM illustrates the knowledge workers' endeavour to use knowledge to support their day-to-day activities through problem-solving and learning practices (Hine et al., 2008). However, the value of PKM is not just limited to the individual level as the combination of both PKM and Organisational Knowledge Management (OKM) can lead to a more effective management of knowledge across the whole organisation (Kassim et al., 2018).

Moreover, the economic impact of KM within the organisation and its influence on financial performance and market competitiveness has been evident (Andreeva & Kianto, 2012). The recognition of the fundamental role of knowledge in value creation spawned the concept of the *Knowledge Economy*, making it one of the pillars of contemporary management thinking (Roberts, 2009). This made KM a predominant field within the business and management landscape for both researchers and practitioners (Moustaghfir & Schiuma, 2013). In the pharmaceutical industry, knowledge is described as the second product after medicines (Riddell & Goodman, 2014) making it an important part of the contemporary knowledge economy. The pharmaceutical industry is not only a knowledge-intensive industry but also a leading economic partner with huge investments in innovation and research. According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the

Pharmaceutical industry employs more than 700,000 employees in Europe, 16% of them working in pharmaceutical R&D. It was the preeminent sector regarding R&D intensity and expenditure as a percentage of net sales (14.4%) in 2014 followed by software & computer services (10.1%) and technology hardware & equipment (8.0%) (EFPIA, 2015, 2016). It is also considered the top investing sector in R&D according to the Industrial R&D Investment Scoreboard in both US and EU (EU, 2015). More than 19% of total business R&D expenditure worldwide comes from the pharmaceutical and biotechnology sector (EFPIA, 2018). In 2016 alone, the European pharmaceutical sector invested over 34 billion euros in R&D to counteract the wild competition with its rivals from the US and emerging economies (EFPIA, 2018).

This research represents a study of the personal knowledge measurement in the pharmaceutical manufacturing context. The research aims to address the identified knowledge gaps in both the theory and application of KM and measurement as explained in the next section.

### *1.2 Research rationale*

This section presents the rationale for the research. It outlines the apparent need to measure the personal knowledge of knowledge workers, the lack of research to date, the potential contribution to knowledge and finally the motives for selection of the pharmaceutical manufacturing as a context for this study.

The duality of the organisational knowledge and personal knowledge was pointed out in several studies arguing that they are distinct but interdependent (Bhatt, 2002; Chatti, 2012; Gang & Yi, 2009; Hine et al., 2008). It has been argued that a successful PKM would result in an improved utilisation of personal knowledge and effective social exchange of knowledge at individual employee level (Razmerita et al., 2009). The OKM integrates a variety of individual

knowledge bases for more efficient performance. That is to say, the intellectual output of any organisation is reliant upon the individual people within that organisation (Hine et al., 2008).

Furthermore, individual participation is important for successful KM in any organisation. One of the explanations is the notion that knowledge is personal by its nature (Chatti, 2012; Vladova et al., 2016). The philosophical foundations of knowledge view the person as a legitimate participant of KM (Rechberg & Syed, 2014). In knowledge creation literature, Nonaka's SECI model acknowledged the role of socialisation and personal interactions for knowledge creation (Nonaka & Takeuchi, 1995). Nonaka emphasised the human and personal nature of knowledge as he described it as: "*a dynamic human process of justifying personal belief toward the truth*" (Nonaka et al., 2000). Bhatt (2002) affirms that knowledge monitoring and control is challenging for organisations. The organisation internalises only a part of the generated knowledge while the rest is internalised by individuals. Thus, capturing and codifying knowledge won't help if the organisation failed to identify who can find and interpret this knowledge or to maintain the social networks required to get the work done (Parise et al., 2006).

Despite this eminent role of personal knowledge in organisations, the research on personal knowledge is quite scant. Cranefield & Prusak (2016) argues that our knowledge on individual approaches to KM is incomplete as little is known on how individual employees handle knowledge-related problems. The personal knowledge has so far received little attention by KM scholars in contrast to the organisational knowledge. Although the organisational knowledge has been the focus of KM scholars, a proper explanation of individual-knowledge relationships is missing from KM literature (Tom H Davenport, 2016; K. Wright, 2005). PKM is a relatively new topic that emerged in the recent years to manage knowledge efficiently (Gang & Yi, 2009). Pauleen & Gorman (2010) confirms that little conceptual or empirical research has been carried out in the field of personal knowledge (Pauleen & Gorman,

2010). KM literature traditionally explored KM efforts of organisations and neglected to study how knowledge workers leverage their knowledge at the individual or personal level (Kassim et al., 2018). This growing need to manage personal knowledge is transforming KM from organisation-centric to worker-centric with more attention to the personal knowledge of individuals (Jarrahi et al., 2019).

Knowledge measurement is not an exception from the lack of attention to personal knowledge. Whereas several models (e.g. Tobin's Q (Tobin, 1969), Skandia Navigator (Edvinsson, 1997) and the IC Rating (Jacobsen et al., 2005)) offer a method to quantify knowledge assets within the organisation (Ragab & Arisha, 2013a), the extant literature provides little or no way to measure the personal knowledge of individual employees. The need of measurement to achieve effective management is not a new concept in management. Since Peter Drucker coined what is known as Management by Objectives (MBO), managers have adopted several measures for key organisational objectives leading to the notion that "*If it can't be measured, it can't be managed*" (Dumay & Rooney, 2011; Greenwood, 1981).

The current study addresses this theoretical gap and proposes a framework to explain and measure the personal knowledge of individual employees enabling organisations to identify knowledge holders. As knowledge is context-specific that depends on a particular time and space (Hoe, 2006; Nikkhah et al., 2018; Nonaka et al., 2000; Vladova et al., 2016), the pharmaceutical manufacturing was chosen as the context for this study. The pharmaceutical industry is a knowledge-intensive sector, however, this sector has not received adequate attention from KM scholars. According to a Scientometric review carried out by the author of over 500 KM articles in 17 different industries, less than 1% of the reviewed research articles had empirical applications in the pharmaceutical industry (Ramy et al., 2018).

It is worth noting that personal knowledge receives high consideration in pharmaceutical regulations. Pharmaceutical personnel are required to have adequate knowledge before

engaging in any manufacturing task (Volume 4: Good Manufacturing Practice Annex 6, 2010; WHO, 2005, 2014). The increasing business and regulatory pressures for managing knowledge make the ability to locate and visualise this valuable abstract resource within organisations vitally important. In addition, Pauleen and Gorman (2010) found that the effective management of personal knowledge leads to effective OKM. In other words, the identification of knowledge holders can enable management to utilise their knowledge to achieve organisational objectives. Moreover, effective measurement of personal knowledge could provide solid evidence that the organisation has the necessary knowledge capabilities to meet its regulatory commitments.

In 2008, the ICH Q.10 pharmaceutical standard introduced KM as an enabler to the Pharmaceutical Quality System (PQS). Product and process knowledge is required to be managed throughout the product life cycle including the transfer of product and process knowledge between development and manufacturing as well as within or between manufacturing sites to achieve product realisation. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach, and ongoing product improvement. KM is believed to facilitate continual improvement, the establishment of a state of control, and achievement of product realisation (ICH, 2009). The World Health Organisation (WHO) demands a science-based understanding of the KM process and Quality Risk Management (QRM) to support their quality decisions and regulatory commitments (WHO, 2013). Similarly, the US Food and Drug Administration (FDA) encourages process understanding and KM initiatives for preventing and detecting data integrity issues (FDA, 2016c). However, current guidelines provide flexible principles rather than rigid frameworks for KM (WHO, 2011b). Hence, the development of better understanding of the personal knowledge in the pharmaceutical industry would assist the progress and the implementation of the regulatory expectations based on a bottom-up KM approach.

Consequently, in the absence of effective KM policies, Knowledge loss is a growing risk for business (Jennex, 2014). The author assumes that the lack of personal knowledge measurement frameworks would hinder the early identification of knowledge holders before they leave or retire. Warnings of the potentially catastrophic effect of the retirement of baby boomers and the subsequent knowledge loss have concerned both academics and practitioners (Trugman-Nikol, 2011). The research-based pharmaceutical industry is one of the main high-tech employers in Europe and globally. It employs a significant portion of knowledge workers in Europe making this industry a barrier against “brain drain” from the European continent (EFPIA, 2018). In 2013, the Pharma Engagement survey conducted by *Randstad* - a multinational human resource consulting firm - showed that 37% of respondents from the pharmaceutical sector intend to leave their job and move to other employers in the next six months (Randstad, 2013) confirming the fears of the loss of knowledge holders in this particular sector.

### 1.3 *Research Aim and Questions*

A research question is a fundamental element of research work, serving to narrow down the focus of the study and therefore, must be clear and well-formulated (Bryman, 2015). This research encompasses one major research question to address the overarching research aim:

- RQ: How is the personal knowledge conceptualised and measured in the pharmaceutical manufacturing context?

The study seeks to examine the Personal Knowledge (PK) measurement in the under-researched context of pharmaceutical manufacturing. The following represents the research aim:

Exploration, development and validation of a personal knowledge measurement framework in the pharmaceutical manufacturing context.

### 1.4 Research Objectives

**Objective 1** *Gain an in-depth understanding of the current practices of the personal knowledge management and measurement focusing on the pharmaceutical manufacturing context.*

This objective is tackled in two phases of this study: the literature review and the exploratory interviews. A literature review is needed to provide the necessary awareness and ability to interpret the published knowledge. It enables the researcher to identify potential contradictions and address the gaps in the existing theories (Jesson et al., 2011). Both quantitative and qualitative approaches are used in this thesis to identify and map the growing research trends in the PKM and knowledge measurement. This review provides an in-depth understanding of the existing theories and frameworks that have been developed by previous researchers.

As the study adopts an industry-specific context, the review included a contextual chapter to review the KM literature in the pharmaceutical industry and explore the regulatory expectations. The pharmaceutical industry is a highly regulated industry (Calnan et al., 2018). KM is recently seen as a better way for proactively managing patient risk and making better risk-based decisions. Historically, and up until the release of the ICH Q, 8, 9, and 10 standards, pharmaceutical regulators paid more attention towards science and risk-based approaches for drug manufacturing and control. Concepts such as “*science*” or “*product/process understanding*” routinely replaced the word “knowledge” (Calnan et al., 2018). In 2008, the International Conference on Harmonization (ICH) described KM along with quality risk management as the enablers of pharmaceutical quality systems (ICH, 2008).

Moreover, the WHO dedicated a special annex (TRS 961 Annex 7) for technology transfer in pharmaceutical manufacturing (WHO, 2011b). Similarly, several international regulatory bodies issued regulations for managing and regulating knowledge and ensuring its communication and transfer (e.g. FDA, 2016; WHO, 2016). As the proposed measurement framework is designed to work in the pharmaceutical industry, the review of all relevant regulatory guidelines is necessary to understand the regulatory expectations of authorities and



compare it with the current practices. The study addresses the gap between regulatory requirements (regulators) on one hand and KM research (academics) and application on the other (practitioners).

Finally, the researcher's objective of the exploratory phase is to discover the current practices and unveil the underlying truth or the inner character of the phenomena under study. The study combines the knowledge extracted from literature with primary data collected from industry experts to draw a clear picture of KM practices in pharmaceutical manufacturing with a particular focus on personal knowledge measurement. This picture reflects not only the in-field interpretations of regulatory guidelines about KM but also the level of maturity of KM in the pharmaceutical industry. It also assesses the value of the personal knowledge measurement among knowledge holders in the pharmaceutical sector.

**Objective 2** *The development of a personal knowledge measurement framework for knowledge workers in the pharmaceutical manufacturing context.*

Identification and critical analysis of the extant frameworks is a necessary step that proceeds the framework development phase. This step outlines the commonalities that can be identified as well as the gaps to be addressed. As the study of the personal knowledge is a relatively new field of research (Cranefield & Prusak, 2016), particularly in the pharmaceutical industry, both primary data collected during the exploratory study, along with learnings from previous models are utilised to develop a new personal knowledge measurement framework for the pharmaceutical manufacturing sector. The developed framework offers an explanation of the different elements and manifestations of personal knowledge in the featured context.

During the exploratory phase, the main constructs of the measurement framework are identified and refined to build the main constructs of the measurement framework. The next step is testing of the proposed constructs in the validation phase. The study sheds light on knowledge measurement process in KM literature. An abductive approach is taken where the

researcher engages both the extant literature with the exploratory study findings in what is known as “*dialectal shuttling*” (Bryman & Bell, 2015) to develop the measurement framework. The developed model would be tested in the subsequent deductive phase.

**Objective 3** *Validate and optimise the proposed PK measurement framework in the pharmaceutical manufacturing sector.*

Representing the final phase of the empirical study, the conceptual framework, developed during the abductive phase, is tested and validated through a survey of a suitable sample of practitioners from the pharmaceutical industry. After the identification of the factors underlying the personal knowledge, Confirmatory Factor Analysis (CFA) is employed to test and optimise the proposed framework. CFA is a widely-used statistical tool in the organisational sciences (Crede & Harms, 2019). CFA is a technique of Structural Equation Modelling (SEM) with a particular focus on the analysis and measurement of priori measurement models. This means that the number of measures and their relationship with the underlying factors must be specified before analysis (Kline, 2015).

At the end of the validation phase, the proposed framework would be assessed for its applicability within the pharmaceutical manufacturing sector. More details about the validation process are included in chapter four.

### 1.5 Operational Definitions

Knowledge: can be defined in this report as “*a dynamic human process of justifying personal belief toward the truth*” (Nonaka et al., 2000).

Knowledge context: is the circumstances in which knowledge is produced, transferred, and applied (Lisciandra & Herfeld, 2019). This research is conducted in the pharmaceutical manufacturing context.

Knowledge workers: are those workers who think for a living and their main capital is their knowledge (Thomas H Davenport, 2005). In this report it refers to the qualified employees (e.g. chemists, pharmacists, biologists and engineers) working in the pharmaceutical manufacturing in technical roles.

Manufacturing: According to the WHO technical report (Series 986, Annex 2), manufacturing is defined as “all operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls” (WHO, 2014).

Measurement is the act of collecting data to quantify the value of a business metric (tangible or intangible) (Evans & Lindsay, 2013).

Personal Knowledge (PK): this term is used within this report to refer to the knowledge held by individuals. PK and individual knowledge (IK) are used interchangeably in this report.

### *1.6 Report Layout*

The outline of this report is comprised of eight chapters as follows:

1. **Chapter One** introduces the research project and its objectives and outlines the structure of the thesis.
2. **Chapter Two** is a comprehensive review of the theories of the Personal Knowledge, PKM and knowledge measurement frameworks. This is the main literature review chapter of the thesis.
3. **Chapter Three** presents a contextual chapter that reviews KM in the pharmaceutical industry. It also focuses on the regulatory expectations of the different regulatory authorities regarding KM. Different knowledge processes and themes are classified in a comprehensive taxonomy and the main approaches for developing knowledge assessment measures are identified.

4. **Chapter Four** describes the research methodology adopted to address the research questions. Based on the critical realistic stance of the research, the mixed-method research design is discussed and justified for its ability to achieve the research objectives in an inclusive manner. A research plan of five distinct stages is detailed by elucidating the aims, methods and techniques used in each stage.

5. **Chapter Five** investigates conceptualisations of personal knowledge and the current status of knowledge measurement in pharmaceutical organisations. This chapter encompasses a thematic analysis of a set of interviews conducted with a number of pharmaceutical industry experts. Thematic analysis is utilised at this stage for data analysis and the interpretation of key patterns and associations. The conceptual framework is developed at the end of this chapter in light of the current literature and the primary data.

6. **Chapter Six** presents the results of the quantitative phase. The conceptual model is tested in a suitable sample of pharmaceutical practitioners. The collected data is used to validate and optimise the proposed models using confirmatory factor analysis.

7. **Chapter Seven** is the discussion chapter where the findings are critically examined and relevant literature is consulted. Moreover, the theoretical and practical implications of the research are approached. Limitations and future research opportunities are tackled at this chapter.

8. **Chapter Eight** is where the conclusion of the research and the anticipated contribution to knowledge are presented.

### *1.7 Summary and Conclusion*

The first chapter introduces the research phenomena and provides an overview of the research rationale, aims, research questions, research objectives, operational definitions and the thesis layout. The next chapter will demonstrate the PK and knowledge measurement theories and growing trends as presented in the academic literature.

## **Chapter 2 : Personal Knowledge and Knowledge Measurement**

### 2.1 Introduction

Research in “knowledge” is as old as humankind. Over centuries and millennia, philosophers were concerned with the search for the ontological interpretations of the word “*knowledge*” (Zaidan, 2012). Epistemology is a stand-alone branch of philosophy concerned solely with the theory of knowledge (Lehrer, 2018). In his dialogue with Socrates and Theaetetus, Plato introduced his definition of knowledge which is commonly translated as “*Justified true belief*”. In spite of the criticism of Plato’s classic definition (e.g. Gettier, 1963), it is still widely accepted (Rechberg & Syed, 2014). According to this definition, a person can claim he/she knows that (P) only if that (P) is true because false knowledge is not possible. He/she also believes that (P) and this belief is justified. In other words, “*There is objective knowledge if there is a body of propositions which are true and which it is rational to believe*” (Dawson, 1950).

Knowledge is a social process (Edwards, 2015a; Sense, 2007). It is worth noting that, the western epistemology often demonstrates a static non-human view of knowledge. This understanding fails to address the social and context-specific nature of knowledge. If knowledge loses its context, it is nothing more than information. This leads to a definition of knowledge as “*a dynamic human process of justifying personal belief toward the truth*” (Nonaka et al., 2000). Knowledge is a state of conscious contact of the person with reality (Zagzebski, 2017). It can be also presented as information, professional insights, values, experience and context (Thomas H Davenport & Prusak, 1998). Knowledge also implies having a special competence, acquaintance with someone or something as well as the recognition of something as information (Lehrer, 2018). To make matters more complicated, 13 distinguishable uses of the phrase ‘to know’ were outlined by Mingers (2008) emphasising the notion that there is no one form of “*knowledge*”. In this dilemma of definitions, the highly

cited definition by Nonaka, Toyama and Konno (2000) is the adopted definition of knowledge throughout this report as it magnifies the humanistic and personal nature of knowledge.

In the last decades, the growing interests in information science and bibliographic materials contributed to the emergence of joint frameworks for data, information, knowledge and wisdom to explain the underlying connections (Bernstein, 2011). One of the commonly accepted illustrations for the interrelationships between data, information, knowledge and wisdom is “Knowledge pyramid” or “DIKW hierarchy” (Ackoff, 1989). Wilson’s processing hierarchy is another illustration of the knowledge pyramid incorporating decision and action as the ultimate purpose of knowledge (Edwards, 2015b; Wilson, 1996). However, inaccurately defining data, information and knowledge by each other presented a logical fallacy in the form of circular definitions (Liew, 2013). For the purpose of this research, data can be defined as a stream of raw facts or simply a flow of events and/or transactions that can be captured by organisational systems (Laudon & Laudon, 2016). In order to generate information from this data, data must be processed and organised into categories which are meaningful and useful to users. Knowledge can be extracted from the generated data in the form of patterns, contexts or rules. The collective capability of applying knowledge to solve problems is called “*wisdom*” which includes when, where and how to apply knowledge (Laudon & Laudon, 2016). At the economic level, knowledge is distinguished from other resources within the organisation by non-excludability and non-exhaustibility and consequently a higher risk of knowledge spillover to competitors who did not share the cost of knowledge creation (Arrow, 1962; Audretsch & Keilbach, 2007). Arrow (1962) emphasised that in the absence of legal protection to propriety information, it cannot simply be sold as a commodity in an open market. While full monopoly can offer the needed protection, it would ultimately lead to inefficient allocation and exploitation of information resources (Arrow, 1962). The ability of an organisation to incorporate and utilise the transferred knowledge to create value is known as the Absorptive

Capacity (ACAP) (Carayannis, 2012). However, the success in exploiting the transferred knowledge is a function of prior knowledge of the organisation as it is necessary to evaluate the acquired knowledge and to use it effectively. The prior knowledge includes (but not limited to) basic skills, languages and awareness of modern technologies (Cohen & Levinthal, 1990).

In the next sections, the researcher will explore the prevalent trends of personal knowledge and knowledge measurement literature. This review is deemed to provide a working definition of personal knowledge, to outline the main processes of PKM and to review the prominent knowledge measurement efforts.

### *2.2 Knowledge and Personal Knowledge*

Personal knowledge can be understood as skills, talents and expertise necessary to handle many situations. It allows the person to solve personal and organisational problems and consequently to access new markets and to use new technologies that need specialised expertise (Tajedini et al., 2018). Personal knowledge is particularly concerned with knowledge held by an individual employee in an organisation in contrast to the collective knowledge held commonly by a group (Chua, 2002; Hoe, 2006).

Personal knowledge is not only raw data but a complex spectrum of talents, innate abilities, insights, facts, connections and experiences that generates human decisions, insights and ideas (McLaughlin & Stankosky, 2010). It can refer also to the legitimate and personal beliefs of an individual that enable him/her to respond to problems rapidly without the application of predetermined rules (Tajedini et al., 2018). It is acquired from our memories, documents, intuitions, personal contacts, books or learning from other colleagues (Razmerita, Sudzina, et al., 2009a).

The relationship between knowledge and individuals has been discussed by several scholars. Knowledge is argued to be personal as it is stored in people's head, created and embodied in a



person, applied or even misused by a person (Wright, 2005). Similarly, Davenport and Prusak emphasised that knowledge is created and applied in the mind of the knower ( cited in Razmerita, Sudzina and Kirchner, 2009). By the same token, knowledge is inherently personal as all knowledge is in a way or another tacit or intertwined with tacit knowledge which is personal (Chatti, 2012). While knowledge can be “computerised”, this is considered as “a shadow knowledge” (Völkel & Haller, 2009) as most of the critical organisational knowledge remains in the minds of people (D. G. Pauleen & Gorman, 2010).

However, some scholars defend the subjective nature of personal knowledge. From this perspective, knowledge is personal as people interpret information differently and adopt different ways of reasoning (Razmerita, Sudzina, et al., 2009a). The researcher advocates a realist understanding of human knowledge where the knowledge has an objective reality independent of the person (Popper, 1966). Similarly, Polanyi (1962) referred to the same controversy as the words “*Personal*” and “*knowledge*” might sound contradicting. He argued although true knowledge is universal, impersonal and objective, the apparent contradiction can be resolved by modifying the conception of knowledge. The personal participation of the knower in all acts of understanding does not make our knowing subjective as comprehension is not an arbitrary passive experience. Knowing is objective as it creates a contact with a hidden reality (Polanyi, 1962). In fact, knowledge is created, used and shared among persons in a dynamic human process to justify true personal beliefs (Nonaka et al., 2000; Nonaka & Takeuchi, 1995). The proposed understanding is that personal or human nature of knowledge does not contradict the objective reality of knowledge as it is only related to the generation and transfer dynamic processes, not the reality of what we know. The knowing process is an active comprehension of things known that utilises certain skills (Polanyi, 1962) these skills are owned by the human.

The extant literature makes a distinction between two types of knowledge: personal and organisational knowledge. The ISO 9001:2015 standard defines the organisational knowledge as the organisation-specific information, gained by experience, shared and used to achieve the organisational goals. Although the OKM is a must for any organisation seeking a competitive edge, personal knowledge is the essential core of KM (Zhang, 2009). The identification of personal knowledge is not only a personal responsibility but also an organisational one (Tajedini et al., 2018). However, it seems difficult to convince traditional companies by the value of personal knowledge for the success of OKM (Pauleen & Gorman, 2010). By the same token, the use of technology for OKM is insufficient for successful KM as the core knowledge assets reside in people (Zhang, 2009). Knowledge can be articulated in the formal business processes and patents but creative and innovative tacit knowledge is held by individuals (Pauleen & Gorman, 2010). It is believed that the bottom-up approach for PKM would reduce friction and mistrust associated with the traditional top-down KM (McLaughlin & Stankosky, 2010). From this understanding, PKM is not about self-promotion, but instead about making employees more effective in the organisation (Agnihotri & Troutt, 2009; Mittelman, 2016). PKM is the path for successful KM in the organisation as a whole (D. G. Pauleen & Gorman, 2010).

Indeed, the idea of managing PK is intertwined with Drucker's concept of "*knowledge worker*" (Drucker, 1999). A person holding mission-critical knowledge who uses knowledge to solve problems and make decisions is described as a knowledge worker (Mittelman, 2016; Razmerita, Sudzina, et al., 2009a). A successful knowledge worker needs to develop critical thinking, problem solving, creativeness and decision making skills (Agnihotri & Troutt, 2009). In addition, effective communication, ability to learn, the ability for physical and virtual collaboration, critical thinking, digital skills and managing information in a particular context are recommended skills for a knowledge worker (Mittelman, 2016). Those individual skills

are influenced by education and work experience (Wright, 2005) where the role of experience can be easily realised by comparing experienced and novice workers (Beijaard et al., 2000). PKM focuses on how people become knowledge workers in the organisation (Pauleen, 2009).

Moreover, the nature of employment of knowledge workers is changing because a life-long job is no longer the norm (McLaughlin & Stankosky, 2010) and dramatic changes in the future of employment have taken place in response to Information and Communications Technology (ICT) breakthroughs that allow the computerisation of job tasks (Schmitt, 2016). In response to that, the knowledge worker has to act as a personal knowledge entrepreneur and engage in lifelong learning to stay competitive in the jobs' market (Jarrahi et al., 2019; McLaughlin & Stankosky, 2010). Last but not least, the performance (of a knowledge worker) is a proxy indicator of his/her knowledge and experience as it is continuously assessed through social interactions (Wright, 2005). This consorts with the common understanding of knowledge as a capacity to act and is being associated with human actions (Iazzolino & Laise, 2013; Nonaka & Takeuchi, 1995).

Knowledge provides the power that managers need to overcome business challenges, shape and enhance performance. It can be either declarative/explicit knowledge (easy to be articulated and coded) or performative knowledge that can also be described as tacit (Spender & Marr, 2006). Tacit knowledge is context-specific, acquired through personal experience or internalisation and would reside within people rather than any physical media or information system (Hoe, 2006; Hsiao & Huang, 2019). Knowledge can be also classified as (1) context-specific knowledge, about a specific setting, team or organisation; (2) technology-specific, e.g. programming knowledge; (3) a combination of both (Nikkhah et al., 2018). A similar classification of knowledge is made between the knowledge privately owned by the organization and the public knowledge which isn't proprietary to any particular organization e.g. industry and occupational best practices (Hoe, 2006). Millar, Demaid and Quintas (1997)

suggested five types of knowledge: know-what, know-why, know-how, know-who and experiential knowledge overlapping with all other types. Similarly, Rechberg and Syed (2014) presented three dimensions of knowledge: practical knowledge acquired by doing things, emotional knowledge important for decision-making process and finally situational knowledge gained through experiences. A more comprehensive framework of knowledge and its representation is proposed by Mingers (2008) who distinguished between four forms of knowledge as follow:

- I. Propositional knowledge: it is merely related to common sense, direct perception, receipt of information and communication with others i.e. *know-what*.
- II. Experiential knowledge: received from previous individual experiences.
- III. Performative knowledge: usually involves some kind of physical motor skills or performance. It is about the *know-how*.
- IV. Epistemological knowledge: it is to *know-why* through formal or scientific methods of discovery.

Early KM models illustrated knowledge as a thing or object that can be captured, stored and reused as managing information was the real focus rather than managing knowledge (Chatti, 2012). Knowledge nowadays is mobile, global and difficult to contain (McLaughlin & Stankosky, 2010). Moreover, tens of frameworks describe KM processes and activities. A qualitative and quantitative content analysis of a total of 160 KM frameworks concluded six basic categories of KM processes: use, identify, create, acquire, share and store (Heisig, 2009). Other taxonomies included more activities such as refine and forget (Edwards, 2015a) or securing knowledge (Van der Spek & Spijkervet, 1997). A review of 119 KM frameworks from around the world identified four contextual success factors that influence knowledge in the organisation: human factors (culture, people and leadership), organizational factors (structures and processes), information technology, as well as management (strategy and

control) (Schmitt, 2015). Similarly, several processes are recognised specifically for the PKM. Jones (2009) suggests problem-solving, exploring and learning as core processes for PKM. PKM implied also the collection, absorption and innovative use of knowledge (Liu et al., 2017). PKM is often presented as a set of skills for problem-solving and decision making. These skills are (1) retrieving information; (2) evaluating/assessing information; (3) organising information; (4) analysing information; (5) presenting information; (6) securing information; and (7) collaborating around information (Agnihotri & Troutt, 2009). It is noteworthy that problem-solving requires self-talk and/or engagement with a group (Jones, 2009) which supports the personal and social nature of knowledge. Pauleen and Gorman (2010) summarise PKM strategy in the following activities: management, lifelong learning, communication and interpersonal skills, use of technology, forecasting and anticipating.

In today's complex environment, knowledge workers are responsible for solving the non-standardised organisational problems using their knowledge and experience (Mittelmann, 2016). Solving problems outside of expertise was associated with limited performance and lack of confidence (Wright, 2005) confirming the value of experience in the decision-making process. Non-routine problems require 'extensive conscious thinking' which allow workers to identify and close gaps in knowledge or in other words to learn. It entails the critical thinking and iterations of deductive and inductive reasoning (Wright, 2005). This requires them to develop certain types of information-oriented skills such as critical thinking, innovation, flexibility, creativity, decision making and secured sharing (Agnihotri & Troutt, 2009; Mittelmann, 2016). Also, experience facilitates the effective recall, use or combination of relevant information to solve a problem in different contexts (Beijaard et al., 2000). The process of problem-solving can be envisaged as a process of sense-making where tacit knowledge is applied in a social and continuous manner and utilising person's experience and worldviews. Effective problem-solving demands team building and collaboration and

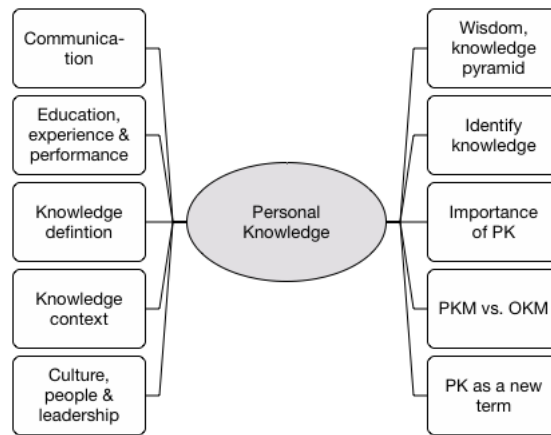
interaction skills to make the right decision (Wright, 2005). Such higher-level skills in PKM have been traditionally called “*wisdom*” (Pauleen & Gorman, 2010).

Communication and networking is another basic element in PKM including perception, intuition, expression, visualization, interpretation and design (Pauleen & Gorman, 2010). It is a must-have skill particularly in the modern virtual world of self-employment (McLaughlin & Stankosky, 2010). However, the organisational focus must be on the individual rather than the social networks and technology (Völkel & Haller, 2009). More recent studies focus on the human element or in other words the personal and cultural dimension of KM (Sense, 2007). For instance, Personal Knowledge Network (PKN), as distinct from the traditional view of PKM, considers knowledge a continuous creation of personal networks (Chatti, 2012). Unlike the (inter-)organizational networks that are assembled for the duration of a specific project, personal networks develop gradually and remain beyond the project boundaries (Grabher & Ibert, 2006). Those external personal knowledge networks refer to knowledge interactions between individuals in different organisations, who know each other personally and interact formally and informally beyond the official work duties. The strength of such networks can influence the knowledge sourcing process and can imply a trade-off between maintaining a high number of weak ties versus few strong ties (Huber, 2013). In contrast to common notion, studies reveal that local contacts are not socially and cognitively closer than non-local contacts. Essentially, the social proximity can be maintained over spatial distances (Huber, 2012). It is worth noting that social networking usually results in “*know-who*” type of knowledge (Jarrahi et al., 2019). The “*know-who*” is a form of tacit knowledge that is difficult to find in firm’s yellow pages but rather in more fluid personal interactions (Grabher & Ibert, 2006).

The personal knowledge identification is crucial for a successful implementation of KM in organizations since personal knowledge identification is not a personal concern but rather an organizational one necessary for optimal and efficient knowledge application (Tajedini et al.,

2018). One effective approach to manage personal knowledge is to locate the workers with particular knowledge (Gang & Yi, 2009). This agrees with the notion that it is impossible to manage assets that are not measured (McLaughlin & Stankosky, 2010). However, finding personal knowledge can be a big challenge within the organisation. According to some studies, knowledge workers are unable to locate their own documents (rather than others' knowledge) in 50% of the cases (Agnihotri & Troutt, 2009). The awareness of personal knowledge would lead to the identification of skills and experiences that the individual needs to perform tasks and consequently improve his/her performance (Tajedini et al., 2018). The self-managing of personal knowledge is a characteristic for knowledge workers as work tasks and challenges are continuously changing (Völkel & Haller, 2009).

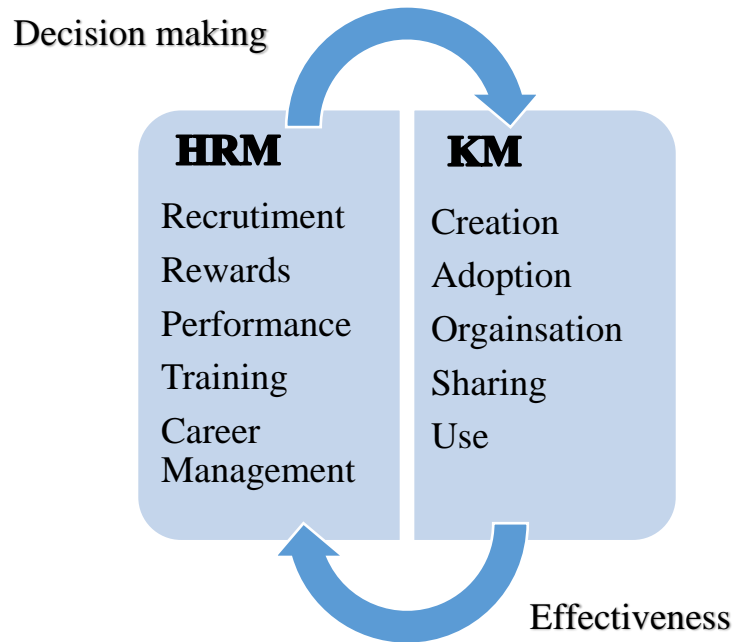
Several approaches were adopted by organisations to find knowledge such as codification, knowledge mapping, network analysis and Personal Knowledge Registration (PKR) (Haraldsdottir et al., 2018). PKR is the registration process of personal (employees') information into a central database to generate an overview of knowledge embedded in the staff that allow management to look for and find valuable knowledge about their employees (e.g. education; language, information technology, writing or mentoring skills; participation in courses and conferences; teaching experience, former work experience and communication skills). However, the incoherent (or not updated) registration of employee's personal knowledge on automated PKR systems limits its value for the organisation (Haraldsdottir & Gunnlaugsdottir, 2018). A proper knowledge culture would facilitate access, storage and update of knowledge that has a potential value for the organisation. Without an efficient extraction process of the identified and organised knowledge, the organisation would fail to utilise this knowledge and might fall into knowledge forgetting (Tajedini et al., 2018).



*Figure 2-1 Personal Knowledge Review Themes*

Finally, knowledge management must be distinguished from Human Resource Management (HRM). In fact, effective HR practices are considered as enablers for a successful KM in the organisation (Currie & Kerrin, 2003; Jimenez-Jimenez & Sanz-Valle, 2013; Klumpp et al., 2013). Knowledge oriented HRM practices are deemed to encourage knowledge dissemination and re-use (Jimenez-Jimenez & Sanz-Valle, 2013). At the same time, without the proper knowledge, HRM won't make the right decisions (Arun Kumar, 2016). Similarly, there is often a confusion between Human Capital (HC) and HRM which is concerned with the management of HC, and the former which is the blend of unique attributes of employees (Chrysler-Fox & Roodt, 2014). HC plays a mediator role between HR practices and performance (P. M. Wright & McMahan, 2011). It combines knowledge, skills, experiences and individual capabilities of employees and management (Agostini & Nosella, 2017). The value of HC comes from its direct impact on organisational performance. HC can have a positive impact on a company's RC due to the skills and competencies of employees that are believed to enhance the firm's reputation and attract new collaborations. Together with structural capital, it is also believed to enhance innovation and strategic renewal (Agostini & Nosella, 2017; Vidotto et al., 2017).





*Figure 2-2 HRM and KM*

Adapted from Kumar (2016)

### 2.3 Knowledge Measurement

A literature review is a critical analysis of a published body of knowledge to interpret what is known about a research field and to identify gaps in the existing knowledge (Jafari & Kaufman, 2006; Jesson et al., 2011). A review of “knowledge measurement” frameworks was found necessary to understand the meaning of measurement in KM context. First, a review protocol was created. A set of review questions and search strings (Table 2-1) were developed after a brainstorming session in order to outline the frames of the review process as follows:

- a. What are the current trends of knowledge measurement in business literature?
- b. How is knowledge measured at an organisational, group and individual level?

The inclusion criteria included English-written, refereed articles, from peer-reviewed journals in business and management field. A total of 138 articles were collected from TU Dublin library electronic databases “TU Dublin Summon”. TU Dublin Summon is a search engine providing access to TU Dublin library’s online collections in a single search. The

collections include but not limited to: Emerald Insight, Science Direct, Sage Journals Online and Scopus together with tens of other resources in different fields (DIT, 2018). Last but not least, references in the found articles were further examined to find more relevant papers that would contribute to the review even if not fulfilling the inclusion criteria e.g. not from the mentioned databases, not journal article, etc. The search results were sorted based on relevance to the search strings and manually filtered according to the inclusion criteria. The following are the main themes in the reviewed literature.

*Table 2-1 Search Strings*

Concept	Search string (s)	
Intellectual capital	intellectual capital in pharmaceutical	IC in pharmaceutical
Human capital	human capital/ determinants	human capital /pharmaceutical
	human capital/measurement	Human capital/ assessment
Relational capital	relational capital determinants	relational capital/ assessment
	relational capital/measurement	relational capital in pharmaceutical
knowledge measurement	knowledge measurement	knowledge/ measurement / pharmaceutical
	IC/ measurement	Intellectual capital or IC and Assessment
Individual knowledge	individual knowledge measurement	elements of individual knowledge
	individual knowledge assessment	
Intangible assets	measurement /intangible assets / pharmaceutical	
Pharmaceutical knowledge	Pharmaceutical knowledge	
	Areas of expertise/pharmaceutical	
Measuring Talent	Talent/Measurement	talent/ assessment

### 2.3.1 Measuring knowledge at the organisational and group level:

The literature has highlighted that the organisations that employ skilful, knowledgeable and innovative employees and at the same time develop good infrastructures and systems are performing better (Chahal & Bakshi, 2016). What's more, it has been argued that effective management of IC, in general, has a positive influence on business performance (Sharabati et

al., 2010). This may explain the growing attention towards intellectual capital in academia and industry (Chahal & Bakshi, 2016). The history of intellectual capital research includes prominent scholars who developed and introduced this area of research. In the eighties, Karl-Eric Sveiby introduced the concept of intangible assets to management in Northern Europe and Scandinavia. Thomas Stewart followed in 1997 with his popular book “*Intellectual Capital: The New Wealth of Nations*” in 1997. This was accompanied by contribution from a number of brilliant minds proposing new accounting practices this time to measure and manage firms’ intangible assets e.g. Kaplan & Norton’s Balanced Scorecard approach in 1996, and Sveiby & Edvinsson’s Intellectual Capital methods in 1997 (De Beer & Barnes, 2003).

Indeed, the world’s modern economy has transformed from an economy of tangible assets to a new order where intangible resources such as knowledge and competencies are prevailing. With the aid of ICT, knowledge is increasingly recognized as a commodity where the knowledge agents have grown to global levels (Dumay, 2009). The measurement of IC at an organisational level requires monetary metrics which are repeatable and quantifiable that did not exist in the traditional accounting practices. Instead, broad terms such as “goodwill” have been used to refer to IC. Goodwill is not exactly the IC although it includes it in addition to other intangible assets. The need to measure intensifies when an organisation is involved in a merger, information alliance or even issuing shares. For instance, Watson-Wyatt, one of the biggest HR consulting companies, referred to the relationship between human capital within the company and its financial performance. In order to reflect the value of the company-owned IC on its stock price, IC must be valued and disclosed (De Beer & Barnes, 2003).

On the other hand, a firm’s intellectual capital can be classified into organisational or structural capital, human capital and relational capital. The Human Capital (HC) includes individual knowledge, skills, abilities, attitudes and due to its weight in literature, it will be discussed in more details in a separate section. Structural Capital is the component which

remains within the organisation when employees leave e.g. patents, networks, procedures and management processes. Relational or Customer Capital refers to external relationships with third parties of relevance to business life such as customers and vendors. Examples for that may include brand, customer loyalty, distributions channels, favourable contracts (Bueno et al., 2014; De Beer & Barnes, 2003; Keong Choong, 2008). While human capital can be assessed based on management and HR capabilities, structural capital reflects the innovation and internal process capabilities. However, networking capabilities and reputation are indicators of relational capital of a firm (Anatolievna Molodchik et al., 2014). The measurement of relational capital indirectly protects firm's relationships with its stakeholders not to be lost to market rivals (Hosseini & Owlia, 2016).

Despite the famous maxim "If it can't be measured, it can't be managed", IC measurement is still a controversial discipline. Edward Deming considered running a company on visible numbers only as a deadly sin. He argued that important things could not be measured as they are either unknown beforehand to the observer or their importance has not been yet established (Deming, 1982). However, measurement is a potential enabler to control, evaluate and improve processes (Ahmed et al., 2006). While it is relatively easy to describe the IC qualitatively, a quantitative measurement is a big challenge for any organisation. Measurement is traditionally defined as "*the assignment of numerals to the properties of objects or events according to rules*" (Bandalos, 2018). The main issue with the measurement of social phenomena is its dependence on proxies and assumptions. It is not as accurate as applied science either (Sveiby, 2010). Measurement is required but as part of the IC reporting process not to be confused with other intangible assets in the balance sheet. The development of an accounting framework for IC is an ongoing journey for academics and practitioners with no one answer for the dispute between accounting and narratives of IC mobilisation (Dumay & Rooney, 2011). Albeit numerous frameworks were developed over the last two decades for IC measurement, it is

incompletely implemented. Few companies have implemented these frameworks, and fewer reported any benefit. Even worse, some leading companies in the development and implementation of IC measurement, such as Skandia, have abandoned the whole initiative (Serena Chiucchi, 2013).

The general concept of IC valuation that any excess value over the company's book value can be truly attributed to its intellectual assets (Bramhandkar et al., 2007). The four main approaches for valuation of knowledge assets in accounting and management literature are:

- A scorecard describing and not necessarily measuring the value of intellectual assets through a set of both financial and non-financial indicators.
- IC expense-investment methods that measure certain IC expenses as a proxy indicator of IC investment and knowledge capital earnings,
- Assessing the overall influence of interactions among IC components within the organisation generally through the gap between market and book value,
- Finally, the measurement of knowledge per individual and using it to calculate the aggregate IC per the whole organisation (Forte et al., 2017).

Kianto *et al.* (2018) highlight four critical themes that should be better understood about knowledge for any successful IC measurement model: multi-dimensionality, human agency and action, contextuality, as well as temporality and dynamics. Discounted cash flow was also considered an evaluative tool for measuring intangible assets (Russell, 2016a). However, financial measures of IC has been long criticised for obscuring where the problem exists and what should be done to solve it (Kannan & Aulbur, 2004). It is worth noting that the concept of IC measurement was also expanded to cover entire geographic regions rather than organisations as a proxy for the regional value creation dynamics (Schiuma et al., 2008).

Generally speaking, four main methodologies have been developed for organisational knowledge measurement:

- a. Financial methods: utilising financial models to calculate company's IC value e.g. Tobin's Q and Economic Value Added;
- b. IC methods: splitting company value to smaller categories through IC classification, development of quantitative metrics and financial valuation e.g. the Skandia navigator ;
- c. Human capital methods: considering human capital as a key component of IC e.g. HR scorecard and Human Capital Index (HCI);
- d. Performance methods: focusing on the impact on knowledge on performance perhaps through statistics on KM systems' use and effectiveness (Matoskova, 2016). The following is an overview of the major measurement frameworks of the organisational IC.

### *1. Financial methods*

These methods measure the amount of IC in the organisation utilising accounting information from the balance sheet and the stock prices (Matoskova, 2016). One of the leading approaches is Tobin's Q (Tobin, 1969). Tobin's Q uses the market-to-book ratio (MTB) to evaluate the company's intangible assets. It can also support investment decisions where the higher Q value discloses an intangible advantage for the rival company (Sveiby, 2010). Tobin's Q replaces book value with the replacement cost of tangible assets in the MTB ratio (Forte et al., 2017). However, like other methods that utilised MTB ratio, Tobin's Q method was criticised for being reflective to changes of the stock market rather than be a robust measure of IC (Ragab & Arisha, 2013).

Human Resource Costing and Accounting (HRCA) is a process of measuring the cost and investments as well as quantifying the economic value of people in the organisation (Biswas, 2013). IC is estimated as the ratio of the contribution of human assets in the organisation to

their capitalised salary expenditures (Sveiby, 2010). The framework was criticised for the lack of reliability and dependence on a multitude of assumptions e.g. service life and forecasted revenues (Ragab & Arisha, 2013).

Economic Value Added (EVA) is determined by deducting the sum of operating expenses, taxes and capital charges from the net revenue (Matoskova, 2016). EVA is a modified form from Market Value Added (MVA) model. In contrast, MVA quantifies the gap between what investors spent since the start-up of the company and the current value of their shares (Bontis, 2001). The unsupported assumption that an increase in EVA is a proxy indicator of the effective management of IC in an organisation makes the reliability of the measurement method questionable (Ragab & Arisha, 2013). Ante Pulic argues that the traditional performance measurement methods ( e.g. EVA) are not suitable to measure the IC performance as they do not really show how much value has been created (Pulic, 2000).

Similarly, the technology broker evaluates the company's IC through the diagnostic analysis of 20 questions followed by a specific audit questionnaire (Bontis, 2001). It defines IC as the sum of four elements: market assets, human-centred assets, intellectual property assets and infrastructure assets (Sveiby, 2010).

Value Added Intellectual Coefficient (VAIC) introduced by Pulic (2000) as a methodology to measure the IC based on the concept of added value for knowledge-based organisations. Knowledge was traditionally used to increase the physical productivity. Now, the productivity of Intellectual work is the priority. From this perspective, IC is not a collection of assets, but a set of knowledge workers who have the capability of transforming and incorporating knowledge into product and service that create value (Iazzolino & Laise, 2013). VAIC measures how much and how efficiently IC and capital employed add value employing: (1) capital employed; (2) human capital; and (3) structural capital (Sveiby, 2010). The value added is the value created per time unit by the knowledge workers. Thus, the Value Added Income

Statement can be usefully employed for measuring the value creation in a knowledge organization. The main criticism of this model is the mono-criterial vision of the firm performance measurement (Iazzolino & Laise, 2013). Moreover, in a recent study employing VAIC as a measure of efficiency in the Islamic banking sector of Malaysia, VAIC failed to establish a consistent correlation with performance and productivity (Aziz & Hashim, 2017). Finally, a measurement framework was proposed by Clausen and Hirth (2016) to examine the impact of intangibles on the firm's value. The tool employs intangible-driven earnings to assess the intangibles value. Traditional proxies for intangible intensity such as R&D spending, R&D stock and number of patents were used to validate the measure (Clausen & Hirth, 2016).

### II. *Scorecard methods*

Scorecard methods are based on non-financial measures of IC that are reported in a scorecard or a graph (Matoskova, 2016). Balanced Score Card (BSC) integrates multidimensional financial, customer; internal process, and learning perspectives where the measures for each perspective are directed by the strategic objectives of the firm (Tuan, 2012). However, BSC neither measure the knowledge nor provide a direct link to KM (Ragab & Arisha, 2013b).

Skandia Value Scheme and Skandia Navigator are other attempts to measure the IC led by the Swedish insurance company, Skandia. The tool involves numerical indicators that provide a balanced overview of financial and non-financial dimensions. The Navigator acted as a planning and follow up tool as well as for the individual performance appraisal (Edvinsson, 1997). The tool has found its way to other enterprises e.g. Dow Chemical inspired by Skandia's multidimensional conceptualisation of organisational value (Bontis, 2001). The navigator consists of 164 indicators covering five components: (1) financial; (2) customer; (3) process; (4) renewal and development; and (5) human. It is worth noting that Skandia has stopped issuing its IC report (Sveiby, 2010). IC Rating <sup>TM</sup> is an extension of the Skandia Navigator



model incorporating measures from the Intangible Assets Monitor; rating efficiency, renewal and risk that has found its way to consulting companies.

Intangible Asset Monitor (IAM) measures four modes of creating value from three forms of intangible assets: People's competence (education and experience), Internal Structure (the organisation, management, legal structure, R&D, software) and External Structure (brands, customer, supplier relations). The management is required to consider the organisational strategic objectives during the selection of IC indicators (Matoskova, 2016; Sveiby, 2010). The model has been criticised for being formatted for internal reporting and lacking a quantitative (overall) figure for IC (Ragab & Arisha, 2013). Likewise, Intangible Assets statement is an IC measuring framework for the public sector based on the IAM with Indicators of: growth, renovation, efficiency and stability (Sveiby, 2010)

Value Chain Scoreboard is a matrix of non-financial indicators assembled into three classes according to the innovation cycle: Discovery/Learning, Implementation, Commercialization (Sveiby, 2010). However, the model and indicators might not fit for all organisations (Ragab & Arisha, 2013).

The IC-Index was first developed by Goran Roos at Intellectual Capital Services Ltd. Then shortly adopted by Skandia in its 1997 IC annual report. Since then, the model has been endorsed by other firms (Roos et al., 1997). The IC-Index consolidates multidimensional indicators in one index as a second-generation model. Thus, the changes in the index score are correlated with changes in the firm's market valuation (Sveiby, 2010). The model provides a managerial advantage as it avoids having a long list of individual indicators that need to be compared and investigated (Bontis, 2001). On the other hand, the discrepancy between IC-Index and the market value over the long term outlined that the tool might be flawed and not reliable. Moreover, the model showed a limited ability to compare IC among different organisations (Ragab & Arisha, 2013).

ICU Report is an IC measurement framework designed for the higher education sector. It consists of three components as follow: (1) Vision of the institution, (2) Summary of intangible resources and activities, (3) System of indicators (Sveiby, 2010). The adopted indicators are classified into human, organisational and relational capital indicators. The main contribution of ICU is presenting IC information in a single document with homogeneous language and criteria. However, few shortcomings have been found. For instance, some indicators require a further clarification and the synergies between teaching and research needs to be highlighted (Sánchez et al., 2009). Last but not least, Pirozzi and Ferulano (2016) proposed an integrated IC and leadership measurement model for healthcare organisations. The proposed framework assesses the performance based on the organizational, citizen-user/customer, human resources and social responsibility results. Also, the new integrated model facilitates the measurement of IC and financial/non-financial performance in a single measurement system. However, the framework is limited to healthcare non-profit organisations (NPOs) and application outside this sector may imply further modifications (Pirozzi & Ferulano, 2016).

### *III. Knowledge Management Evaluation Methods*

This section can be seen as complementary to the IC measurement process. As investments in knowledge management dramatically increased, the need to formally track and capture the knowledge developments within organisations is growing too. Knowledge maturity level reflects the capabilities within the organisation and how it influences the KM processes (Khatibian et al., 2010). Maturity assessment frameworks can be also seen as an internal benchmarking that motivate businesses to embrace successful KM practice allowing strengths to be shared and consolidated. Furthermore, they can be an enabler for product and process understanding and continuous improvement with a direct effect on quality, innovation and employees' development (Jochem et al., 2011). KM can be also presented as an approach to achieve corporate sustainability. This implies the implementation of a methodological

approach for managing knowledge. That is to say, KM maturity models enable corporate sustainability through providing the necessary structure for assessment and benchmarking which in turn facilitate continuous improvement and enhance stakeholder value (Robinson et al., 2006).

Several models were developed in order to evaluate the level of maturity of KM practices within organisations. Many of the proposed models adopt the Capability Maturity Model (CMM) proposed by Carnegie Mellon University (Oliva, 2014). Jochem, Geers and Heinze (2011) proposed five levels of maturity of KM based on knowledge use and renewal. These levels of maturity include either: *initial* with non-formal characters, *repeated* implementing proactive initiatives, *defined* with formally established processes, *managed* with quality-driven designs and finally *optimised* showing a sustainable knowledge-intensive process. KM lifecycle within the organisation inspired business researcher to develop more models where the history of KM within the organisation predicts futures KM activities. For instance, an organisation's lack of awareness of the need for KM qualifies it to stage zero on the KM maturity scale. The first stage of the KM lifecycle implies awareness but lack of actions to implement KM. The organisation is qualified to stage two of maturity when it is actively implementing knowledge management but not part of the organisation-wide strategy. It is more like isolated silos. The last stage of maturity is reached when KM becomes a part of the organisational strategy and routinely reviewed (Edwards et al., 2005). Similarly, STEPS framework offered a KM maturity roadmap passing through five stages: start-up, take-off, expansion, progression and sustainability (Robinson et al., 2006).

Whereas previous models ignored the role of knowledge culture, Oliva (2014) implicitly outlined the role of culture oriented towards knowledge creation as well as the use of knowledge. Based on this understanding, his model distinguished between four levels of maturity: insufficient, structured, oriented and integrative. Last but not least, APQC's levels of

KM Maturity <sup>SM</sup> is a diagnostic tool helping KM practitioners assess their KM programs. It consists of five levels starting from initiate, develop, standardise, optimise and finally innovate (Hubert & Lemons, 2017).

On the other hand, KM performance methods measure the impact of knowledge. These methods can be classified into financial, non-financial and survey-based methods. The financial performance measures employ financial metrics to assess the performance of KM system such as stock process, profitability and ROI (Matoskova, 2016). A study of over 700 Flemish manufacturing and service firms reveals an indirect positive impact of KM on the financial performance that surpasses the KM implementation costs over the long term (Andries & Wastyn, 2012).

Non -Financial methods evaluate the KM outcomes based on the responses to interviews or surveys. Thus, it depends on the respondent's judgement and their perception of KM (Matoskova, 2016). Choy, Yew and Lin (2006) propose 38 metrics for measuring KM outcomes that can be classified into five categories as follow: (1) systematic knowledge activities; (2) employee development; (3) customer satisfaction; (4) good external relationship; and (5) organisational success. Other non-financial indicators are suggested such as increase in sales, reduction in cycle time or the number of complaints. However, the assumed correlation between these measures and KM effectiveness might not be established in all cases (Ragab & Arisha, 2013). Some of the performance methods focus on evaluating the performance of particular systems e.g. electronic knowledge repositories or electronic communities of practice (Matoskova, 2016).

Evaluation of the success in some KM processes such as knowledge creation and knowledge sharing is another approach for KM performance measurement. In their study in the banking sector, Shih, Chang and Lin (2010) emphasise on the role of knowledge creation in the accumulation of human capital which in turn positively impact both structural and customer

capital. Likewise, a total of 914 survey responses from 14 Korean organisations were utilised to develop and validate a reliable and valid psychometric measurement model on organizational knowledge conversion and creation practices (Song et al., 2012). Knowledge creation is generally measured through monitoring the undertaken initiatives towards the generation of new ideas, new ideas that elaborate existing knowledge and the knowledge incorporated into new products (Mitchell & Boyle, 2010).

The measurement of knowledge sharing can take the form of hard data measures such as the frequency of length of something (number of personal postings or contributions to meetings), as well as via surveys that examine the willingness to share knowledge and the underlying factors (Matoskova, 2016). Wang (2013) developed a 20-item scale for knowledge sharing in Chinese cultural context based on knowledge donating measures and knowledge collecting measures (Wang, 2013). A similar study in the public sector (Dubai Police Force) used a 5-point Likert scale to measure the attitude towards knowledge sharing, willingness to share knowledge, trust, organisational structure, leadership, reward, time, and information technology (Seba et al., 2012). Social network analysis (SNA) is concerned with knowledge diffusion at the group level. This includes network density analysis (the number of actual links per network over the overall number of possible links) and average number of downward links (the span of control) (Matoskova, 2016). Su, Yang and Zhang (2017) have adopted a weighted network and knowledge diffusion efficiency measurement approach. The new approach examined network topological parameters, knowledge collaboration level and knowledge collaboration relationship strength and has proved superior to traditional unweighted or subjective methods.

#### *IV. Human Capital (HC) measurement*

HC can be understood through three key dimensions: knowledge either from training, education, experience or personal development; abilities as a way of doing things and

behaviours that lead individuals to do their tasks via mental models, paradigms and beliefs (Martín-de-Castro et al., 2011). To that end, Mehralian, *et al.* (2013) suggested three main indicators of HC in the Pharmaceutical sector: learning and education; experience and expertise; and innovation and creation. Human Capital Value Metric (HCVM) proposed wages as a proxy indicator of employee value assuming that qualified employees bring value above and beyond his/her wage (Bukowitz et al., 2004). A review of the major models in the last 60 years revealed that the key indicators of HC in the organisation are talent, education, experience, knowledge, skills, attitudes, creativity and leadership (Vidotto et al., 2017). Regardless of the apparent significance of HC for business progress and its popularity in academic research, there are few consistent frameworks dedicated to measure it (Bukowitz et al., 2004; Mehralian et al., 2013b; Vidotto et al., 2017) which rarely provide any financial justification for investments in HC (Cantrell et al., 2006).

Furthermore, the diversity of HC scales sheds light on the context-specific nature of HC measurement. Having said that, the most appreciated measures for HC are those identifying the performance levers and evaluating HC contributions to the organisational value (Baron, 2011; Robinson, 2009). Furthermore, company strategy was found to influence their choice of HC measures. For instance, innovation measures are more employed in differentiation-oriented firms, and efficiency measures are preferred in companies following a cost-leadership strategy (Gates & Langevin, 2010).

Vidotto *et al.* (2017) proposed a HC measurement framework relying upon three factors: leadership and motivation; qualifications; as well as satisfaction and creativity. Another scale from the Indian banking sector chose competence, creativity, manager's attitude and staff attitude as dimensions of HC in addition to other dimensions describing RC and SC (Chahal & Bakshi, 2016). Family firms displayed some unique intangibles characterising their HC including leadership, self-motivation, entrepreneurship, feeling of membership, emotional

family component, creativity, skills, knowledge acquired from family members and knowledge owned by non-family members (Claver-Cortés et al., 2015). Watson Wyatt's Human Capital Index<sup>®</sup> is another attempt to assess the HC based on five dimensions: rewards and accountability; workplace; recruiting and retention excellence; communication integrity; HR service technologies (Watson Wyatt, 2001).

The British Civil Aviation Authority (CAA) developed a balanced scorecard to measure the HC based on three bases: external customer perception of CAA's performance, achievement of objectives and assessment of staff expertise. The proposed measures included strategic performance measures, outcome measures (e.g. turnover rates, absence rate), operational data (e.g. number of training days) and workforce data (e.g. headcount, demographics). However, the adoption of CAA approach for HC measurement is challenging because of the time required for data collection and analysis (Robinson, 2009). Other studies distinguished between project-based organisations in comparison with traditional businesses of repetitive operations as the temporary nature of projects implies different HC measures (Demartini & Paoloni, 2011). Proxy measures were also utilised as rough assessment tools of HC (Wright & McMahan, 2011). These diverse approaches advocate the context-specific nature of HC measurement as previously argued by Robinson (2009) and Baron (2011). Regarding the design of the HC measurement tool, Massingham, Nguyen and Massingham (2011) advocated 360-degree peer review to minimise the bias associated with self-reporting assessments.

Talent is typically noted as part of HC. Employees who have unique capabilities and possess a high value for their organisations are called "talents" (Nijs et al., 2014). Many organisations identify groups of high-potential talents (talent pools) through structured, semi-structured or even informal procedures. The identification includes a nomination process followed by an additional assessment of the nominees, e.g. leadership competency rating (Silzer & Church, 2010). Despite that the global talent measurement market is expanding (over US\$3 billion per

annum), talent measurement is a sophisticated process and many firms lack the necessary expertise to measure it (Bell, 2013; Nijs et al., 2014).

### 2.3.2 Measure Knowledge at Individual Knowledge:

While HC describes the knowledge within a group or the whole organisation, measurement of personal knowledge focuses on the knowledge of individual employees. Individual employees are envisaged as key players in knowledge management and development (Rechberg & Syed, 2014). However, the individual versus the collective distinction of HC is an arguable topic. On the one hand, macro-level scholars argue that HC is the aggregate of knowledge, skills and experiences owned by individuals. They argue that knowledge is scale-free; it applies similarly either at an individual or organisation level (Faucher et al., 2008). On the other hand, psychologists and micro-level scholars advocate the synergistic effect of the aggregate of individuals, i.e. the unit-level knowledge is more (can be less) than the sum of each (Wright & McMahan, 2011). Measures such as the replacement cost of tangible assets (Tobin, 1969), market share (Edvinsson, 1997) or retention excellence (Watson Wyatt, 2001) are not suitable predictors of knowledge at the individual level. Taking into consideration the definition of knowledge as “*a justified true belief*”, the review of the IC measures in the above section (2.3.1) demonstrate that many of the employed metrics are not knowledge measures (e.g. market share, customers lost, IT expenses in Skandia Navigator). This supports the notion that the measures of the organisational knowledge and IC are not always accurate measures for the personal knowledge of individuals which in turn urge the need to develop specialised models for individuals.

Davenport (1999) has envisaged an individual employee as a human capital investor who can invest his knowledge and gain profits. A high level of education (as a measure of knowledge) was associated with higher earnings (Davenport, 1999). Similarly, Schultz (1961) affirms that differences in earnings correspond closely to differences in education suggesting that one is the result of the other (Schultz, 1961). Yet the research on personal knowledge



measurement is relatively scarce and measurement scales are considerably few. Measurement of Individual Knowledge (Mink) framework (Ragab and Arisha, 2013b) suggests ten individual knowledge indicators (IKI) in the organisational context: education, training, experience, IT literacy, business communications, business process interactions, personal network performance, creativity and financial indicators. It can be a tool for both internal monitoring and/or external presentation (Arisha & Ragab, 2013). A standardised test can be another approach to measure knowledge at the individual level. However, this method is criticised by being limited only to the explicit knowledge component (Matoskova, 2016) in addition to the complexity of finding the right answers for the questions (Borgatti & Carboni, 2007). In order to overcome the latter problem, Borgatti and Carboni (2007) proposed a consensus method that analyses the pattern of agreement among participants to a knowledge quiz.

A situational Judgement Test (SJT) is another technique for measuring personal knowledge. SJT consists of a set of situations within certain professional context. In order to solve or react in these situations, the individual is supposed to possess certain knowledge. However, these methods were criticised for fakability and bias (Matoskova, 2016). Peeters and Lievens (2005) examined the impact of faking on the incremental validity of SJT in a sample of college students. The study found that faking significantly impacts SJT validity where students selected the more favourable responses to achieve higher scores (Peeters & Lievens, 2005). Finally yet importantly, *know-how* form of knowledge (performative knowledge), which is predominately tacit and acquired through experience, is generally evaluated via practical testing (e.g. success or failure in riding a bike and to which level) (Mingers, 2008).

On the other hand, performance appraisal refers to the organisational HRM activities to assess employees, improve their performance, develop their competencies and justify rewarding (Fletcher, 2001). This process is often used to allocate bonuses, merit pay, employee promotions based on the periodic assessment. The outcome has a direct impact on the

organisation and economy, such as the distribution of wages, who leads organizations, and who is laid off (Cappelli & Conyon, 2018). Different measures of performance are adopted including objective indicators (e.g. the number of units produced), subjective measures (e.g. relationship with customers) or a combination of objective and subjective measures. While objective measures are simple and standardised, they are not suitable to assess multitasking jobs. Subjective measures are flexible and comprehensive but they depend on the evaluator's judgement (Bayo-Moriones et al., 2019).

The performance measurement can take the form of self-assessment, feedback from co-workers and customers or a direct assessment by manager(s) (Lloyd, 2009). Performance appraisal is apparently not a knowledge measurement process. Cappelli and Conyon (2018) argue that appraisal score is not a reflection of the employee's initial human capital at the recruitment stage but it informs about the variance of his/her performance over time. However, knowledge is acquired over a longer period of time through individual processes such as direct experience and lifelong learning (Hoe, 2006; Mingers, 2008). Unlike performance appraisal, knowledge measurement aims to identify and allocate knowledge assets, benchmarking against other companies and monitoring the development of the firm's IC overtime (Matoskova, 2016). Moreover, while performance appraisal is a standard practice in nearly all organisations (Ward, 1997), the literature review reflects a sporadic implementation of different knowledge measurement approaches.

### *2.4 Summary and Conclusion*

Measurement is a popular topic in KM literature; nevertheless, most of the measurement literature address the organisational level at macro-level. Either measurement of IC, HC or maturity models focus on the knowledge of the group, the whole organisation and sometimes

the entire region or society. Despite the growing interest in the PKM, relatively few studies focus on the personal knowledge of individuals in the organisational context, and even fewer aim to objectively measure it. Few papers in KM provided categorisation and anatomy of knowledge forms and its truth, e.g. Millar, Demaid and Quintas (1997) and Mingers (2008), but neither utilised this for identifying knowledge holders. The need to measure knowledge and identify knowledge holders is justified at both macro and micro-level. The context-specific nature of knowledge justifies the need to customise the measurement frameworks to one or a group of similar industries to avoid validity problems. This highlights an urgent need to develop a measurement framework considering the nature of the pharmaceutical industry. As knowledge measurement process is context-specific, as previously mentioned, chapter five (the exploratory study) will provide more insights about current measurement practices, the level of KM maturity, components of personal knowledge and the significance of its measurement from practitioners' perspective within the pharmaceutical industry.

In the next contextual chapter, the researcher will explore the prevalent trends of KM in the pharmaceutical industry with a focus on the personal knowledge. The regulatory expectations of the main global regulatory bodies are critically reviewed and compared with the trending academic research themes.

## **Chapter 3 : Knowledge Management in the Pharmaceutical Industry**

### 3.1 *Introduction*

The acknowledgement of knowledge as a pivotal strategic resource in the current smart economy has impelled considerable organisational change in knowledge management (KM), where organisations endeavour to exploit their intellectual assets to drive value creation. This progressive movement by individuals and organisations to manage their intellectual assets developed into KM (Davenport & Völpe, 2001). The pharmaceutical industry is not an exception of this trend, not only as a knowledge-intensive industry but also as a leading economic partner with transcendent investments in innovation and research. According to the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Pharmaceutical industry employs more than 750,000 employees in Europe, 16% of them working in pharmaceutical Research and Development (R&D). It was the preeminent sector regarding R&D intensity and expenditure as a percentage of net sales (15%) in 2016 followed by software & computer services (10.6%) and technology hardware & equipment (8.4%) (EFPIA, 2018). The pharmaceuticals and biotechnology sectors are among the top investing sector in R&D worldwide according to the Industrial R&D Investment Scoreboard (European Commission, 2018).

It comes as no surprise that major pharmaceutical regulatory authorities have realized the significance of KM. International Council for Harmonisation (ICH) recommends the management of drug and process knowledge from development and up to product discontinuation as an enabler of effective quality management systems. On the other hand, technology transfer between development and manufacturing, and within or between manufacturing sites is considered as an integral part of new drug product realisation (WHO, 2011b). From this perspective, KM creates the basis for the manufacturing process, control strategy, process validation approach, and ongoing continual improvement (ICH, 2009). Food and Drug Administration (FDA) has paid close attention in successive guidelines to the

management of Electronic Records along with its efforts to enhance data integrity in pharmaceutical premises ensuring delivery of safe, effective and quality product to the patient (FDA, 2003, 2016b).

Thus, as knowledge is another core product of the pharmaceutical industry (Riddell & Goodman, 2014), managing stocks and flows of knowledge in this sector emerges as a key economic and regulatory objective as well as a growing area of academic research. Nonetheless, some knowledge-intensive industries such as pharmaceuticals have not received adequate attention in industry-specific publications (Ramy et al., 2017). With few other review articles surveying the applications of KM in specific fields (e.g. construction industry (Walker, 2016), energy sector (Edwards, 2008) and public sector (Massaro et al., 2015), this contextual chapter comes as a comprehensive industry-specific systematic review of KM research within the pharmaceutical sector identifying key themes, addressing extant research gaps, assessing regulatory expectations, and providing an overview of the progress of KM with a particular focus on the role of PK.

### 3.1.1 Systematic Review Questions

A comprehensive, unbiased search is considered as one of the crucial differences between a traditional narrative review and a systematic review. Moreover, traditional reviews suffer from lack of thoroughness, inconsistency and bias by researchers that they are not always undertaken as a genuine piece of investigatory science (Jesson et al., 2011; Tranfield et al., 2003). For this reason, the author committed to systematic review techniques in order to synthesize a reliable and enhanced knowledge stock as will be clarified in the methodology section. Several research papers in the field of KM have followed systematic review methodology as the basis of the review process for example: Costa and Monteiro (2014), Klammer and Gueldenberg (2016), and Massaro et al. (2016). These papers were also taken into consideration while developing the review protocol.

In order to develop a systematic review, the author developed a set of research questions and a review protocol in the early stages of the review. The review questions are developed to achieve the first research objective and to gain an in-depth understanding of KM practices in the pharmaceutical manufacturing context. The proposed questions are believed to develop the researcher's collective understanding of the field which is a pre-condition for doing good empirical research (Boote & Beile, 2005). Also, those questions are critical to the systematic review as the other aspects of the process flow from it (Tranfield et al., 2003). The questions embody a mixture of quantitative and qualitative review aspects. They are designed to provide a comprehensive overview where both the academic literature and industry-specific regulations are reviewed. Regarding the questions structure, questions are organized as a major question, followed by thorough minor questions.

*Q.1 How is the KM literature in pharmaceutical/biopharmaceutical industry developing?*

*1.1. Which knowledge processes/ themes are predominantly studied by current research? Or what is the focus of KM process research in the pharmaceutical industry?*

*1.2. What are the recent trends in co-authorship distribution and author affiliations?*

*1.3. Which countries are leading in this track?*

*1.4. Which department or function was more represented in pharma industry KM research?*

*1.5. What are the most utilized research and data collection methods in pharmaceutical industry KM research?*

*Q 2. What is the significance of the identified academic research themes from a regulatory perspective? Or What are the expectations of regulatory agencies with regard to the identified academic research themes?*

*Q 3. What is the future of KM research within the pharmaceutical industry?*

### 3.1.2 Review Methodology

The high expectations of improving the quality of reviews through well-defined methodologies led to the development of systematic review protocols (Jesson et al., 2011). Systematic review protocol encompasses specific research questions, the population that is the focus of the study, the search strategy and terms for identification of the relevant studies. Studies that meet all inclusion criteria and manifest none of the exclusion criteria needs to be integrated into the review (Davies & Crombie, 1998; Tranfield et al., 2003).

The author commenced his review by identifying the research questions. These questions are deemed to construct the pillars of the whole literature review (Jesson et al., 2011; Tranfield et al., 2003). After refining the review questions, the timeframe of review is set to be the last twenty years (1996-2016). This period represents the prosperous period of KM research (Ma & Yu, 2010; M. A. F. Ragab & Arisha, 2013). Furthermore, the timeframe took into account the relative novelty of online KM journals. According to Serenko & Bontis (2013) ranking of the KM journals, the top ranked four KM journals ( JKM, KMRP, IJKM and JIC) have been published online only since 1997, 2003, 2005 and 2000 respectively.

The criteria for inclusion comprise peer-reviewed electronic business journals in the English language retrieved from the *Emerald Insight* and *Science Direct* database as the top KM journals are published on them e.g. Journal of Knowledge Management (JKM) and Journal of Intellectual Capital (JIC) (Serenko & Bontis, 2017). Peer reviewed journals are favoured because they are quality assured (Jesson et al., 2011). Search strings were synthesised from the top ranked keywords in two comprehensive keyword analysis studies in the KM discipline: Fteimi and Lehner in (2016) along with Ribière and Walter in (2013). Thus, potential search strings were enumerated based on relevance (Table 3-1). The list was updated during the search process. It was meant not to tightly plan the review process as this may inhibit researchers' capacity to explore, discover and develop ideas (Tranfield et al., 2003).



*Table 3-1 Review Search Strings List*

KM in pharmaceutical	Knowledge sharing in pharmaceutical	Knowledge creation in pharmaceutical
Biotechnology knowledge	Data mining in pharmaceutical	Creating knowledge in pharmaceutical
Intellectual capital Pharmaceutical	knowledge measurement in pharmaceutical	Knowledge transfer in pharmaceutical industry

Articles that appeared in the research results were manually checked for relevance through title, keywords and abstract analysis. After the exclusion of duplicates, articles were screened against the inclusion and exclusion criteria by reviewing the titles and abstracts (Pati & Lorusso, 2018). If the pharmaceutical or biopharmaceutical industry was not the research field/sample, the article was excluded. Articles which cannot be classified under knowledge management research domain were also excluded. The exclusion criteria covered editorials, unpublished works and/or journals that do not have online domains (Table 3-2).

*Table 3-2 Inclusion and exclusion criteria*

Inclusion criteria	Exclusion criteria
KM theories and processes	Not related to KM
With applications in pharmaceutical industry	Applied exclusively in other industries
Peer reviewed journal articles	Editorials and position papers
In English language	Articles that use languages other than English
Published online between 1996 and 2016	From journals that don't have online domains and unpublished work.

A full-text assessment followed where the full-text articles were scrutinised to assess relevance to the review questions. The retained articles addressed a KM related topic exclusively in the field of pharmaceutical industry or in conjunction with other industries. To mitigate the risk of bias of the reviewed studies (Moher et al., 2015), 141 eligible articles were quality- assessed for the clarity of research objectives, adequacy of description of the data collection methods and finally the link between data, results and conclusion as advised by Kitchenham and Charters (2007). Four articles were excluded at this stage due to ambiguous methodology and irrelevance to the pharmaceutical industry. Ultimately, 137 articles were

retained for analysis after application of inclusion/exclusion criteria and quality assessment. A limited number of non-business journal papers (e.g. medical journals) and papers identified by cross-referencing citations were included during the review process (Figure 3-1).

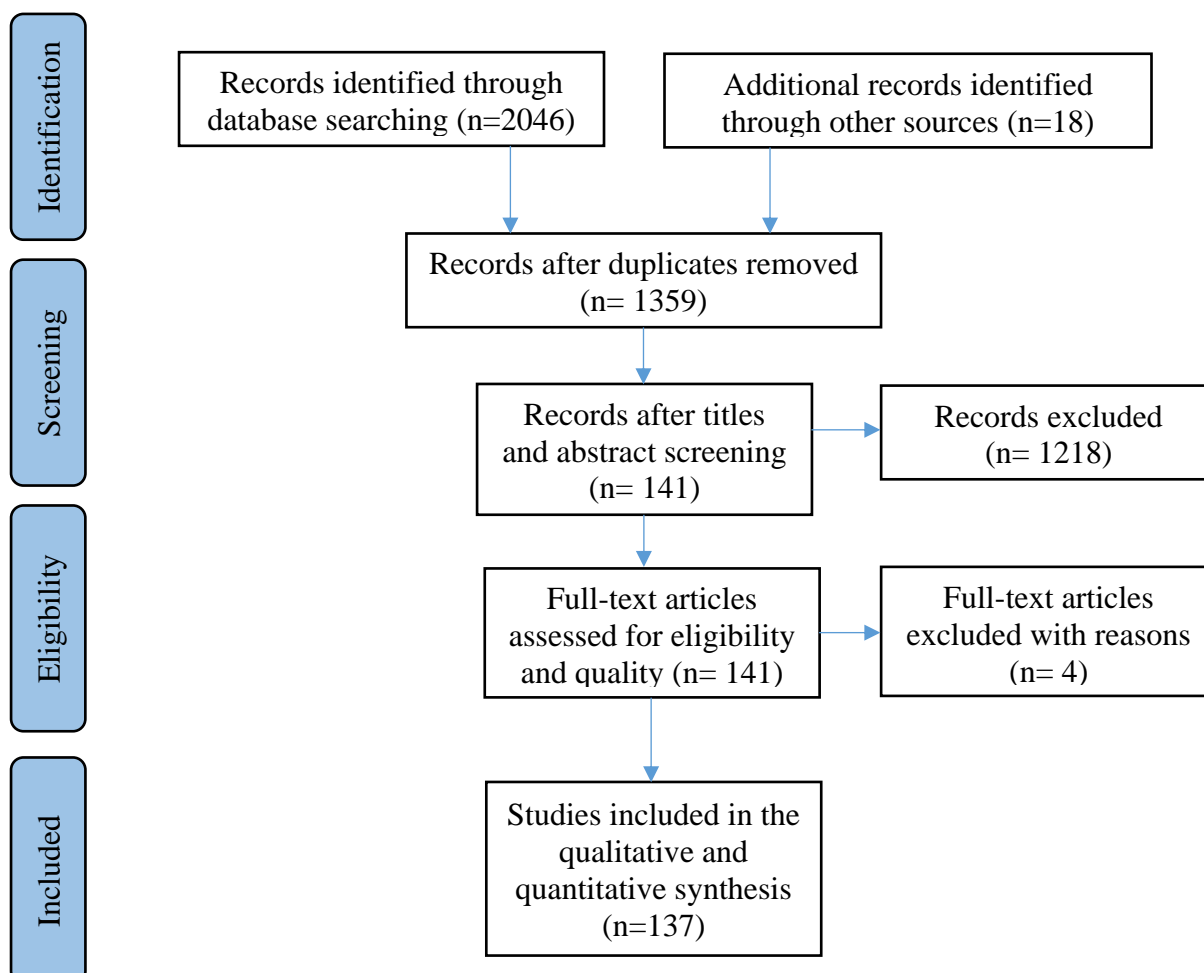


Figure 3-1 Systematic review process -PRISMA flow diagram (Moher et al., 2015)

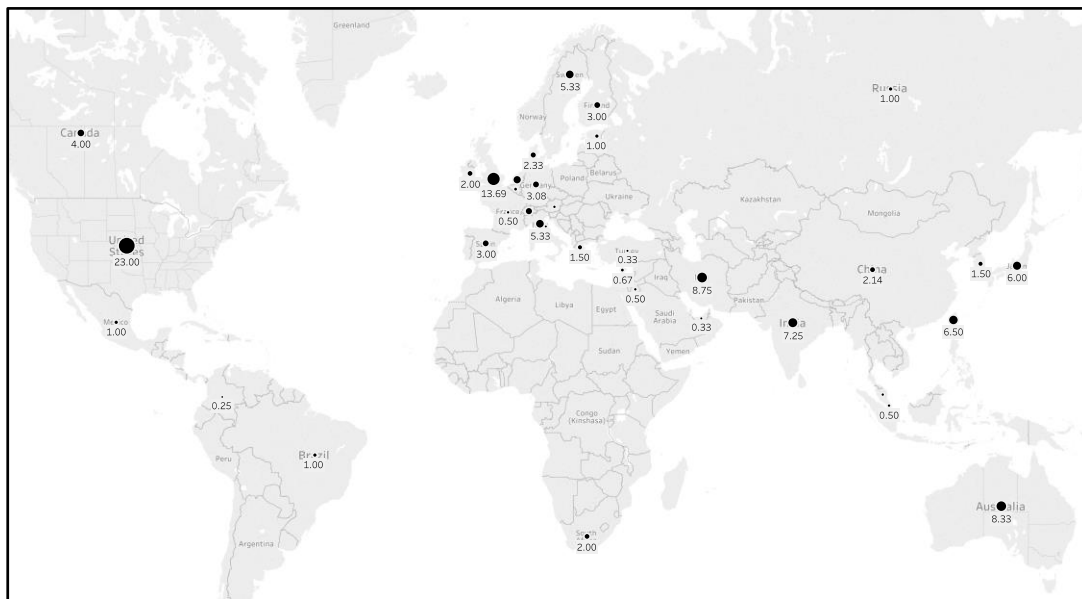
After acknowledgement of main themes and processes in KM literature; the identified themes were scrutinised in the regulatory guidelines of five major regulatory bodies. The reviewer collected all the published guidelines for the pharmaceutical industry on the official websites of World Health Organisation (WHO), FDA, ICH, The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) and EudraLex- European Union (EU) Legislation. At the end, 128 guidelines were searched for KM related topics in light of the identified themes from the academic literature review. The

analysis recognises the significance of research themes from regulatory perspective as well as the possible research gaps in this field.

### 3.2 Findings

#### 1. *Scientometric Trends*

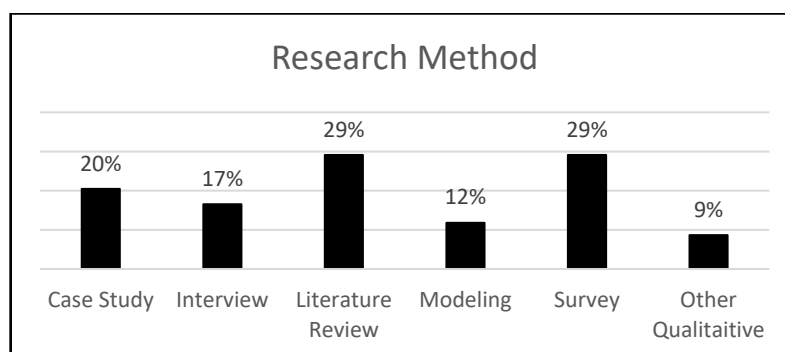
Initially, findings indicate that KM in the Pharmaceutical industry has become a well-established academic research area. Authorship trends show that approximately 93% of articles are published by academic researchers, while the remaining 7% are the product of practitioner work. A significant increase in collaborative research is also evident, as the number of co-authored papers has increased from 62% to 85% over the past ten years. In order to identify the leading countries in the KM field, the relative contributions of 36 countries whose papers were included in this review are traced and ranked using the Equal Credit counting method (Chua and Cousins 2002; Lowry et al. 2007). The USA and UK were ranked highest with regards to productivity (18% and 11% respectively of all reviewed articles); followed by Iran (7%), Australia (7%) and India (6%) as shown in (Figure 3-2). It is worth noting that country contribution in this research addresses the country of residence of the author not necessarily where the research was carried out.



*Figure 3-2 Country Productivity*

From a functional perspective, more than 60% of the articles do not specify the particular department where the study was conducted. Among articles which do specify the function under study, 83% fall within pharmaceutical development and innovation functions in contrast to only 8% in production, 4% in sales and 4% in the supply chain. It is worth noting that 72 % of the reviewed papers were conducted exclusively in the pharmaceutical industry.

In terms of Methodology, only 29% of the articles are literature review papers; while over 70% are empirical studies employing one or more data collection methods, e.g. surveys (29%), case studies (10%) and interviews (17%) (Figure 3-3).



*Figure 3-3 Research and Data Collection Methods*

## II. *Research Themes*

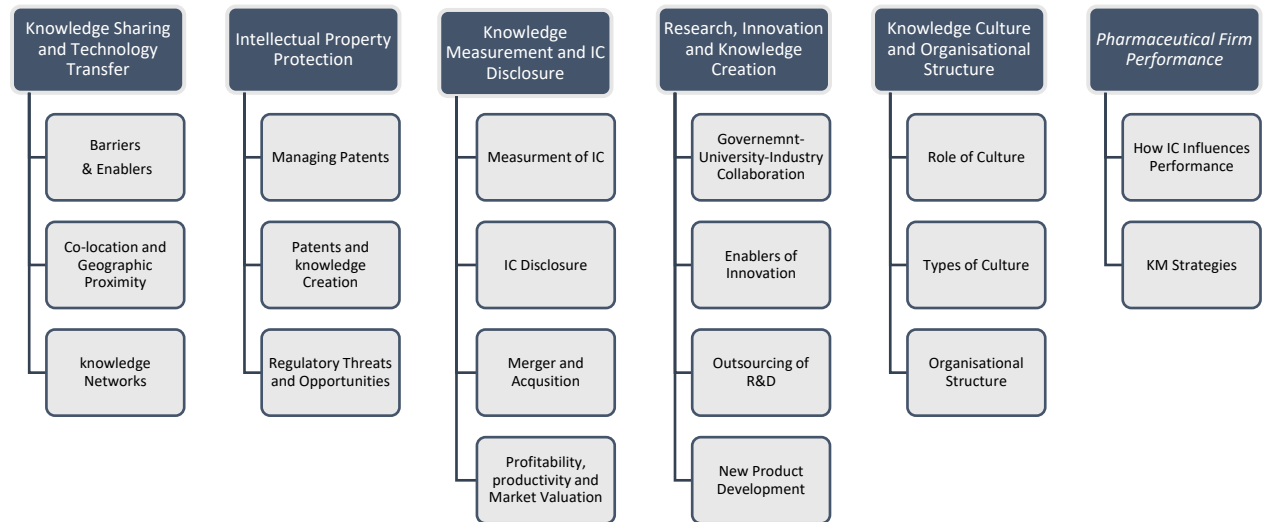
A hybrid method of quantitative keyword analysis and qualitative thematic analysis was proposed to identify the common research topics or themes. Over 20 concepts were used to code the articles according to the prevalent research theme. The most frequent themes and keywords (after exclusion of generic keywords, e.g. knowledge management, pharmaceutical, etc.) are presented in (Table 3-3). More than 20% of the reviewed papers included “Intellectual Capital” as the most frequently used keyword. Innovation, Knowledge Sharing and Knowledge Transfer come in the second, the third and the fourth rank respectively regarding keyword/research theme frequency.

*Table 3-3 Themes and Keyword Analysis*

<b>Rank</b>	<b>Themes &amp; K. processes</b>	<b>Frequency</b>	<b>Keywords</b>	<b>Frequency</b>
<b>1</b>	Intellectual Capital	29	Intellectual Capital	27
<b>2</b>	Innovation	25	Innovation	18
<b>3</b>	Knowledge Transfer	14	Knowledge Sharing	10
<b>4</b>	Knowledge Sharing	13	Knowledge Transfer	10
<b>5</b>	Organisational Performance	12	New Product Development	9
<b>6</b>	Organisational Culture	12	Research and Development	9
<b>7</b>	Intellectual Property	10	Intangible Assets	8
<b>8</b>	Knowledge Creation	9	Organizational Learning	7
<b>9</b>	New Product Development	6	Organizational Culture	5
<b>10</b>	Organisational Learning	6	Project Management	5

The identified themes and keywords offer a birds-eye view of the KM landscape through a taxonomy of KM research in the pharmaceutical industry providing researchers with a map of the current literature and insights into future research. The paper presents a classification of KM publications into six areas: knowledge sharing and technology transfer, Intellectual Property Protection (IPP), knowledge measurement and Intellectual capital (IC) reporting, innovation and knowledge creation, organisational knowledge culture and structure as well as

pharmaceutical firm performance (Figure 3-4). Table 3-4 presents the key articles under each of the featured themes.



*Figure 3-4 Literature Map*

Table 3-4 Key articles under the featured themes

Category	Reviewed Articles
<b>Knowledge Sharing and Technology Transfer</b>	(Yang et al., 2014); (Iwasa & Odagiri, 2004); (Boasson & Boasson, 2015); (Allarakhia & Walsh, 2011); (Sternitzke, 2010); (Kale & Little, 2005); (Hohberger, 2016); (Chávez & Viquez, 2015); (Russell, 2016a); (L. Bollen et al., 2005)
<b>Pharmaceutical Firm Performance</b>	(J.-K. Wang et al., 2006); (Mehralian et al., 2016); (Rémy Magnier-Watanabe & Senoo, 2008); (Rémy Magnier-Watanabe & Senoo, 2010); (Rémy Magnier-Watanabe et al., 2011); (Remy Magnier-Watanabe & Senoo, 2009); (Lindner & Wald, 2011); (Guzman, 2008); (J. Evans & Brooks, 2005); (Ebrahimi et al., 2008); (Bigliardi et al., 2012); (Filieri et al., 2014)
<b>Research, Innovation and Knowledge Creation</b>	(Vishnu & Kumar Gupta, 2014); (Tahvanainen & Hermans, 2005); (SubbaNarasimha et al., 2003); (Singh & Kansal, 2011); (A.-A. A. Sharabati et al., 2010); (Palacios-Marques & Garrigos-Simon, 2003); (Pal & Soriya, 2012); (Narula2016; Naidenova2013; (Mehralian, Rasekh, et al., 2013); (Mehralian, Rasekh, et al., 2013); (Kamath, 2008); (Y.-C. Huang & Wu, 2010); (Hine et al., 2008); (Ghosh & Mondal, 2009); (Erickson & Rothberg, 2009); (Chizari et al., 2016); (L. Bollen et al., 2005); (Boekestein, 2006); (Boekestein, 2009); (Abhayawansa & Azim, 2014); (Sydler et al., 2014); (Russell, 2016b); (Rossi et al., 2015); (Nito, 2005); (Mehralian et al., 2012); (Mehralian et al., 2014); (L.-S. Huang et al., 2011); (Boekestein, 2009)
<b>Intellectual Property Protection</b>	(Wakefield, 2005); (Styhre et al., 2008); (Qureshi & Evans, 2015); (Akhavan et al., 2015); (Pedroso & Nakano, 2009); (Mets, 2006); (Lilleoere & Hansen, 2011); (Lawson & Potter, 2012); (Hemmert, 2004); (Gray et al., 2011); (Dooley & Kirk, 2007); (Delaney, 1999); (Criscuolo, 2005); (Coradi et al., 2015); (Chávez & Viquez, 2015); (Brachos et al., 2007); (Bourouni et al., 2015); (Azan & Huber Sutter, 2010); (Allen et al., 2016); (Santos, 2003); (Mohan et al., 2007); (Malik, 2012); (Iwasa & Odagiri, 2004); (Filieri et al., 2014); (Chang et al., 2007); (Buchel et al., 2013); (Bourouni et al., 2015)
<b>Knowledge Culture and Organisational Structure</b>	(Mehralian et al., 2012); (Malik, 2012); (Kim et al., 2014); (Vishnu & Gupta, 2014); (SubbaNarasimha et al., 2003); (A.-A. A. Sharabati et al., 2010); (Pal & Soriya, 2012); (Kamath, 2008); (Garcia Morales et al., 2008); (L. Bollen et al., 2005); 1
<b>Knowledge Measurement and IC Disclosure</b>	(Terziovski & Morgan, 2006); (Styhre et al., 2002); (Sternitzke, 2010); (Standing & Kiniti, 2011); (Sharma & Goswami, 2009); (Roth, 2003); (C. Parisi & Hockerts, 2008); (Palacios-Marqués et al., 2016); (O'Dwyer et al., 2015); (Nightingale, 2000); (Mehralian et al., 2014); (Lowman et al., 2012); (Lauto & Valentin, 2016); (Kneller, 2003); (Khemka & Gautam, 2010); (Kazadi et al., 2015); (Kale2005; Huang2011; Hohberger2016; (Herrmann & Peine, 2011); (van Geenhuizen & Reyes-Gonzalez, 2007); (Gassmann & Reepmeyer, 2005); (Garcia Morales et al., 2008); (Filieri et al., 2014); (Chen et al., 2008); (Chang et al., 2007); (Cardinal & Hatfield, 2000); (Styhre et al., 2008); (Mets, 2006); (Lowman et al., 2012); (Lauto & Valentin, 2016); (Kazadi et al., 2015); (Gassmann & Reepmeyer, 2005); (Cardinal & Hatfield, 2000); (Boasson & Boasson, 2015); (Mohan et al., 2007)

*Publication years*

The review shows that the majority of included articles have been published between 2004 and 2016 as shown in (Table 3-5).

*Table 3-5 Publications per year*

Year	Intellectual Property Protection	Knowledge Culture and Organisational Structure	Knowledge Measurement and IC Disclosure	Knowledge Sharing and Technology Transfer	Pharmaceutical Firm Performance	Research, Innovation and Knowledge Creation	Miscellaneous	Total
1996							1	1
1997							1	1
1998							1	1
1999				1				1
2000						3	1	4
2001								
2002						1	1	2
2003			2	1	1	2	1	7
2004	1			2			5	8
2005	2	1	3	2	1	3	5	17
2006		1	1	1		2	2	7
2007				4		3	4	11
2008		3	2	1	2	4	9	21
2009		1	4	1		1	3	10
2010	1	1	2	1	1	2	2	10
2011	1	2	2	2		3	3	13
2012		1	2	2	3	2	1	11
2013			3	1			3	7
2014	1	1	4	1	2	2	4	15
2015	2		1	6		4	3	16
2016	2	1	3	1		4	3	14



### *Knowledge Sharing (KS) and Technology Transfer:*

More than 19% of the reviewed articles addressed knowledge sharing and transfer signifying that Knowledge transfer (KT) holds a special significance in the Pharmaceutical industry. Knowledge transfer (KT) and sharing are the fundamental knowledge processes and the leading research topic in KM/IC publications (Ramy et al. 2017). While World Health Organisation (WHO) dedicated Annex 7 of Technical Report Series no.961 to discuss dynamics and controls of process/technology transfer occurring at some stage in the life-cycle of most products in the pharma industry (WHO, 2011b), the real significance of KS comes from the fact that it is the component that facilitates continuous knowledge creation (Akhavan et al., 2012) and is a key driver of long-term success in a knowledge-intensive organisation (Coradi et al., 2015). Accordingly, enablers and deterrents of knowledge sharing come to the focus of the field studies in various industrial domains. Within the pharmaceutical context, a thorough investigation by Qureshi and Evans (2015) identifies nine categories of deterrents which are classified as either structural barriers, cultural barriers, or managerial barriers. Structural factors include lack of physical proximity and the associated high cost of KS as well as IT infrastructure limitations. Cultural factors encompass knowledge-hiding, the lack of socialisation, the lack of trust, the organisational politics and the non-educational mindset as a pure commercial drive dominates the interactions within the pharmaceutical organisation.

Additionally, poor leadership and time pressure are classified as managerial barriers for KS. Conversely, documentation, education and training, reading standard operating procedures, recognition of work, meetings, seminars and conferences, staff updates and voluntary mentoring are identified as intra-organisational knowledge sharing mechanisms in pharma (Qureshi & Evans, 2015). Although the perceived loss of knowledge power, the perceived reputation enhancement, and the perceived enjoyment in helping others as well as social ties and trust can influence employees' attitude towards KS (Akhavan et al., 2015); empirical

evidence indicates that trust, motivation to transfer knowledge, management support and learning orientation are crucial for the effectiveness of knowledge transfer and innovation (Brachos et al., 2007). As enablers and deterrents for KS are found not to be the same for everyone within the pharmaceutical firm, the diverse nature of roles in this industry needs to be considered in any knowledge sharing initiatives within the organisation. For example, scientists and technicians in R&D present different views and practices regarding their perception of the enablers/barriers. Indeed, reinforcing the KS enablers to leverage knowledge among pharmaceutical R&D professionals would potentially accelerate the innovation process and thus decrease new products' time to market and consequently reduce cost (Lilleoere & Hansen 2011).

Also, Knowledge Networks (KN) are increasingly considered vital channels to achieve strategic objectives in project-based organisations particularly the pharma R&D (Bourouni et al., 2015; Mohan et al., 2007). The structural indexing and knowledge dictionaries can identify knowledge agents and evaluate intra-organisational knowledge sharing. Enhancing knowledge flow among development phases can be crucial to shortening the product to market timing. Indeed, structural indexing contributes to KT through the identification of members who actively share knowledge and evaluation of the degree of knowledge sharing as well (Wakefield, 2005).

As physical proximity is one of the suggested barriers for *Knowledge Sharing and Technology Transfer* (Lilleoere & Hansen, 2011), several studies handle this topic in the pharma explicitly. For instance, studies conducted in the R&D department of the multinational drug manufacturer *Novartis* reveal that the co-location of dispersed project teams increases face-to-face communications leading to a faster and more precise flow of personal knowledge. In the same study multi-space work areas were found to simulate knowledge creation SECI

model (Nonaka & Takeuchi, 1995) by enabling socialisation, externalisation and combination of knowledge (Boutellier & Ullman, 2008; Coradi et al., 2015).

On a macro scale, an equally significant aspect of inter-organisational KS is geographic distribution. Higher quality risk can accompany offshore manufacturing due to challenges of KT from headquarters (Gray et al., 2011). The location of the pharmaceutical firm is found to influence the intensity of communication between different firms but not innovation. Relocation (e.g. into industry clusters) and expensive real estate investments can be replaced by enhancing the social connections through technology (Allen et al., 2016; van Geenhuizen & Reyes-Gonzalez, 2007). However, it has been argued that having an R&D laboratory near corporate headquarters can enhance new drug productivity as proximity is necessary for the integration of R&D with other functions and strategic goals for product innovation (Cardinal & Hatfield, 2000).

It was also found that pharmaceutical firms often cite more patents from other geographically close firms. An elaborate analysis of US pharmaceutical patent citations between 1963 and 1999 affirmed that 37% of cited firms are less than one mile away from the citing firm and more than 50% are within 50 miles apart or 26% if we excluded self-citations. Further, a positive relationship was found in the same study between patent quality and geographic proximity to other knowledge-intensive institutions and activities (Boasson & Boasson, 2015). In order to overcome geographic proximity challenges, researcher mobility within the R&D networks is the commonly adopted approach. Whereas the use of international assignments is limited to the transfer of project-specific knowledge, building social relations between researchers through assignments was found to increase KT and reduce inter-unit attrition as well (Criscuolo, 2005; Iwasa & Odagiri, 2004).

*Intellectual Propriety Protection (IPP):*

There is no industry where firms build their competitive advantage more closely to IPP than the pharmaceutical industry. However, in response to dramatic transitions in bioscience and computational chemistry, biopharmaceutical companies commence newer approaches for managing their IP and innovation including open access, closed pool, exclusive and non-exclusive licensing (Allarakhia & Walsh, 2011). Although exclusive licensing is more preferred in the pharmaceutical industry (2:1), the findings support the notion that non-exclusive licensing contributes more to the overall firm's performance. This can be explained by the increase in the organisational knowledge exchange, decrease the cost of knowledge transaction, and the value of increased use of knowledge returns to the innovator through non-exclusive links. Moreover, non-exclusive licensing provides a strategic advantage to the company and reduces market uncertainty by decreasing competition. The organisational performance was measured in terms of efficiencies of sales and Human Capital (HC) in addition to Return on Asset (ROA) and Return on Investment (ROI) (Malik, 2012).

The significance of IP for the pharmaceutical industry comes from the notion that patents are used as a proxy indicator for knowledge creation (Nerkar, 2003). Also, patent citation studies in pharma exploit patent-related data to estimate the quality of innovation, diffusion of knowledge and geographic localisation of knowledge (Chávez & Viquez, 2015). For this reason, patents can affirm the firm's value and market performance. Association between company value, reported intangible assets and R&D capitals have been found to exist (Russell, 2016b).

In a highly dynamic global economy, enforcing IP protection laws implies significant economic costs (Mazzoleni & Nelson, 1998). Considering the importance of IPP as an incentive for innovation in advanced countries where there is both a superior scientific and technological infrastructure and a rich market for new drug products, WHO was conscious of the challenges that can face developing countries due to IPP regulations (WHO, 2006a). For

instance, from 1990 onwards, innovative Indian pharmaceutical firms targeted generic market in advanced countries which enforced them to comply with IPP regulations not only for the product but also for processes. Indian firms are facing challenges due to changes in patent law and the development of new technologies, particularly in the biotechnology field. Since 1995, a progressive increase in R&D budgets has been observed in order to build the required knowledge bases in addition to hiring experienced scientists and targeting retiring post-graduates from overseas universities. Moreover, building research networks with overseas research institutes has emerged as a key mechanism for knowledge acquisition (Kale & Little, 2005).

#### *Knowledge Measurement and IC Disclosure:*

Empirical evidence supports the notion that the nature and value of knowledge assets differ from one industry to another with a direct impact on investment decisions. By using Tobin's Q model for knowledge measurement, it is noticed that not only the level of intellectual capital (IC) and competitive intelligence are both higher in consumer industries (such as pharmaceuticals) in comparison to business to business industries, but also investments in knowledge assets are less promising in business markets (Erickson & Rothberg, 2009). Measurement of pharmaceutical IC at the organisational level relies on the identification of most relevant constructs or indicators in each industry. According to a Delphi study in the pharmaceutical and telecommunication sectors, the management experience and technical knowledge are on the top of the HC indicators in pharma (Palacios-Marques & Garrigos-Simon, 2003).

Regarding structural capital, organisational culture, the ratio of investment in R&D and the number of R&D projects are the highest priority indicators. Additionally, mutual trust with customers and their satisfaction are the highest priority RC indicators in comparison to the co-authorship with academic centres (Mehralian et al., 2013). However, the disclosure of IC in the

balance sheet (BS) is still a measurement barrier and an opportunity for improvement in the pharmaceutical industry, particularly in developing countries. In studies of IC disclosure in top pharma companies in India and Bangladesh, the computed figures of IC show that the enormous value of IC remains unreported in BS. This highlights that the lack of standardised accounting guidelines on this vital asset results in unreporting of resources of billions in firm's annual reports which impacts their performance in the stock market (Abhayawansa & Azim, 2014; Singh & Kansal, 2011).

Intellectual capital is widely adopted as a predictor for firm's profitability in the pharmaceutical sector and the intangible asset capitalisation is associated with firm's market value (Sydler et al., 2014). Healthcare patents perform both disclosure and signalling functions; reflecting firm's innovative capabilities and enhancing the capacity to raise necessary start-up capital (WHO, 2006a). However, no significant relationship was observed either between IC and productivity or market valuation. Also, it was found that Market to Book (MB) and Return on Asset (ROA) are significantly correlated with IC. While Return on Equity (ROE) in pharma is double the ROE in less knowledge-focused industries such as textile (i.e. the investors are getting more return on their shareholder equity), ROA is nearly equal for both. A better understanding of IC may enhance the profitability and the productivity of companies (Pal & Soriya, 2012). Likewise, in the pharmaceutical sector in Iran and India, two comparable studies found that the performance of IC can explain profitability but not productivity or market valuation (Ghosh & Mondal, 2009; Kamath, 2008). However, this argument is subject to controversy as companies which generate more profits are able to invest more in IC (Naidenova & Parshakov, 2013).

Merger and Acquisition (M&A) can be used as a cost-effective way to gain access to new product platforms, technologies and patents. Traditional pharmaceutical companies with depleted research pipelines but sufficient cash can acquire innovative biotech firms as a source

of new products (Rossi et al., 2015). A study of the influence of M&A on the total value of the pharmaceutical company acquired revealed that the total value of the companies in 135 acquisition situations under investigation have increased approximately 6 times on acquisition. This increase is mainly attributed to knowledge related intangible assets and goodwill which substantially overlap with IC. The Pharma companies which are not being acquired are potentially undervalued because of intangible assets underestimation under current accounting systems (Boeckstein, 2009).

#### Research, Innovation and knowledge creation (KC):

The emergence of new discoveries in the twenty-first century will urge Pharmaceutical manufacturing to employ innovation and cutting edge knowledge and technology as ways of doing business (FDA, 2004b). Genetics, bioinformatics, High-Throughput Screening (HTS) and in-silico simulation have allowed pharmaceutical research to exploit economies of scale and economies of speed in drugs experimentation and development. Nowadays, pharmaceutical industries do not typically fit to the classic economy of scales theories as they transformed into R&D intensive rather than production intensive. In other words, the industry has become more dependent on patents rather than production volumes to secure profits. Due to the low success rates for drugs under development (two drugs of every 10,000 synthesised substances will become a marketable medicine), long development time (up to 10 years) as well as high cost for drug development (€ 1,926 million) (EFPIA, 2018), the increase of success rates and development speed would substantially reduce the development cost and avoid late costly failures (Gassmann & Reepmeyer, 2005; Nightingale, 2000).

The Pharmaceutical industry, more than other industries, is dependent on scientific advances developed in the public sector particularly in basic sciences. It was found that following a basic science patent, at least 19 research publications and 23 additional patents are filed. If the innovation is of radical type and associated with a market breakthrough, additional patents are

expected to be filed earlier (Sternitzke, 2010). Historically, the role of the public sector in drug discovery was limited to basic research to elucidate the basic pathological mechanisms. However, this role has significantly expanded in the biotechnology era (Stevens et al., 2011). For example, the preliminary evaluation of innovation expenditure structure of the Estonian biotechnology sector reflects the prominent role of public fund, which is estimated to be more than 80% of the total budget. In spite of that, the low level of R&D expenses in Estonian biotech companies (15.7% compared to revenues) against 60% in Europe and 45.7% in the USA reflects the challenges facing emerging countries in the biotechnology industry (Mets, 2006).

In contrast with publicly funded drug research model in EU and US universities, it is noticed that drug discovery in Japanese companies occurs predominately in-house which may be no longer compatible with the global competitiveness (Kneller, 2003). In Ireland, governmental investment in research and innovation is a strategy to compensate the loss of its old competitive mandate of low-cost manufacturing capabilities by the emergence of new competitors (O'Dwyer et al., 2015). Thus, the collaboration between industry and universities provides local competitive capabilities to solve industry problems in Multinational Enterprises (MNE) subsidiaries without the need to refer problems back to head offices (O'Dwyer et al., 2015).

In such a complex R&D environment, information sharing and intrinsic motivation are recognized as important drivers for organizational creativity (Sundgren et al., 2005); there is a significant influence of knowledge transfer on firm innovative capability ( $r= 0.893$ ) too (Palacios-Marqués et al., 2016). As the bulk costs of R&D comes from the clinical phases, sharing knowledge and experiences coming from terminated projects would be of high significance too. Knowledge facilitators in clinical trials play an outstanding role in promoting knowledge sharing. (Styhre et al., 2008). Knowledge facilitator plays a catalyst role in KC and sharing by raising the level of trust between members of organisations and building a care climate (Roth, 2003). Evidently, KC process has a direct positive impact on HC which in turn



has a positive significant impact on both structural and relational capital (RC) (Mehralian et al., 2014).

The surveyed literature highlights some of the dynamics of innovation within pharma organisations. Management support, design of effective policies and effective management of knowledge are found indispensable if the organisation wants to adopt an innovative environment. Additionally, Job satisfaction explains up to 25% of the variance in innovation regression models (Khemka & Gautam, 2010). Transformational leadership shows a positive relationship with innovation (Garcia-Morales et al., 2008). Both information and organisation capital play a mediating role in the impact of HC on innovation. Also, a significant positive relationship has been established between organisation capital and innovation confirming the remarkable role of intangible assets in generation and enhancement of innovative capabilities (Huang et al., 2011). Wikis and Innovation contests are used in pharma to leverage collective intelligence and enhance innovation in large companies (Lauto & Valentin, 2016; Standing & Kiniti, 2011). Conversely, outsourcing of R&D and clinical studies for new product development (NPD), combined with lack of integration among outsourced clinical research organisations (CRO) and the associated knowledge losses as well as regulatory delays create innovation risks (Lowman et al., 2012). Meanwhile, FDA warned from the threats of broad interpretations of 21 CFR part 11 (electronic records and electronic signatures) on innovation and technological advances without any benefit for patient health (FDA, 2003).

#### *Knowledge Culture and Organisational Structure:*

The American FDA encourages management to implement quality systems and procedures that support a communicative organisational culture. Under such quality systems, knowledge communication is promoted through the creation of a work culture that appreciates employee suggestions and uses them for continual improvement (FDA, 2006). Specific beliefs and knowledge-related values can be sources of competitive advantages in pharma. For instance,

values such as love, care and trust contribute significantly to the firm's performance and knowledge creation (Magnier-Watanabe & Senoo, 2009). For similar reason, the know-how or technical skills are not as important success factors as tacit knowledge sources held by knowledge workers (Styhre, Roth and Ingelgrd, 2002; Magnier-Watanabe and Senoo, 2009).

Knowledge culture is a way of organizational life that empowers people to create, share and use knowledge for the good of the organisation (Oliver & Kandadi, 2006). In the pharmaceutical industry, knowledge culture is believed to compensate for the lack of organisation memory in temporary project teams where ICT alone has a limited value. Factors like the support of informal communication, tolerance towards mistakes, positive project culture and commitment of top management significantly contribute to open knowledge transfer within and/or between projects (Lindner & Wald, 2011). Similarly, Evans and Brooks (2005) argued that just providing new technology in order to facilitate collaborative practices does not necessarily create a more collaborative culture in pharmaceutical supply chain environment (J. Evans & Brooks, 2005). Organisation memory held by ageing workers can be transferred to the younger workers through bridges of socialisation and adequate organisational climate to facilitate circulation of tacit knowledge (Ebrahimi et al., 2008).

The organisational characteristics of pharmaceutical firms such as structure and strategy affect knowledge acquisition activities including knowledge storage, diffusion and application where the national culture must also be considered (Magnier-Watanabe & Senoo, 2008). In fact, the organisational characteristics can have even more influence over KM than the national culture (Rémy Magnier-Watanabe & Senoo, 2010). In the pharma industry, open culture where employees are able to raise questions and feel at ease explains 31% of the variance in four modes of SECI process compared to only 16% for the bureaucratic culture (Magnier-Watanabe et al., 2011). In pharmaceutical R&D, bureaucratic culture has a negative impact on knowledge workers' job satisfaction while innovative or supportive culture positively influence them

(Bigliardi et al., 2012). Wang (2006) claims that the information culture, excessively concerned about financial costs and technical compatibility of KM systems, can ultimately be hostile towards KM implementation. Moreover, the Knowledge sharing and externalisation of tacit knowledge can also be limited by intra-organisational political constraints (Wang, 2006) .

#### Pharmaceutical Firm Performance:

Human and Relational Capital is deemed to positively impact business performance (Sharabati et al., 2010). Several empirical studies have underlined this paradigm utilising either ROA/ return on sales (ROS) as performance measures (Vishnu & Gupta, 2014); whereas, Value Added Intellectual Coefficient (VAIC) (Chizari et al., 2016) or generation of new patents were used as proxies for technical knowledge of firms (SubbaNarasimha et al., 2003). Bollen, Vergauwen and Schnieders (2005) argue that each of the three components of IC individually and collectively influences firm performance. By way of illustration, in spite of the direct relationship of HC and firm performance, it offers little value without appropriate Structural Capital (SC). At the same time, HC is necessary for the proper formation of SC and RC (Bollen et al., 2005). In contrast, Vishnu and Gupta (2014) research in Indian pharmaceutical firms denies the relationship between RC and performance. Meanwhile, IC performance (particularly the physical capital) and firm profitability not productivity or market valuation are thought to be related (Mehralian et al., 2012). KM performance is considered as a predictor of superior financial performance in terms of higher profit ratios (ROA, ROS) and lower cost ratios (OPEX) (Holsapple & Wu, 2011).

The literature revealed that KM strategies influence organisational performance in the pharmaceutical industry (Kim et al., 2014). Four types of KM strategies are identified in the literature: external/internal codification strategy and internal/ external personalisation strategy. Information system maturity in the pharmaceutical firm, as well as knowledge intensity, would be the determinants for the most effective KM strategy (Kim et al., 2014). Also, integrating

external and internal knowledge sources has increased the probability of obtaining higher level of organisational performance. However, the internal organisational tensions between the tacit-oriented and explicit-oriented strategies, which are difficult to reconcile, would negatively impact the performance. (Choi et al., 2008).

### III. *Regulatory Insights*

In order to understand KM from the pharmaceutical regulators' perspective, the researcher conducted a thorough review of KM requirements in 128 Good Practices (GxP) quality guidelines. The review revealed a slightly different pattern of interests and expectations in comparison with the academic business journals (Figure 3-5).

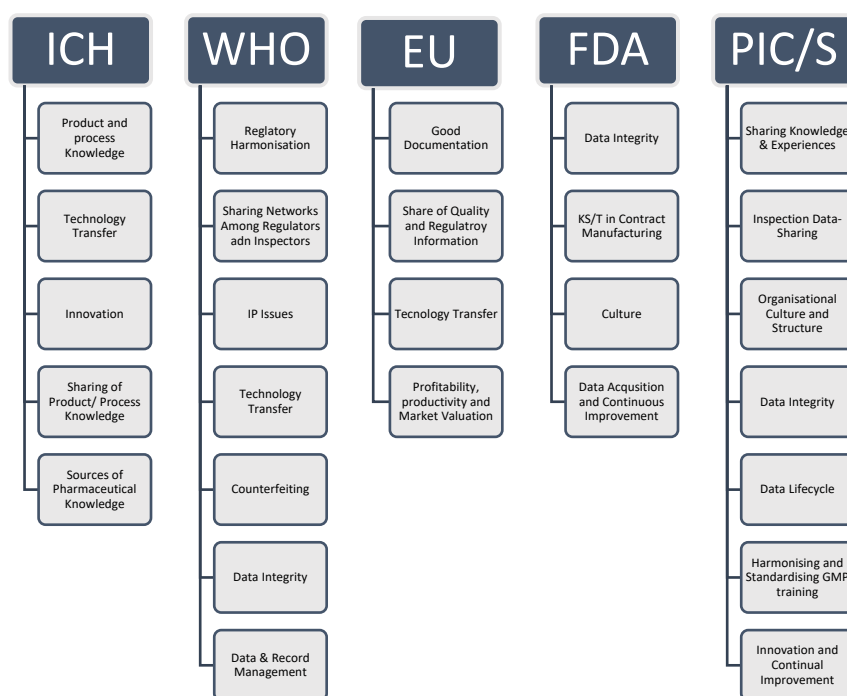


Figure 3-5 Key themes in regulatory guidelines

An overview of the current thinking and expectations of key regulatory bodies regarding KM is presented as follow:

### ***ICH***

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From the previous review sections, KM expresses a considerable level of maturity as an academic research field in the pharmaceutical industry. Despite that, Calnan *et al.* (2018) suggest that KM shows less mature roles at industry level which might hinder the achievement of ICH Q10 desired state. Whereas Quality Risk Management (QRM) is assigned a full ICH guideline (i.e., ICH Q9), KM received less attention by regulatory agencies (Rathore et al., 2017). This section and the following highlights the major KM requirements as explained by regulators.

For instance, ICH Q10 considers KM together with QRM as the enablers of its effective implementation throughout the product lifecycle. Proper implementation of these guidelines can facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities. It summarises the goal behind the technology transfer process in pharmaceutical firms in the transfer of product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation. In fact, one of the objectives of ICH Q10 is to facilitate continual improvements, identify the appropriate product and process improvement as well as innovation. Last but not least, ICH Q10 suggests monitoring of all innovations that might enhance QMS (ICH, 2008).

Other ICH guidelines refers sporadically to KM with a focus on KS/KT. ICH Q9 suggested the need for further studies related to technology transfer should be assessed through QRM (ICH, 2005). ICH Q11 endorses the management and sharing of product/process related knowledge throughout product lifecycle including knowledge related to drug substance and its manufacturing process.

It is argued that this enhances the manufacturing process and establish a control strategy especially in cases of product ownership changes (e.g. through acquisition). Suggested sources of drug knowledge include but are not limited to process development activities, technology transfer activities to internal sites and contract manufacturers, process validation studies over the lifecycle of the drug substance, and change management activities (ICH, 2012).

### **WHO**

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For the purpose of earlier detection of potential problems, WHO guidelines pay close attention to regulatory harmonisation and participation in information (e.g. from inspections and clinical studies) sharing networks among regulatory agencies with special considerations to confidentiality and intellectual property issues e.g. (WHO, 1999, 2003, 2017). WHO works towards provision of high assurance of quality, efficacy and safety of drugs. Parallel efforts are exerted to contain escalating costs of drug prices by minimizing duplication of inspection activities through: better networking, improved information sharing, enhanced collaboration, increased mutual trust and confidence. The organization help manufacturers actively collaborate in information sharing among national, regional and international inspection authorities (WHO, 1999). WHO efforts are also directed towards the collaboration among Pharmacopeias through work-sharing and harmonisation in accordance with Good Pharmacopoeial Practices (GPhP) (WHO, 2006b). Information sharing efforts with the European Directorate for the Quality of Medicines & Healthcare (EDQM) extends to certification programs (WHO, 1999). Risk communication and sharing risk-related knowledge are also addressed in WHO guidelines (WHO, 2013). Finally yet importantly, sharing public alerts and warning alerts for imported drugs or medical devices can prevent similar faulty products from being exported to other markets (WHO, 2017).

WHO identifies the technology transfer (including process knowledge and product development history) as the middle stage in the drug lifecycle where GMP regulations must apply (WHO, 2013, 2014). The organisation requires validation of the process of data transfer (WHO, 2016). Whenever the transfer involves analytical methods, it is required to conduct this validation by the development department before the transfer to manufacturing quality control. Periodic checks are necessary to ensure the accuracy and reliability of the process (WHO, 2006c). As a general requirement, mechanisms should be addressed to facilitate the transfer of

information not only between manufacturers and customers but also to the relevant regulatory bodies (WHO, 2010b).

With regard to IPP, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) is led by WHO, where the focal point is public health protection from the implications of counterfeiting (WHO, 1999). The ever-changing business strategies and their accompanying intra- and intercompany transfers of technology obliged The WHO Expert Committee on Specifications for Pharmaceutical Preparations in its 42<sup>nd</sup> report to assign a special guideline to address this issue (TRS 961 Annex 7). However, this guideline is meant to be a flexible framework rather than a rigid technology transfer guidance. Although a multifunctional team is proposed to manage the transfer process, it is affirmed to be under the umbrella of a quality system (WHO, 2011b).

WHO requires pharmaceutical manufacturers to build their quality decisions and regulatory commitments on science-based understanding of the process and QRM which can offer greater freedom of how to comply, hence enhances innovation (WHO, 2013). Development of quality culture in the pharmaceutical organisation is believed to improve transparency about failures and ensure good data management strategies are in place. Besides, data integrity and protection occupied a featured position in WHO regulations. Pharmaceutical firms are expected to develop appropriate tools and strategies for the management of data integrity risks based upon their own GxP activities, technologies and processes (WHO, 2016).

### ***EU GMP***

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EU Guidelines for Good Manufacturing Practices (EudraLex) has adopted Good Documentation Practices as an enabling tool for knowledge management throughout different stages of product lifecycle (EudraLex, 2015). Similar to WHO, PIC/S and ICH recommendations, the guidelines encourage agents, brokers, distributors, repackers or relabellers to share regulatory and quality information with the manufacturers and customers (EudraLex, 2004; ICH, 2000; PIC/S, 2017; WHO, 2010a). EudraLex requires analytical



method transfer protocol (EudraLex, 2006) with no explicit transfer framework as in WHO TRS961 Annex 7. However, it confirmed the coverage of technology transfer by cGMP regulations as a part of product lifecycle (EudraLex, 2011).

### ***FDA***

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FDA pays special attention to process understanding and knowledge management as effective strategies for preventing and detecting data integrity issues (FDA, 2016c). On the other hand, FDA accentuates the knowledge sharing and transfer in contract manufacturing as explained in the quality agreement (FDA, 2016a). The agency highlights the role of senior management in the creation of communicative organisational culture as a tool for improving knowledge sharing and communication in addition to cross-functional groups to share ideas for improvement purposes (FDA, 2006).

In addition, FDA commends the role other knowledge processes such as data acquisition and accumulation over the lifecycle as an important way for continuous improvement which in turn can facilitate the scientific communication with the agency (FDA, 2004a). Similarly, following process validation FDA guidelines would support process improvement and innovation (Services & FDA, 2011).

### ***PIC/S***

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In response to the increasingly complex global supply chains in the pharma industry, PIC/S facilitates voluntary inspection data-sharing between member authorities. This is deemed to enable risk-based assessment of the need to carry out inspections based on shared confidence in inspected firms (PIC/S, 2011b). It has not escaped our notice that data sharing and transfer in PIC/S guides is focused on inspection data rather than knowledge created in pharmaceutical firms. The statute of the International Medicinal Inspectorates Database (IMID), which aims at establishing a database of GMP inspections carried out (or to be carried out) by IMID participating Regulatory Authorities, was adopted by PIC/S to reduce the number of duplicative inspections (PIC/S, 2012). The PIC/S committee is cooperating with other global

agencies such as WHO, EMA, the ICMRA (International Coalition of Medicines Regulatory Authorities) and United Nations Children's Fund (UNICEF) with regard to training and sharing of inspections' information (PIC/S, 2011a, 2015, 2016b; WHO, 2003).

The data integrity is essential for the successful implementation of GMP, as such, the requirements for good data management are embedded in the current PIC/S guidelines to GMP/GDP for Medicinal products. Good data management practices (GDMP) are envisaged as fundamental enabler for the integrity of the generated data. The manufacturer or distributor undergoing inspection is required to enforce GDMP that ensure the accuracy, completeness and reliability of data. (PIC/S, 2016a). Moreover, the suggested expansion of the scope of QMS to the development phase is presumed to facilitate innovation and continual improvement and build up the link between pharmaceutical development and manufacturing activities (PIC/S, 2017).

The data lifecycle (from generation through to discard at the end of retention period) is also featured in GMP guidelines including cross-boundaries data transfer emphasising the relationship with the product lifecycle. In case of computerised systems, interfaces should be assessed and addressed during computer system validation to guarantee the correct, accurate and complete transfer of data (PIC/S, 2016a, 2017). Risk review should be considered especially for supply chains and outsourced activities to assess the extent of data integrity controls required (PIC/S, 2016a). It is noteworthy that PIC/S has repeatedly warned of inappropriate interpretation of guidelines making them barriers to technical innovation or the pursuit of excellence (e.g. PIC/S, 2011c).

Organisational culture and behaviour are a complementary part of the effective data governance system when combined with an understanding of data criticality, data risk and data lifecycle. The value behind this appears in the empowerment of employees to report failures and opportunities for improvement. This reduces the incentive to falsify, alter or delete data

(PIC/S, 2016a). GMP inspectors have to be sensitive to the effects of organisational culture and structure on the organisation behaviour where data reporting differs between open and close cultures. In order to ensure data integrity within the pharmaceutical organisation, appropriate values, beliefs, thinking and behaviours need to be demonstrated consistently by management, team leaders and quality personnel (PIC/S, 2016a).

Table 3-6 Regulatory insights into Knowledge Management

KM Theme	EU GMP	ICH	FDA	WHO
Knowledge Sharing and Technology Transfer:	N/A	ICH Q9 on quality risk management (4.5.); ICH Q9 on quality risk management. (II.3); ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7 (17.60); ICH Q11 - Development and Manufacture of Drug Substances (9); ICH Quality Risk Management Q9 (II.3.); ICH pharmaceutical quality system Q10 (1.6.1); ICH pharmaceutical quality system Q10 (3.1.2)	FDA Guidance for Industry: Contract Manufacturing Arrangements for Drugs: Quality Agreements (1.e.); FDA Guidance for Industry: Contract Manufacturing Arrangements for Drugs : Quality Agreements (1.d.); FDA Guidance for Industry: Contract Manufacturing Arrangements for Drugs : Quality Agreements (1.e.); FDA Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations (3); CFR Title 21 Part 820 Quality System Regulations	WHO TRS 1003 Annex 4 (4.1.1.2.); WHO TRS 996 Annex 4 (1.1.); WHO TR S 996 Annex 1 (4); WHO TRS1003 Annex 4 (1.5.); WHO TRS 953 (2.1.3.); WHO TRS 953 (2.1.9); WHO TRS 953 (2.1.13); WHO TRS 953 (8.1); WHO TRS 953 (8.1.1); WHO TRS 953 (17); WHO TRS 1003 Annex 4 (4.2.4.3.); WHO TRS 1003 Annex 4 (4.4.); WHO TRS 981 Annex 2 (1.1.); WHO TRS 981 Annex 2 (glossary); WHO TRS 961 Annex 7; WHO TRS 957 Annex 2 (17.60); WHO TRS996 Annex 5 (7.6.); WHO TRS996 Annex 5 (Appendix 1); WHO TRS 973 Annex 4 (1.4.); WHO TRS 973 Annex 4 (3.3.); WHO TRS 986 Annex 2 (1.4.); WHO TRS 986 Annex 2 (7.17); WHO TRS 981 Annex 2 (1.2.); WHO TRS957 Annex 5 (14.11); WHO TRS 953 (8.2.)
IPP	N/A	N/A	N/A	WHO TRS1003 Annex 4 (1.6.); WHO TRS 953 (2.1.7., 2.1.11)

Knowledge Measurement and IC Disclosure	EudraLex Annex 15: Qualification and Validation	ICH pharmaceutical quality system Q10 (2.8.)	FDA Guidance for Industry: PAT: A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance (1.d.)	WHO TRS 961 Annex 7 (1.4)
Research, Innovation and Knowledge Creation	N/A	ICH Q11 - (3.1.3.); ICH Q10 (Glossary); ICH Q10 (1.1); ICH Q10 (1.5.3.); ICH Q10 (1.6.); ICH Q10 (1.6.1.); ICH Q10 (3.2.3.); ICH Q10 (4.2.b);	FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures - Scope and Application (III.B.); FDA Guidance for Industry: Process Validation: General Principles and Practices (1); FDA Guidance for Industry: Data Integrity and Compliance With CGMP (Draft) (III.1.c)	WHO TRS 981 Annex 2 (1.1)
Knowledge Culture	N/A	N/A	FDA Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations (B.2.)	WHO TRS 996 Annex 5 (1.4.)
Pharmaceutical Firm Performance	N/A	N/A	N/A	Knowledge strategies: WHO TRS 996 Annex 5 (1.4., 5.4., 5.5., 7.5.)

### 3.3 Discussion and Implications:

The pharmaceutical industry is not only one of knowledge-intensive sectors, but also an industry with a direct effect on health promotion (Mehralian et al., 2016). It comprises distinct characters making pharmaceutical knowledge management a unique process. Being research-intensive, highly innovative and a great source of IC (Kamath, 2008), building networks of R&D personnel with research institutions, providing ultimate protection of IP rights, having high influence of political, legal and administrative factors on technology acquisition (Hemmert, 2004), achieving a high level of maturity in project management (Wakefield, 2005), involving suppliers in product development activities (Lawson & Potter, 2012), involving collaborative research with universities and governments (Dooley & Kirk, 2007), presenting sophisticated drug discovery and development systems (Criscuolo, 2005), facing challenges of regulated prescription drugs (Pedroso & Nakano, 2009), being one of the fast-growing economic sector (Singh & Kansal, 2011), together with huge economic productivity and high number of employees (Bigliardi et al., 2012) are some of reasons for choice of the pharmaceutical industry as the empirical research field of many articles in KM literature. Nevertheless, 28% of the reviewed articles included mixed samples from different industries. This might be attributed to selection of convenience sample of knowledge-intensive companies without an industry-specific research scope.

Based on an in-depth review of the literature, key trends emerged. Domination of academic authorship (93% of authors) along with 20% increase in co-authorship reflect the academic maturity of the research area. Participation of practitioners is relatively limited (7%) in spite of the colossal investments in KM by pharma companies (Riddell & Goodman, 2014). This also supports Calnan *et al.* (2018) argument that the role which “*knowledge*” plays in the pharmaceutical industry is still immature and disabling the ICH Q 10 desired pharmaceutical quality system. This argument has also been made in other sectors e.g. public sector KM

publications (Massaro et al., 2015). This can also accentuate what has been described by Ragab and Arisha (2013) as a theory-practice gap in KM literature in general.

Furthermore, the review found that the UK and USA are responsible for nearly one third of publications within the review period. This supports the findings of Ramy et al. (2017) which underline the prevalent contribution of North America, Western Europe, and Australia in KM publications. However, a compelling interest in KM has been recognized in Iranian, Indian and Taiwanese academic institutions reflecting the future role of emerging economies in pharma industry. Since R&D is considered the key space for knowledge creation (Ingelgård et al., 2002; Parisi et al., 2006), most of the studies ignored other functions (e.g. manufacturing, sales or quality) or other sources of knowledge in a pharmaceutical organisation (e.g. process validation studies; manufacturing experience, continual improvement, and change management activities). However, from a regulatory perspective, managing the knowledge throughout commercialisation and manufacturing phases until product discontinuation is believed to be as important as managing drug development knowledge (ICH, 2009).

Taxonomical analysis of literature affirms six main knowledge processes/ themes extensively covered by researchers in the pharmaceutical industry.

### Publication years

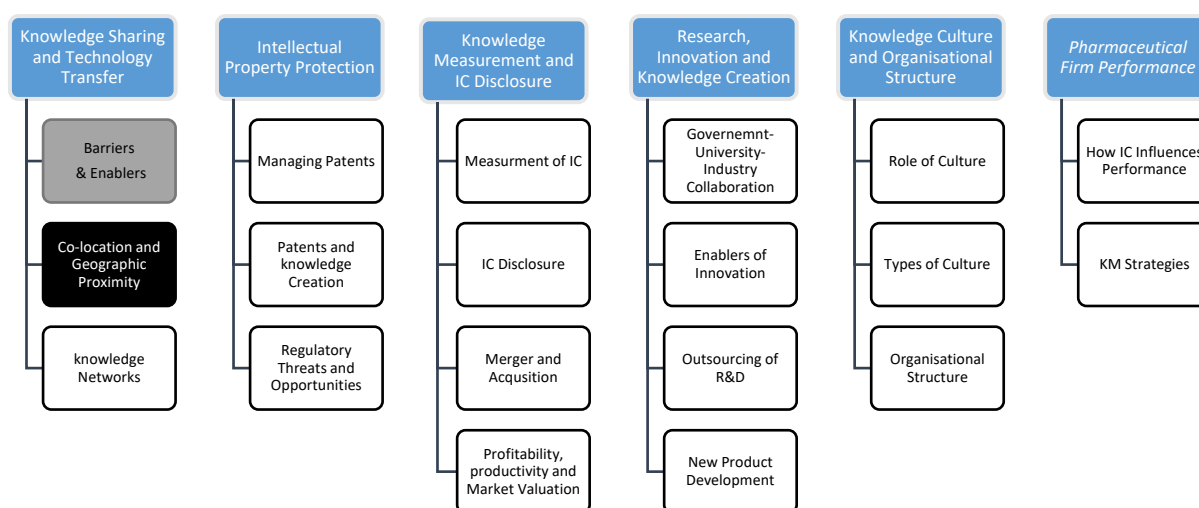
The review shows that the majority of included articles have been published between 2004 and 2016 as shown in (Table 3-5).

*Table 3-5 Publications per year*

Year	Intellectual Property Protection	Knowledge Culture and Organisational Structure	Knowledge Measurement and IC Disclosure	Knowledge Sharing and Technology Transfer	Pharmaceutical Firm Performance	Research, Innovation and Knowledge Creation	Miscellaneous	Total
1996							1	1
1997							1	1
1998							1	1
1999				1				1
2000						3	1	4
2001								
2002						1	1	2
2003			2	1	1	2	1	7
2004	1			2			5	8
2005	2	1	3	2	1	3	5	17
2006		1	1	1		2	2	7
2007				4		3	4	11
2008		3	2	1	2	4	9	21
2009		1	4	1		1	3	10
2010	1	1	2	1	1	2	2	10
2011	1	2	2	2		3	3	13
2012		1	2	2	3	2	1	11
2013			3	1			3	7
2014	1	1	4	1	2	2	4	15
2015	2		1	6		4	3	16
2016	2	1	3	1		4	3	14



In spite of that, the research in some other potential areas is relatively scarce (e.g. PKM, knowledge acquisition, knowledge integration). The reviewer observed an overemphasis on the OKM while the PK received little attention in the reviewed literature. Only two out of 19 subthemes (Figure 3-6) have approached the personal dimension of knowledge. Conversely, IC is the most frequently used keyword and research theme in pharmaceutical KM literature. As a part of company intangible capital, patent-related keywords (e.g. patent citation, analysis, research, count, etc.) are mentioned 10 times in the review pool reflecting the importance of IP rights (structural capital) as a research subject. All the knowledge measurement articles were dedicated for the IC measurement and disclosure.



*Figure 3-6 Personal versus organisational knowledge presentation in the reviewed literature*  
*(black shading= personal knowledge; white shading= organisational knowledge; grey shading= mixed)*

The influence of pharmaceutical IC on profitability, productivity and market value is addressed in several papers (e.g. Pal and Soriya, 2012). Pharmaceutical IC reporting in BS suffers from inconsistency and lack of standardised guidelines. Indeed, this phenomena is not exclusive to the pharmaceutical industry and was highlighted in other industries (Ragab & Arisha, 2013). Yet, Intellectual Capital, knowledge measurement or disclosure are not addressed by CGMP guidelines. While M&A implications were a subject of academic research

in pharma companies, regulatory publications focus on knowledge transfer after product/process acquisition or data acquisition during product lifecycle (FDA, 2004a). Although KM is explicitly required in ICH Q10 1.6.1.(ICH, 2008), regulatory authorities didn't address either measurement or disclosure of IC. With poor reporting and disclosure of IC in pharma (Abhayawansa & Azim, 2014), further research is needed to induce industry-specific measurement frameworks not only at the organisational IC level but also at the personal knowledge level.

Barriers and enablers of KS, as well as impact of co-location and geographic proximity on knowledge sharing in the pharmaceutical facilities, are thoroughly studied in academic literature and partially covered by the regulatory requirements to support a communicative culture. No doubt, the return on investments in KS can be manifested in the creation of new knowledge (Lilleoere & Hansen, 2011) and evading knowledge loss from pharmaceutical organisation. Use of KS enablers, non-exclusive licensing, networks as well as workspace designs and co-locations is believed to enhance the flow of knowledge and accelerate the drug development phase. Technology transfer and method/process transfer are regulated practices under pharmaceutical quality systems (ICH, 2009; WHO, 2011b); case studies or empirical research is quite limited in this area.

Governmental role in innovation, either through the outputs of basic science or public funding of growing industry R&D, is emphasised in the literature. Collaboration between industry and universities as well as overseas research centres is found crucial for advances in global competitiveness in the pharma industry. Dynamics of innovation as managed by the Triple Helix model can be a meticulous explication of this phenomenon (Etzkowitz & Leydesdorff, 2000; Leydesdorff & Meyer, 2006). When the FDA announced the Pharmaceutical CGMPs for the twenty-first Century in 2006; corrective actions, innovation and continuous improvement were considered as three complementary improvement

approaches in Pharmaceutical Manufacturing (FDA, 2004b). However, only innovation has received considerable attention in the surveyed literature. It is worth noting that the term “creation” was mainly used by the regulators to signify creation of data and/or electronic records (FDA, 2016b).

The review explored the role of pharmaceutical organisational culture and structure in knowledge management. The review highlighted the notion that some values are found to be associated with the prosperity of knowledge within workspace (Magnier-Watanabe & Senoo, 2009) and new technology is not able alone to bring about a successful KM system (Chatzkel, 2007). The KM performance of the company was found in general related to its market performance. Yet, the organisational performance was not considered by any of the five regulatory bodies.

### *3.4 Summary and Conclusion*

The pharmaceutical sector is one of the pillars of the world’s economy. A significant proportion of its value lies in intellectual assets generated through a continuous innovation process and lengthy product development cycles within a strict regulatory environment. The purpose of this chapter is to present an inclusive review of Knowledge Management processes in the pharmaceutical industry with a focus on key regulatory concerns.

The review identified a range of knowledge processes that were investigated in the pharmaceutical context and highlights their role in the organisation. The academic empirical research within the pharmaceutical industry partially addresses the regulatory concerns. Regulatory bodies require KM across the product lifecycle and outline the role of the individual as a holder of knowledge, meanwhile, the KM scholars focus on the organisational rather than the PKM (bottom-up) approaches. Also, the findings indicate that prior KM studies focused on the pharmaceutical development and innovation activities, ignoring other ICH Q10 suggested

sources of pharmaceutical knowledge such as pharmaceutical manufacturing. In this dilemma, the industry practitioners refrain from serious contribution to academic research. This supports the notion that knowledge management in the pharmaceutical industry is still a growing research area, particularly in manufacturing (non-research) functions. This study attempts to address this theory and practice gap by developing a framework for the identification and measurement of personal knowledge in the pharmaceutical manufacturing context.

Chapter five is dedicated to the exploratory study in the pharmaceutical industry. The proposed measurement framework is developed in light of the exploratory study findings and the extant literature. In the next chapter, the author defines his research methodology and embraced philosophy.

## **Chapter 4 : Research Methodology**

### 4.1 Background

This study can be understood in light of Kothari's (2004) definition of research as an academic activity that comprises definition and redefinition of problems; it can take the form of an original contribution to the existing stock of knowledge through the formulation or generalisation of a theory (Kothari, 2004). The research is undertaken to discover things in a systematic way and thereby increase knowledge. The “*systematic way*” declares that the research must be based on logical relationships, not just beliefs (Saunders et al., 2008). The need for research reflects a state of incomplete knowledge or unanswered questions in many science disciplines. It is also related to the compulsive need for growth experienced by *Homo Sapiens* which drive humanity to endless requirements of increased performance in all aspects of life (Remenyi et al., 1998). Also, the research is motivated by the identified research problem and the highlighted gaps as outlined in the previous chapters.

It is clear that the good research should be capable of generating dependable data. This can be achieved by following the structure of the scientific method which leads to a desirable, decision-oriented research (Blumberg et al., 2014). This chapter outlines the researcher's approach to meet the criteria of good research at all the stages of this study. Although the choice of appropriate data collection techniques and analysis procedure is important for any research (Figure 4-1), issues underlying this choice should be considered by the researcher (Saunders et al., 2008). This chapter discusses the research philosophies and approaches relevant to this study. It provides explicit justification of the adopted methodologies, strategies, time horizon and highlights their impact on the research process. It also outlines the research design, the research plan and the ethical considerations of the study.

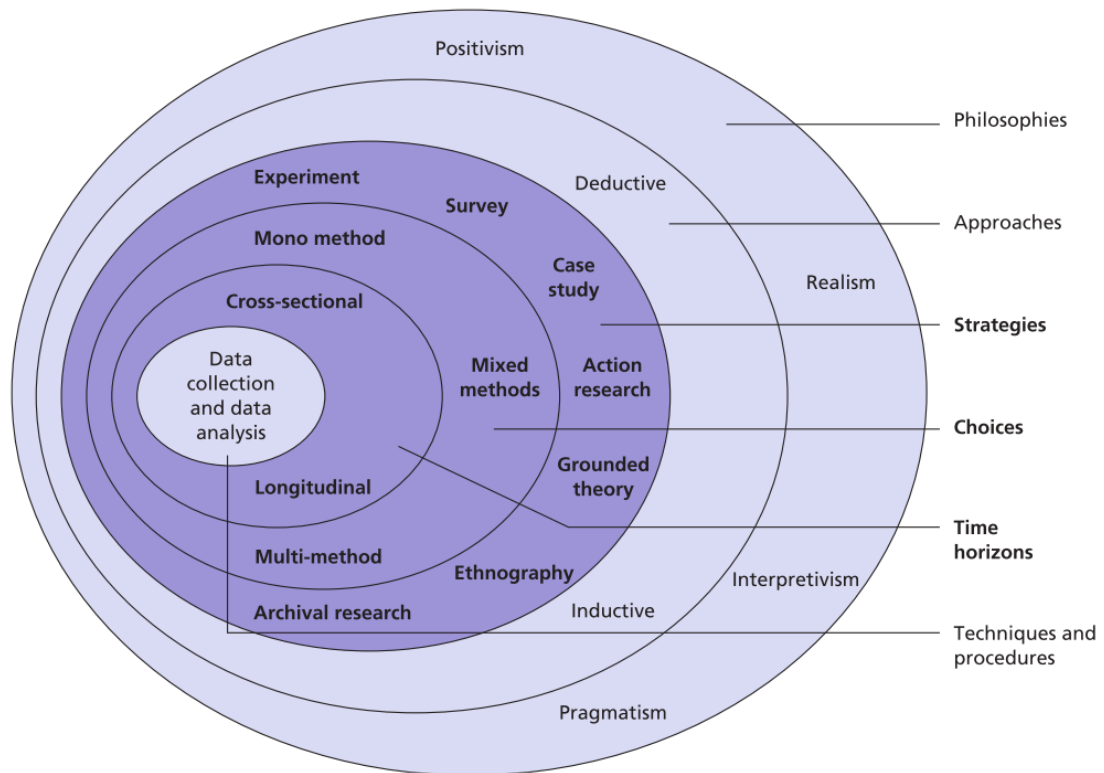


Figure 4-1 *The Research Onion* (Saunders et al., 2008)

## 4.2 Research philosophy

Ontology defines the nature of the social reality upon which the research is based. It is the recommended starting point for any research (Grix, 2003). Two main ontological positions are recognised in the academic literature: objectivism and subjectivism (constructivism) (Bryman & Bell, 2015). Objectivism is an ontological approach that assumes the reality exists external to social actors' minds. In contrast, the subjectivism suggests that the social reality is the creation of the social actor and consequently, it is in a continual state of revision. It also implies the existence of multiple realities (Saunders et al., 2016). Popper (1966) advocates that human knowledge is objective and impersonal where people are not only theory producing but also a consumer of others' theories whether in science, religion or even poetical myths. Popper's objective knowledge is independent of the person's subjective belief, in other words, it can be understood without submerging in the subjective minds of people (Tell, 2004).

This objective understanding of knowledge is in line with the researcher's proposition of the personal knowledge of pharmaceutical manufacturing employees. According to the law of contradiction (one of the three fundamental laws of logic), two contradictory prepositions cannot both be right or in other words for all propositions *P*, it is impossible for both *P* and not *P* to be true (Encyclopedia Britannica, 2019). As previously explained, knowledge is a justified true belief. This definition implies that knowledge must always be true as false knowledge is impossible (Hunt, 2003). Therefore, the research adopts the single objective reality position as multiple realities (subjectivism) would inevitably lead to a contradiction. The research thus adopts that it is not possible to measure and compare the knowledge unless it is objective and where external standards (not from the social actor mind) are used to evaluate the generated knowledge (Tell, 2004).

Epistemology is the theory of knowledge or simply the possible ways of gaining knowledge of social reality (Grix, 2003). The modern western epistemology recognises two great epistemological traditions: *Rationalism* and *Empiricism*. While *Rationalism* claims that true knowledge is the product of mental processing rather than sensory experience, *Empiricism* limits true knowledge to sensory experiences (Nonaka & Takeuchi, 1995). Similarly, two main paradigms are recognised in social science research which have their roots in the 20<sup>th</sup>-century philosophical thinking: quantitative and qualitative paradigms. The quantitative paradigm is also known as the positivist, the traditional or the empiricist paradigm (Creswell, 1994). Positivism is adapted from natural science. It has three basic principles: objectivism, value-free research, and research independence (Blumberg et al., 2014). In a positivist view of the world, the research adopts the philosophical stance of a natural scientist where only observable phenomena produce credible data (Saunders et al., 2008). It also proposes a nomothetic epistemological approach with existent regularities and law-like generalisations in social settings (Easton, 2010). However, as explained by Sveiby (2010), the measurement of a social



phenomenon (e.g. the personal knowledge) depends on proxies and assumptions which make it less accurate than measurement in the applied science settings (Sveiby, 2010). For this reason, the positivist paradigm is not appropriate for this study. Furthermore, the conclusive theory testing within social science is complicated by diversity, complexity and changing nature of organisations as well as the element of personal volition in human behaviour (Cusumano et al., 2008).

In contrast, the interpretivist approach advocates a value-laden nature of the study. The interpretivist describes reality as subjective and multiple as the social actors interact with their research outcomes (Creswell, 1994). Interpretivism appeared as a criticism of the application of the scientific model to the study of social phenomena. Whereas the positivist aims to explain human behaviour, the interpretivist aims to understand it (Bryman & Bell, 2015). Interpretivism exploits the heritage of *Phenomenology* (Saunders et al., 2008). From this perspective, each situation is perceived in a unique way as a function of circumstances and involved individuals. In other words, research is not independent of the researcher, but it is an intrinsic part of it (Remenyi et al., 1998).

For pragmatism, an idea is true if it is useful and has practical consequences or simply if it works (Gray, 2013). Accordingly, there may be multiple realities as no single viewpoint furnishes the complete picture (Saunders & Tosey, 2013). In other words, only concepts that support actions are connected to the matter in hand. This can be described as a reconciliation between subjectivism and objectivism (Saunders et al., 2016). According to Gray (2013) pragmatism has become popular in recent decades as it provides an epistemological justification for the use of mixed methods research (MMR). MMR is that type of research in which a researcher join qualitative and quantitative research techniques to achieve breadth and depth of understanding and corroboration (Schoonenboom & Johnson, 2017). However, the pragmatist position underestimates the role of the philosophical assumptions in the appropriate

exploitation of research methods (Maxwell & Mittapalli, 2010). The idea of multiple realities was found incompatible with the researcher's perspective of knowledge as both objective and intransitive. Due to this ontological disagreement, both interpretivism and pragmatism philosophies were excluded.

Realism as a research philosophy shares the principles of Positivism and Interpretivism (Blumberg et al., 2014). Similar to positivism, it argues that social sciences can apply the same principles of data collection and interpretation as natural science. It also endorses the view of external reality to scientists' minds. There are two major forms of *Realism*. *Direct* or *Naïve Realist* believes reality can be accurately understood via the aid of our sensory experiences and thus are deemed superficial (Bryman & Bell, 2015). Conversely, *Critical Realism (CR)* emerged as a response to increasing critique to Positivism that dominated the early decades of the 20<sup>th</sup>-century and was strongly associated with the British Philosopher Roy Bhaskar. Bhaskar confirms that the world is structured, differentiated and changing (Danermark et al., 2002).

Unlike *Naïve Realist*, *Critical Realist* differentiates between the objects under research, and the terms used for their description. While the former positivist approach works well in the natural science context where it is possible to measure reality in controllable systems, this seldom happens in social science. *Critical Realist* claims that our knowledge of the world is fallible where conditions and social relations affect our perception. In spite that the world is socially constructed from a *Critical Realist* perspective, it is not entirely so (Easton, 2010). It is argued that reality already exists independent of our perceptions, but it is impossible to attain a "God's eye point of view" purely independent of any particular viewpoint (Maxwell & Mittapalli, 2010). The self-contradiction of *Naïve Objectivism* and *Relativism* comes from the fact that in their more radical forms they entail that it is meaningless to search for general knowledge. Critical Realism keeps the reality existing independently of our knowledge. It

considers the facts theory-dependent but not theory-determined (Danermark et al., 2002). For a critical realist, the reality is both independent of humans and stratified : the real, the actual and the empirical (Mingers, 2004).

The Researcher assumes that personal knowledge must have an objective nature independently existing and external to social actors. This assumption is found necessary to measure and compare employee's individual knowledge in an objective way. Also, measurement error and biases are inevitable and need to be considered. The study design meets the critical realist assumptions by offering an explanation for the observed organisational events through understanding the underlying latent causes which in turn would reveal the deep social structure behind them (Saunders et al., 2016).

### *4.3 Research Approach*

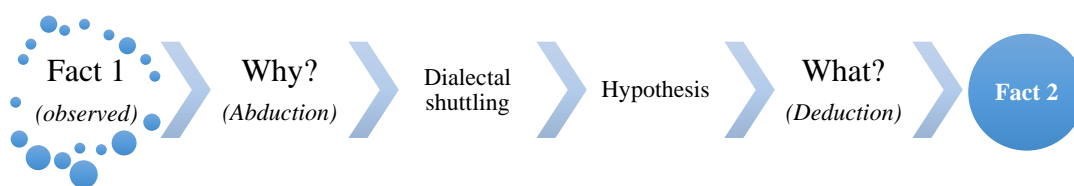
As emphasised in chapter one, a key objective of this research is to understand the structure behind the personal knowledge of knowledge workers in the pharmaceutical manufacturing organisation then exploit this understanding to develop and validate a measurement framework. To achieve this, three reasoning approaches are frequently encountered in literature: induction, abduction and deduction. Induction is a theory-building approach. Through the analysis of collected data, a theory is formulated (Saunders et al., 2008). However, the inductive argument doesn't build high strength in the relationships between premises and results; so it cannot be generalised as a conclusion is seen only as a hypothesis (Blumberg et al., 2014). In other terms, the truth of premises is not a guarantee of the truth of the conclusion (Schechter, 2013).

As this research topic is relatively new, limited literature and few frameworks explain the dynamics of personal knowledge, particularly in the pharmaceutical manufacturing context (Ramy et al., 2018). This suggested that the study commences with an exploratory phase. During this phase 15 interviews with pharmaceutical industry experts were conducted to

explore the current practices and provide more understanding of literature observations (including regulatory literature). The discovered themes and structures of knowledge within the pharmaceutical sector were further compared with evidence from the extant literature. The new explanations are integrated to build the research hypotheses and the proposed framework. This back-and-forth movement between induction and deduction is termed “abduction” where new ideas are generated from the combination of both (M. Saunders et al., 2016). Similarly, Bryman and Bell (2015) call the process of back-and-forth engagement with the social world and literature “*dialectal shuttling*”. Abduction can also be described as a process of forming concrete explanatory hypotheses (Denecker et al., 1996) and inference to the best explanation or interpretation of data (Ketokivi & Mantere, 2010). Moreover, the critical realist method is deemed to be abductive as it moves from experiences in the empirical domain to the underlying structures in the reality domain (Mingers, 2004). As will be detailed later, this study adopts Mixed Methods Research (MMR) to address the research problem by combining inductive and deductive reasoning through abductive thinking (Creswell & Clark, 2018).

On the other hand, deductive theory exploits the available body of knowledge and relevant theoretical ideas to deduce a hypothesis (or hypotheses) that can be subjected to testing (Bryman, 2015). Therefore, the truth of the conclusion in deduction is dependent on the input propositions (premises) conditional that the reasoning is made without mistakes (Schechter, 2013). Deduction can be seen as the mirror image of induction. Whereas the induction uses data to build a new theory, the deduction completes the cycle by using data to test the theory (Eisenhardt & Graebner, 2007). The deductive approach demonstrates a highly structured rigid methodology. The problem under study should be reduced to the simplest elements through the process of Reductionism. However, the prominent feature of the deduction is Generalisation when applied on a sufficient sample (Saunders et al., 2008). In pursuance of validating the proposed framework, the deductive approach is suggested. The researcher

deductively tests the model (hypotheses) developed from the exploratory phase in the following explanatory phase. Abduction and deduction reasoning are sequentially used in research through what can be described as the double movement of reflective thought. Abduction proceeds by observing a fact then during the course of scrutinising (back-and-forth movement) the reason behind it, hypotheses are generated. Deduction comes after to test the capabilities of proposed hypotheses to explain the observed fact (Blumberg et al., 2014). Combining both approaches can be represented in (Figure 4-2). As a side note, there is no rigid division between the different reasoning approaches and it is common to combine more than one approach at one stage of the study (Saunders et al., 2016).



*Figure 4-2 Combining Abduction and deduction*

### 4.4 Research Strategy

In critical realism philosophy, the researcher uses either or both quantitative and qualitative data to explore not only what is immediately experienced but also the structures and relationships that lie beneath (Saunders & Tosey, 2013). While quantitative research explores the relationship between variables to validate objective theories, qualitative research help discover how people interpret social or human phenomena (Creswell, 2014). This study adopts Mixed Methods Research (MMR) techniques. The exploratory phase utilises qualitative semi-structured interviews followed by quantitative surveys in the explanatory phase. In case of relatively novel research topic, Creswell and Clark (2011) suggest to qualitatively explore to

learn about the studied phenomena, theories and variables and then to follow up with a quantitative study to validate the exploratory findings as the mixed method is the ideal approach in such situations (Creswell & Clark, 2011). From a critical realist perspective, quantitative methods (e.g. factor analysis) are employed in the deductive phase to confirm the underlying structures of the latent variable “the personal knowledge” and to validate the developed explanations from the qualitative phase (Mingers, 2004).

MMR design can be realised in two main philosophical positions: critical realism and pragmatism (Saunders et al., 2016). Indeed, critical realism provides philosophical and epistemological assumptions not only compatible with both qualitative and quantitative research methods but also leverage the cooperation between them. MMR gains an advantage from combining the benefits of qualitative and quantitative approaches which enable more solid conclusions that wouldn't be possible by any of them alone (Maxwell & Mittapalli, 2010). Mixed methods are also deemed to provide the required dialogue between different perspectives to deepen rather than triangulate the understanding of the research phenomenon (Maxwell & Mittapalli, 2010). This research couples both a qualitative exploratory phase (semi-structured interviews) to understand and explain the manifestations of personal knowledge in the pharmaceutical organisation and a quantitative validation phase (survey) that deductively test the proposed relations in the research phenomena and understand the underlying factors.

### *4.5 Research Scope and Time Horizon*

This study takes an industry specific approach where the pharmaceutical manufacturing is the research field. According to EudraLex guidelines volume 4, pharmaceutical manufacture can be defined as “*All operations of purchase of materials and products, production, quality control, release, storage, distribution of medicinal products and the related controls*”

(European Commission (b), 2017). From this perspective, the study explores the personal knowledge of all technical employees (knowledge workers) in the following functions:

- Warehousing.
- Formulation, filling, tabletting, primary packaging, etc.
- Secondary packaging.
- Quality Assurance.
- Quality Control.
- Technical services.

Due to the similarities and overlap among manufacturing functions, only manufacture-related technical jobs were considered during the framework development. The following support functions are considered out of the scope of this study:

- Research and Development (R&D)
- Sales
- Marketing
- Procurement and logistics.
- Human Resource (HR)
- Occupational Health and Safety (HSE)
- Facilities, Utilities, Machines, Equipment (FUME) and maintenance engineers.
- Other supporting services.

While longitudinal studies allow researchers to study changes and development as he/she observes people or events over time with control over the studied variables (*Saunders et al., 2008*), this study adopts a cross-sectional time horizon where the data collection relies on organised collections or snapshots at a particular time (Saunders & Tosey, 2013).

### *4.6 Research Design*

In MMR, data is collected and analysed utilising both quantitative and qualitative methodological paradigms. Quantitative and qualitative methods can be either concurrent (conducted in parallel) or sequential (one dependent on the other) as in this research (Creswell & Clark, 2018). It is believed that this combination offers more advantages for the research rather than the use of any single methodology (Čížek, 2009). The purpose of the sequential MMR in this study (QUAL  $\longrightarrow$  QUAN) is the development of the hypotheses (model) by the qualitative techniques that would be confirmed quantitatively in the next phase (Schoonenboom & Johnson, 2017). It is important to mention that this research adopts equal-status mixed methods research (QUAL  $\longrightarrow$  QUAN) where qualitative and quantitative elements share the same value and weight and are continuously interacting (Schoonenboom & Johnson, 2017).

The first phase of this study is an extensive literature review for relevant academic and regulatory literature (Figure 4-3). This is followed by 15 interviews (qualitative) with a selected group of pharmaceutical industry experts. Thematic analysis is adopted to identify key themes and relations (Braun & Clarke, 2006). The ultimate goal of this phase is to abductively develop concrete hypotheses, explaining the personal knowledge, in the form of a conceptual framework.



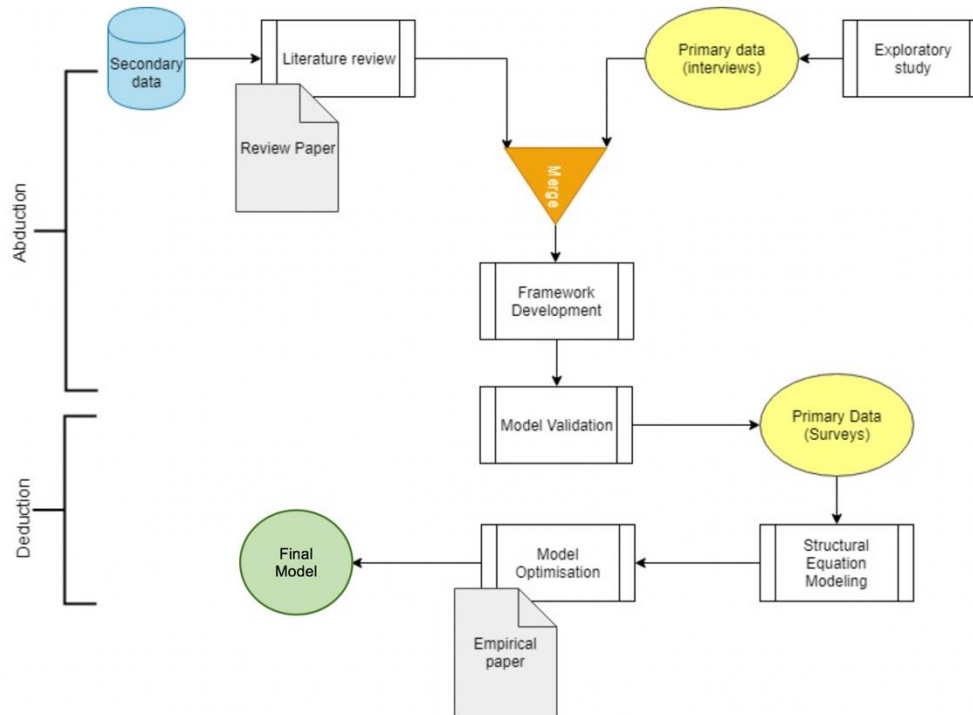


Figure 4-3 Research Design

The subsequent phase is the validation phase employing quantitative techniques. The data obtained through the survey are analysed to evaluate and confirm the underlying factors of the personal knowledge using confirmatory factor analysis.

#### 4.7 Research Plan

It was once recorded that Benjamin Franklin said “*by failing to prepare, you are preparing to fail*”. In order to answer the research questions and achieve the subsequent objectives, a detailed plan was prepared. The research plan consists of an exploratory study, framework development and framework testing/validation. In the following sections, each stage of the plan will be explained in further details.

### I. The exploratory study

This stage is seen as an extension and a complementary component to the previous stage.

There are three ways to conduct an exploratory study: reviewing relevant literature, interviewing experts and conducting focus groups (Saunders et al., 2008). The focus group method was excluded as it was technically impossible to join geographically dispersed industry experts (in 9 countries) together in one session. Both the literature review and semi-structured interviews were employed instead. A related point to consider, the exploratory stage is not subsequent to the literature review phase. Both phases are interacting and engaged together and abductively leading to the framework development. Chapter five is dedicated to the findings of the exploratory study.

#### *(i) Interviews*

Interviews are one of the most commonly used data collection tool in the social sciences (Brinkmann, 2014) and are considered a good subjective exploratory tool rather than an objective scientific hypothesis testing tool (Kvale & Brinkmann, 2009). An interview is a verbal exchange where the interviewer gains insights and understanding of the interviewee's experiences, opinions, predictions and processes (Rowley, 2012). It can be also defined as a purposeful conversation where the interviewee responds to interviewer's concise questions by providing reliable data, relevant to research objectives. It is either structured, unstructured or semi-structured (M. Saunders et al., 2016). Structured interviews follow a rigid structure and highly standardised techniques. On the other hand, unstructured interview pursues a free and flexible style for questioning as no predetermined questions are required (Kothari, 2004). As a midway between the previously mentioned forms of interviews, semi-structured interviews show some level of predetermined structure but maintain flexibility in addressing interview topics too (Longhurst, 2010). They were chosen for the exploratory study as a tool for understanding what is happening in relation to specific research (Saunders et al., 2008). It is

clear that a well-crafted interview can achieve objectivity in the sense of being unbiased and free from prejudice. By the same token, reliability can be attained once leading questions were ruled out during interviews. This is deemed to enhance the consistency and the trustworthiness of research (Kvale & Brinkmann, 2009).

Interviews can also be classified into face-to-face interviews, telephone interviews and internet-mediated (Saunders et al., 2016). Both face-to-face and electronic (internet-mediated) interviews were employed according to the geographic location of the participant. Face-to-face interviews were limited to only one interviewee who was based in Dublin. For internet-mediated interviews, several social media tools were used based on convenience including Facebook messenger, WhatsApp and Skype. Camtasia Studio 8, a professional desktop recording and video editing software, was utilised for recording the online interviews and facilitate any necessary sound editing.

*Table 4-1 Semi-structured interview themes*

Theme	Rationale	Research Objective
Practitioners definition of Knowledge	The introductory question, ice-breaking	Objective 1
Establishment of KM in industry	Reflects the extent of KM adoption in the industry	Objective 1
The significance of knowledge in pharma	To know the value of KM from the subject's perspective. Prepare for the next question about Knowledge measurement	Objective 1
KM Maturity	To explore the status of KM in the company	Objective 1
Individual Knowledge Assessment	To examine the importance of IK assessment, guides to the following question	Objective 2
Elements of Individual Knowledge	To identify parameters for framework design	Objective 2
Framework Application	Explore the usability of the proposed framework	Objective 2

The interview design started by identifying the key themes to be covered during the interview process (Table 4-1). Later, a group of questions were suggested below each of the ten interview themes. Both interview questions and themes were developed drawing on the identified theory gaps and reflecting the research objectives (Rowley, 2012). The included questions were not obligatory and the interviewer was allowed to rephrase them as required or

add necessary probing questions. The researcher utilised open end questions to explore the industry practices and provide suitable answers for the relevant research questions. As an ethical commitment, the interviewer avoided any guiding enquiries in the course of interviews and kept a neutral position. Probing questions are also used to clarify the answers and explore the new topics opened by the interviewees. Those questions were non-directive such as “*can you elaborate?*” or “*can you give some examples?*”. Active listening was practiced to allow the interviewees to freely express their opinions. The interview themes along with the suggested questions were reviewed by the researcher and the supervisors for clarity and grammatical accuracy. Examples of the utilised question are represented in (Table 4-2).

*Table 4-2 Suggested Interview Questions*

How to explore the theme (a suggested question)	Theme
1. How do you understand/define the word “knowledge” in the pharmaceutical industry context? <ul style="list-style-type: none"> <li>• Can you give some examples of knowledge in your function (department)?</li> </ul>	Practitioners definition of Knowledge
2. Do you think knowledge management is a well-established domain within the pharmaceutical industry? <ul style="list-style-type: none"> <li>• If yes, please elaborate.</li> <li>• If no, please explain.</li> </ul>	Establishment of KM in industry
3. In your own opinion, is there a need to better manage knowledge across the product lifecycle within the pharmaceutical sector? <ul style="list-style-type: none"> <li>• Please explain your answer with some examples of where more effective management/use of knowledge could improve outcomes?</li> </ul>	The significance of knowledge in pharma
4. Does your organisation currently have a strategy for knowledge management? <ul style="list-style-type: none"> <li>• If yes, please elaborate.</li> <li>• If no, please explain.</li> </ul> 5. Has your organisation adopted any specific initiative to promote knowledge management practices (e.g. knowledge sharing platforms, social networks, Wikis, etc.)? <ul style="list-style-type: none"> <li>• If yes, please elaborate.</li> <li>• If no, please explain.</li> </ul>	KM Maturity
6. Do you think it is important to assess/ measure the knowledge of individual employees? Please justify.           7. Does your organisation attempt to evaluate individual knowledge of employees? <ul style="list-style-type: none"> <li>• If yes, please elaborate.</li> <li>• If no, please explain.</li> </ul>	Individual Knowledge Assessment

How to explore the theme (a suggested question)	Theme
Tip: you can skip Q.7. if the answer to Q.6. is “yes” and the subject explained their method of assessment.	
8. Are you able to evaluate and compare the individual knowledge of your employees? <ul style="list-style-type: none"> <li>• If yes, how do you evaluate their knowledge?</li> <li>• If no, why not?</li> </ul> 9. What are the main knowledge aspects you need to evaluate in your employees? <ul style="list-style-type: none"> <li>• Give some examples, Please.</li> </ul>	Elements of Individual Knowledge
10. If you had a tool to measure and compare individual knowledge of your employees, would this offer any value to the pharmaceutical industry from a quality, regulatory or business perspective? How?	Framework Application

At the beginning of each interview, the basic demographic information about the participant and his/her organisation was collected. Demographic information included: country of residence, organisation type, the approximate number of employees, product category (conventional, devices, biologics, etc.), ownership of the organisation, job title and participant function or department. These data are obtained to aid the interpretation of the collected data and the discovered trends. It was also used to establish a good rapport with the interviewee before starting with the questions. After the collection of the demographic data, questions on the interview themes followed. Every question was considered to set the context for the following question (Rowley, 2012). The review of the relevant regulatory guidelines (chapter three) did not provide a comprehensive definition of knowledge for practitioners. The first theme introduced the knowledge concept to the interviewees and collected their insights within the pharmaceutical manufacturing context. The literature outlines that KM is a well-established academic domain (Ramy et al., 2018) and a regulatory requirement (ICH, 2008).

Understanding the degree of establishment of KM in the industry practices was the focus of the second theme. The significance of knowledge is examined and the current efforts for KM are assessed in the next theme. The fourth interview theme focuses on KM maturity in the pharmaceutical organisation. Jochem, Geers and Heinze (2011) describe KM maturity based

on knowledge use and renewal. The interviewer probed the KM strategies, processes and initiatives taking place in the pharmaceutical organisations to assess KM maturity and the level of KM standardisation. The fifth and sixth themes explore the understudied area of personal knowledge measurement and identify the current processes for identifying knowledge holders (if any). The interviewees then were asked to assess the value of the measurement framework to understand the practical implications of the study.

The recorded interviews were saved as MP4 files and were uploaded to a private channel on YouTube.com for automatic transcription. The YouTube account is managed by the same DIT google account and has the same security features. The account is password protected and private (not publicly broadcasted). The automatic transcription features in Youtube.com facilitated the preliminary transcription of the recorded interviews. However, it was followed by a manual quality check to ensure the accuracy of the transcription.

### *(ii) Interview pre-testing (Pilot interviews)*

Pilot interviews were conducted with four volunteers from Technological University Dublin (formerly Dublin Institute of Technology) in March 2018. The aim of the pilot interviews was to ensure the clarity and coherence of interview questions as well as to familiarize the interviewer with questioning and probing activities needed during the course of the interview. The selection of the pilot interviewees is based on convenience and findings are not included in the data analysis phase. All participants spoke fluent English and had an academic affiliation (three PhD candidates and one lecturer in the College of Business). Despite that they did not have relevant industrial experience, they were able to assess the clarity of the language and the logical flow of the questions. It was also an opportunity to familiarise the interviewer with the interview themes before the commencement of research interviews.

The pilot interviews were recorded for two reasons: first to ensure the reliability of the used recording devices before the beginning of the research interviews (quality check); second to

provide a reference to the recommendations as well as the learned lessons from the pilot interviews. However, the pilot interviews were not transcribed as it was found unnecessary and hand notes were sufficient at this stage. Notes taken during the pilot interviews helped refine the questions and avert any potential misunderstanding. All interviews (including pilot interviewees) were conducted in English. It was assumed that English is a commonly used language in the pharmaceutical sector (including the pharmaceutical international regulatory agencies) and all the selected interviewees spoke English fluently.

### *(iii) Interview sampling and selection*

Sampling is the examination of a representative group from the entire population. The purpose of which is to gain an understanding of the characters of the population through testing a sample (Lucey & Lucey, 2002). The selected sample should represent the attributes of the population; hence, it is called a “*representative sample*” (Bryman & Bell, 2015). The population targeted in the exploratory study was industry experts who have long experience in the pharmaceutical manufacturing industry. As defined in section 4.5, this includes production, quality and technical services related functions. This would include senior and middle managers, directors as well as industry consultants. The pharmaceutical industry is controlled by internationally-harmonised regulations (FDA, 2020). Due to the global nature of the pharmaceutical industry, there was no restriction on the country of the participant. Furthermore, the sample includes participant from multinational enterprises as well as domestic organisations of different sizes. This provided a bird’s eye view of the current practices in the pharmaceutical industry. Sampling techniques are categorised as either probability or non-probability sampling. In the probability methods, every member of the sample has a known and equal chance of being selected. In contrast, the researcher deliberately selects participants in non-probability sampling based on specific criteria or convenience (Saunders et al., 2016). Table 4-3 provides a summary description of the main sampling techniques.

*Table 4-3 Sampling techniques Adapted from Kothari (2004)*

Sampling Technique	Description
Deliberate sampling	Purposive non-probability selection e.g. convenience and judgement sampling.
Simple random sampling	Probability sampling where all the members of the population have an equal chance of being selected.
Systematic sampling	Random selection of every $n^{\text{th}}$ element until the full sample is collected.
Stratified sampling	To obtain a random sample from a non-homogeneous population.
Quota sampling	Fixed sample size. Cost-efficient.
Cluster sampling	Grouping the population then selecting a cluster as a sample.
Multi-stage sampling	For big inquiries over a large geographical area.
Sequential sampling	Based on a complex mathematical sampling plan.

As the researcher focused on the main functions in the manufacturing sector, non-probability deliberate sampling is applied for sample selection. The non-probability sampling approach is considered the most practical approach for exploratory studies (Saunders et al., 2008). A purposive sample that represents all the key functions in the pharmaceutical manufacturing is assumed to be suitable to this stage of research where senior managers and experts are targeted as a source of data (Figure 4-4).



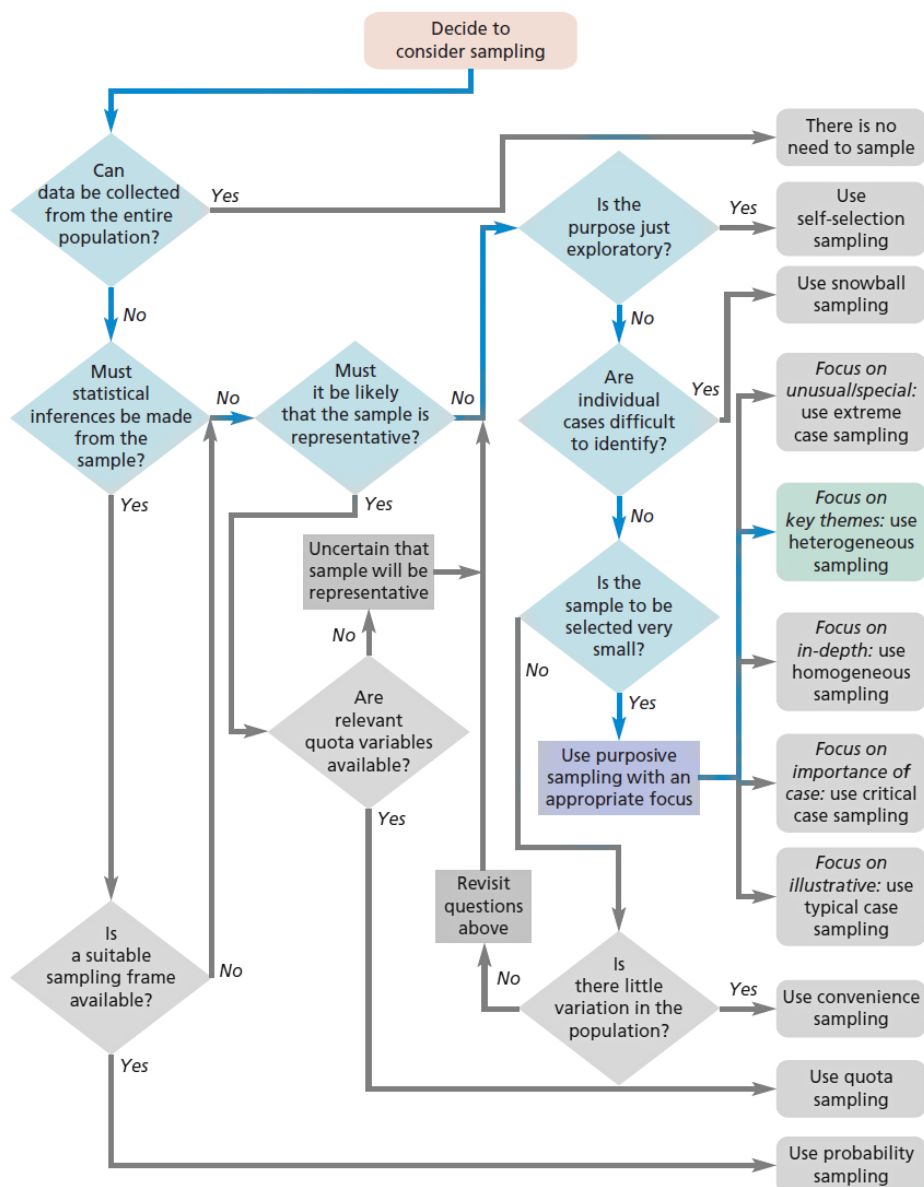


Figure 4-4 Decision map for selection of non-probability sample (Saunders et al., 2008)

Note: The selected path is in colour

In purposive sampling, the interviewer deliberately selects the participants out of the population (i.e. not randomly selected). The sample is considered a form of judgement sampling rather than a random sampling technique. Purposive samples are quite common in qualitative studies where the researcher's main concern is to develop hypotheses rather than generalising findings over wider populations (Kothari, 2004). Although formal generalisations are overvalued as the only source of knowledge and development, it is often possible to

generalise based on strategically selected critical case study as an alternative or supplemental approach. Strategic case selection supports the assumption that if it is valid for this case, it is valid for all (or many) cases. This can be attributed to the nature of social science and its tendency to offer concrete context-dependent knowledge rather than general context-independent theories (Flyvbjerg, 2011).

Regarding sample size, there is no consensus on the suitable sample size for qualitative research. However, 12 interviews are the recommended sample size providing that it is collected from a homogenous population (Rowley, 2012; Saunders et al., 2016). All the interview candidates not only belong to the same industry but also to complementary functions (production, technical services and quality) that share pre-requisite qualifications. WHO requires scientific education in chemical, pharmaceutical and biomedical disciplines for key personnel supervising pharmaceutical manufacturing and quality activities (WHO, 2011a). Data saturation is suggested also to determine the acceptable sample size (Saunders et al., 2016). Data saturation is achieved when new interviews bring little or no new ideas (Saunders et al., 2008). For reasons above, the study population is considered homogeneous, covering all key functions in the pharmaceutical manufacturing industry and the sample size is determined to be 15 interviews or until data saturation whichever is more. After 15 interviews, the researcher concluded that data saturation has been achieved and no more interviews are required.

### *(iv) Thematic analysis*

All interviews were transcribed and uploaded to NVIVO 12 for Mac software. NVIVO is a Computer- Assisted Qualitative Data Analysis Software (CAQDAS) that was used during the qualitative phase of this study. It provides a powerful tool for data classification, analysis and visualisation. It organises, stores and retrieves data in several formats helping the researcher find hidden connections (NVIVO, 2018). After a preliminary transcription using YouTube

automatic captioning, the researcher completed the transcription of his own interviews to ensure the accuracy of the transcription and to familiarize himself with the content. Transcripts along with the researcher's notes during interviews constituted the data corpus for the qualitative study. Three stages of interview analysis are followed: coding, condensation and interpretation (Kvale & Brinkmann, 2009).

The “*code*” in qualitative research is a word or short phrase that assigns a summative meaning for a piece of data (Saldaña, 2015). The researcher utilises several coding techniques in this study including in-vivo, process, descriptive, structural and focused coding to analyse the data over several cycles. To identify the underlying patterns and structures of the research phenomena hidden within the interview data, thematic analysis was chosen. Thematic analysis can be described as a process to identify and analyse themes in qualitative data. This can also examine the underlying ideas and assumptions contained in the latent themes (Maguire & Delahunt, 2017). The research adopted the six-phases of thematic analysis (Figure 4-5) following the guidelines of Braun and Clarke (2006) as well as the six-steps practical guide by Maguire and Delahunt (2017).



*Figure 4-5 Thematic analysis adapted from Braun and Clarke (2006)*

The analysis included six steps or stages as follow:

### Step 1: become familiar with the data:

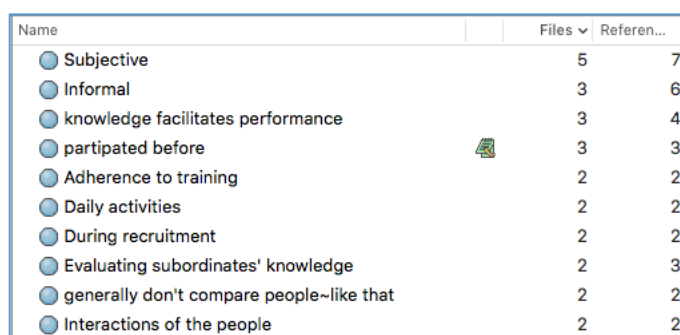
This phase is considered a preparation for the next coding phases. As explained above, the researcher personally interviewed the selected cases and conducted the transcription himself. Before starting the coding process, at least one more check of the transcript including proof reading and grammar check. This repeated review (at least four times) enabled the researcher to familiarise himself with the data corpus so as to have a holistic understanding of the aspects of interviews.

At this stage, all the transcripts were uploaded to NVIVO 12 Mac version, the Computer Assisted Qualitative Data Analysis software (CAQDAS) in this study. All transcripts and NVIVO files were saved, and backup copies were saved on a private cloud (Google Drive).

### Step 2: generating initial codes:

The study is exploratory and followed an open coding system, i.e. there weren't any pre-set codes from literature (Maguire & Delahunt, 2017). Several types of codes were utilised throughout the thematic analysis process. In the first coding cycle, the process started with a structural coding to split the data corpus into ten segments, i.e. one for each main question. Despite that structural codes overlapped in the second coding cycle, it was found necessary to link the generated in vivo, process and descriptive codes to the proper context in the first cycle. In vivo coding emphasises on the actual spoken words by the interview participants. It is a useful way to understand stories and experiences in the participant's own words (Manning, 2017). Process codes use the gerund to describe or refer to a certain activity or process in the interview (Saldaña, 2015). Descriptive codes describe the patterns in the data set (Maguire & Delahunt, 2017). With all these types of codes, the researcher embraced a splitter approach generating over 716 codes in the first cycle (Figure 4-6). The coded data could be a single phrase, a sentence or a group of sentences. Stated thus, the coding process is speculated as a

part of data analysis where data is aligned in meaningful groups (Braun & Clarke, 2006).



Name	Files	References
Subjective	5	7
Informal	3	6
knowledge facilitates performance	3	4
participated before	3	3
Adherence to training	2	2
Daily activities	2	2
During recruitment	2	2
Evaluating subordinates' knowledge	2	3
generally don't compare people~like that	2	2
Interactions of the people	2	2

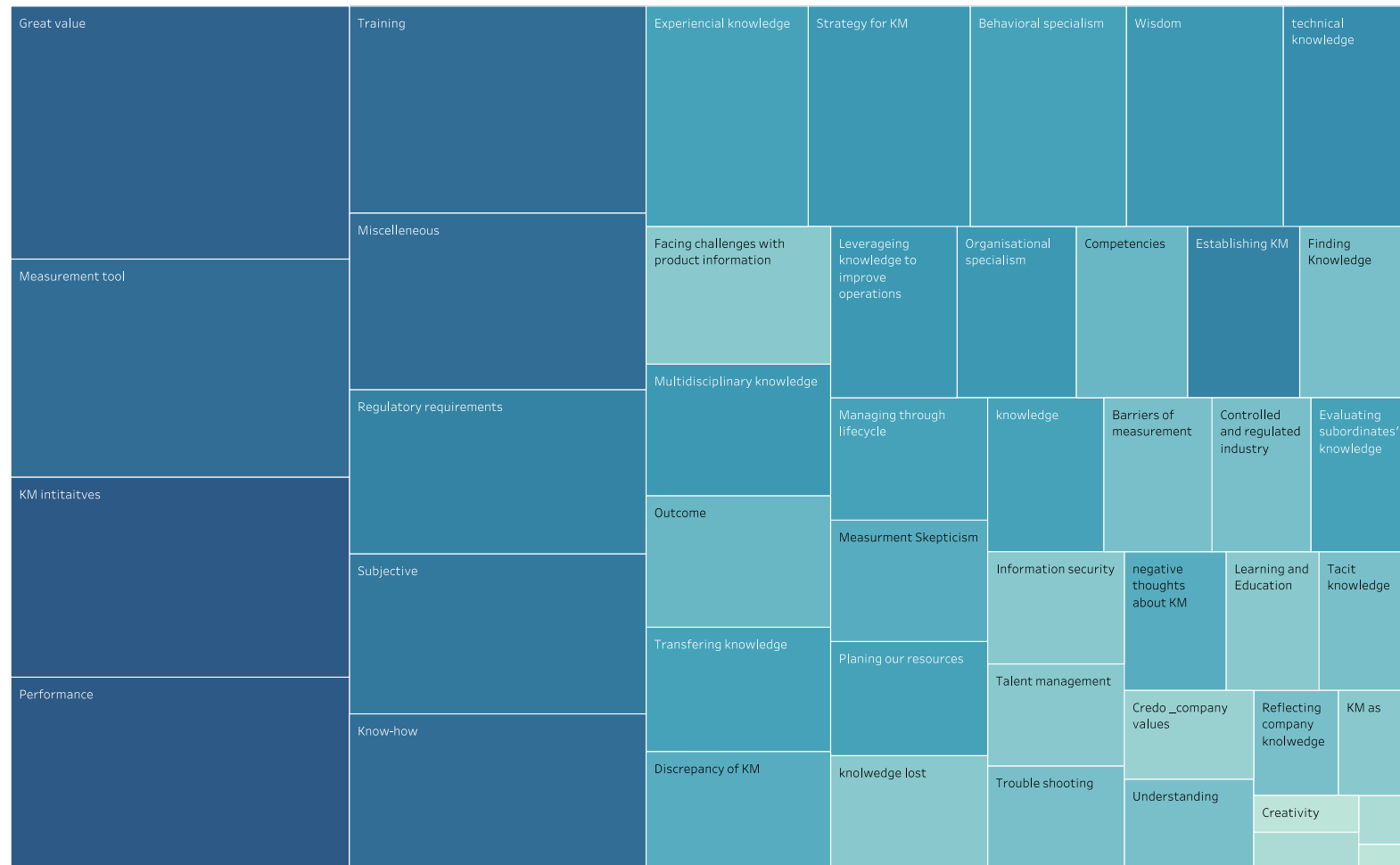
Figure 4-6 A screenshot showing a sample of initial codes in NVIVO (the first coding cycle)

### Step 3: searching for themes

The theme is a patterned response that reflects a meaning within the data set (Braun & Clarke, 2006). The goal of the thematic analysis is to discover the hidden patterns or themes in data so as to address the research questions (Maguire & Delahunt, 2017). The second coding cycle inspected the relations and patterns as they appear in the data corpus. Focused coding was employed at this stage of assembling related codes under one category. Focused coding is a second coding cycle technique which is led by a dominant theme. It recodes the data set to investigate the recurrent patterns and layers of meaning (Saldaña, 2015). This process needs further reading and back-and-forth scanning of the interviews' transcripts. Focused codes evolved to meaningful themes after two more cycles of coding. Initial themes were developed based on researcher understanding of the analysed phenomena as explained by the pharmaceutical industry practitioners. Using NVIVO 12 for Mac, the researcher was able to assemble codes (called nodes in NVIVO) to create initial themes or categories that can be easily revised in the next cycles. This enabled the researcher to speculate on the possible patterns and themes in the provided data.

Forty-six categories were recognised within the first coding cycle and were used as a basis for the initial themes. The preliminary themes are summarized in (Figure 4-7). The themes are sorted by the number of interviews that manipulated each theme (colour coded in the tree-map). Also, the size of each field in the tree-map reflects the sum of instances where underlying codes

are used. This was considered as a quantitative measure of the relative significance of the generated themes.



Color shows sum of interviews under this theme. Size shows sum of instances. The marks are labeled by Themes.



Figure 4-7 Preliminary Categories

### Step 4: Review themes

Initial themes that were generated in the previous phase in the codes section of NVIVO 12 were further reviewed and refined. In order to facilitate the review of themes, mind maps were adopted. The mind map is an effective and widely used data visualisation format that was used to represent the identified themes and the underlying codes (Figure 4-8). It consists of a central image surrounded by a radial diagram that represents the different connections among the portions of the illustrated information. It is considered an efficient personal learning tool to develop individual solutions and memorable results (Eppler & Usi, 2006). The main themes identified at this stage are knowledge maturity, understanding knowledge, the value of knowledge measurement, knowledge dynamics, industry practice (in relation to the personal knowledge measurement), training, regulatory knowledge, experience, behavioural specialism, learning and education, performance, technical knowledge, wisdom and organisational specialism.

It is worth noting that the last nine themes are directly associated with the individual employee knowledge (personal knowledge) that was further refined in (Figure 4-9). The first five themes were more concerned with current KM practices in the pharmaceutical organisations as will be discussed in detail in the next sections. Following the recommendations of Maguire and Delahunt (2017), a special miscellaneous category was created to include codes that didn't fit under any suitable theme.



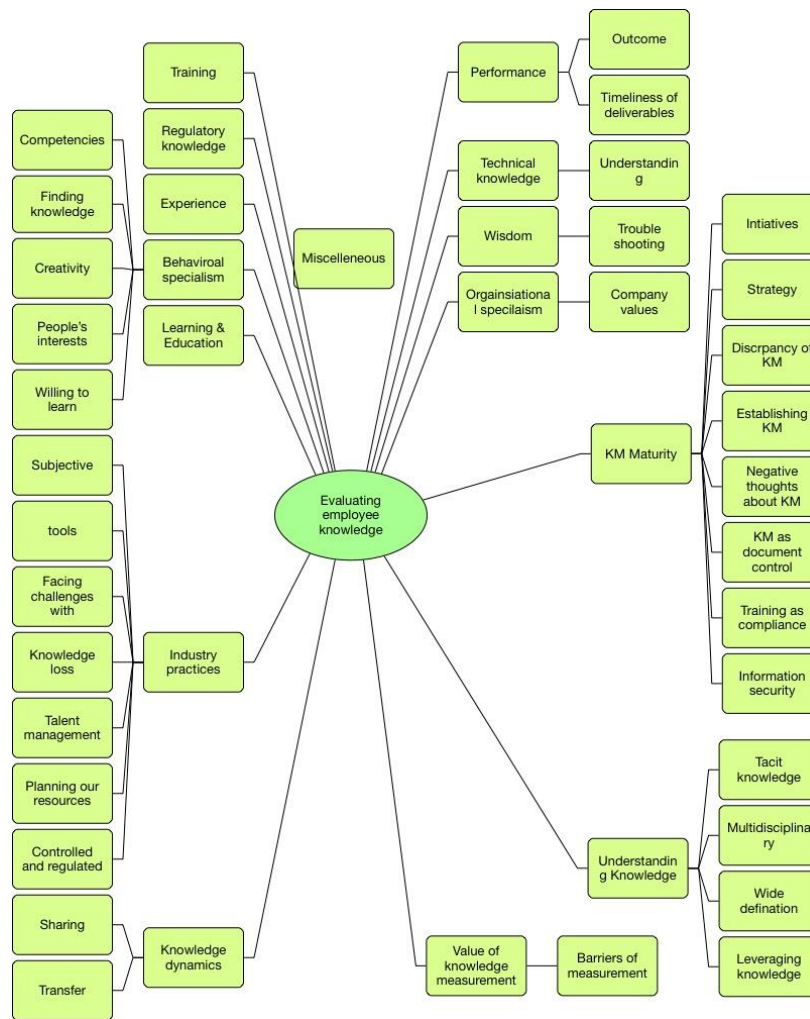


Figure 4-8 Revised themes

At this step, the researcher re-examined the generated themes closely from the last phase. Themes are deemed to show coherence and at the same time are distinct from each other (Maguire & Delahunt, 2017). The data and codes associated with each theme were investigated for relevance. As a result, some of the initial codes were changed and new codes were added. The naming of some themes was revised to describe the underlying data more accurately. Redundant themes were merged. Several initial themes were renamed or re-categorised as subthemes under a more general theme. The forty-six preliminary themes and subthemes evolved to 14 revised themes plus a miscellaneous category (Figure 4-8). As personal

knowledge is the focus of this study, key themes and subthemes of personal knowledge are further refined as shown in Figure 4-9.

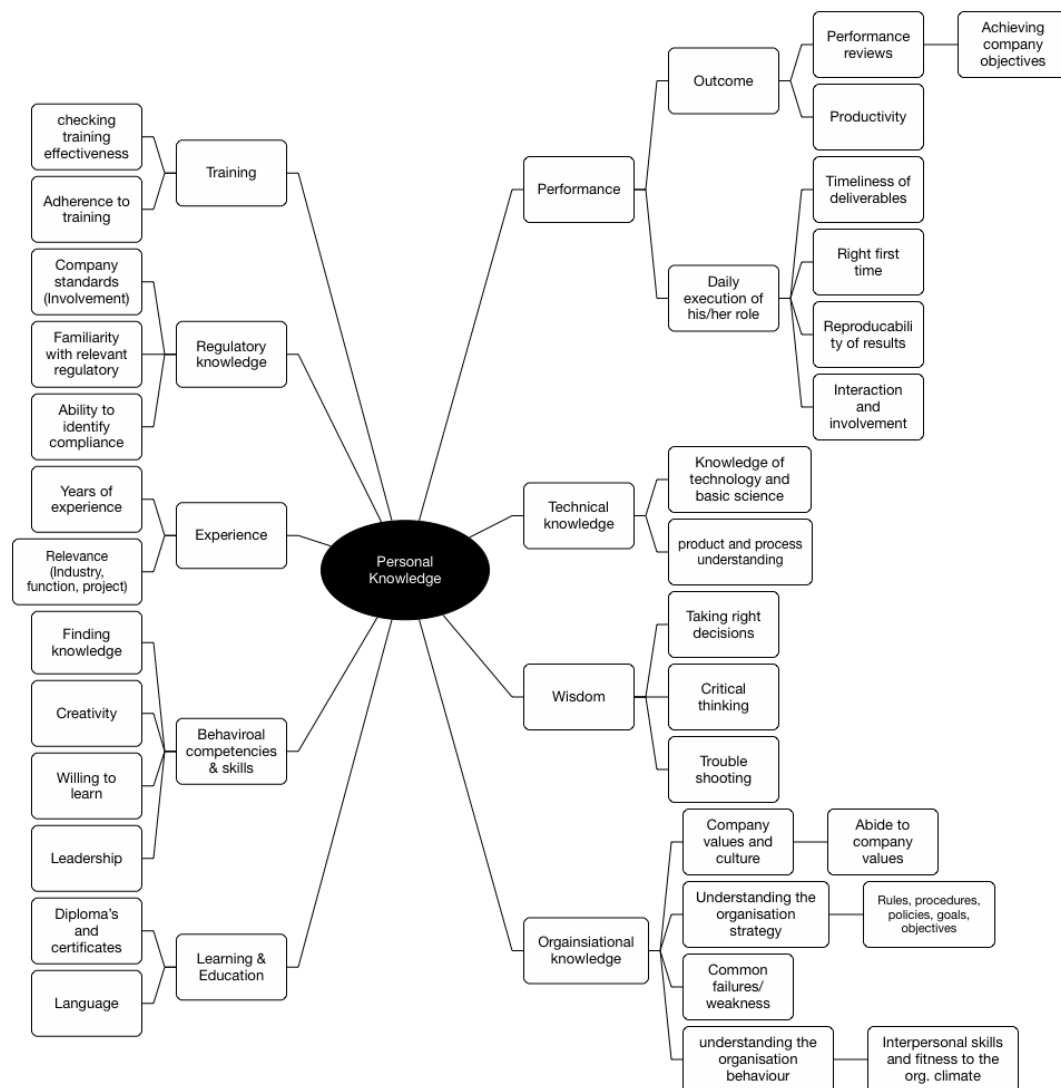


Figure 4-9 The Personal knowledge Themes-Revised

### Step 5: Define themes

As a final refinement of the captured themes, the researcher combines themes that sound too similar to be independent themes. Some underlying subthemes and even codes were also moved to a more relevant place on the mind map. At this phase, the final themes and subthemes are appointed and the underlying interactions are illustrated in the form of a thematic map (Figure 4-10). It is noteworthy that two academic researchers with experience in qualitative methods were invited to check the classifications and coding. This practice is argued to reduce

potential bias in the data interpretation (Rowley, 2012). All their recommendations were taken into consideration during data analysis.

The first theme in the thematic map (Figure 4-10) is training, learning and education that was regarded by interviewees as source of employee knowledge in the pharmaceutical organisation. This included the knowledge of foreign languages that facilitates communication and understanding of regulatory requirements especially in the multinational work environment (80% of the sample). Training was considered as the second angle in the knowledge base. Both adherences to training as well as training effectiveness were seen as a determinant of knowledge acquired from training. It is worth noting that respondents did not differentiate between assessing knowledge stock and assessing knowledge acquired after specific training. Moreover, relevant experience in a similar function, as well as involvement in pertinent projects, has been argued to be necessary to build employee knowledge.

The outcome of knowledge was repeatedly perceived by the interviewed managers as the main indicator of knowledge. The performative knowledge theme included the Know-How manifestations of knowledge. The product and process understanding theme refers to the comprehension of the particulars of processes and products. It implies also the deep understanding of the basic science base (including know-why). This dimension describes also employee's familiarity with modern manufacturing technologies. The organisational understanding theme means employee's understanding of the prevalent culture, company values and the behaviours that fit within a certain work environment. Strategic goals and organisational policies are another part of employee's knowledge about the organisation. The interviewees also referred to knowledge about weakness points and historical failures that have been encountered. Wisdom theme comprises taking the right decision, critical thinking and creative problem-solving skills. Finally, communication and networking theme encompasses

those skills that the interviewees endorsed their role for the flow of knowledge and integration within the organisation.

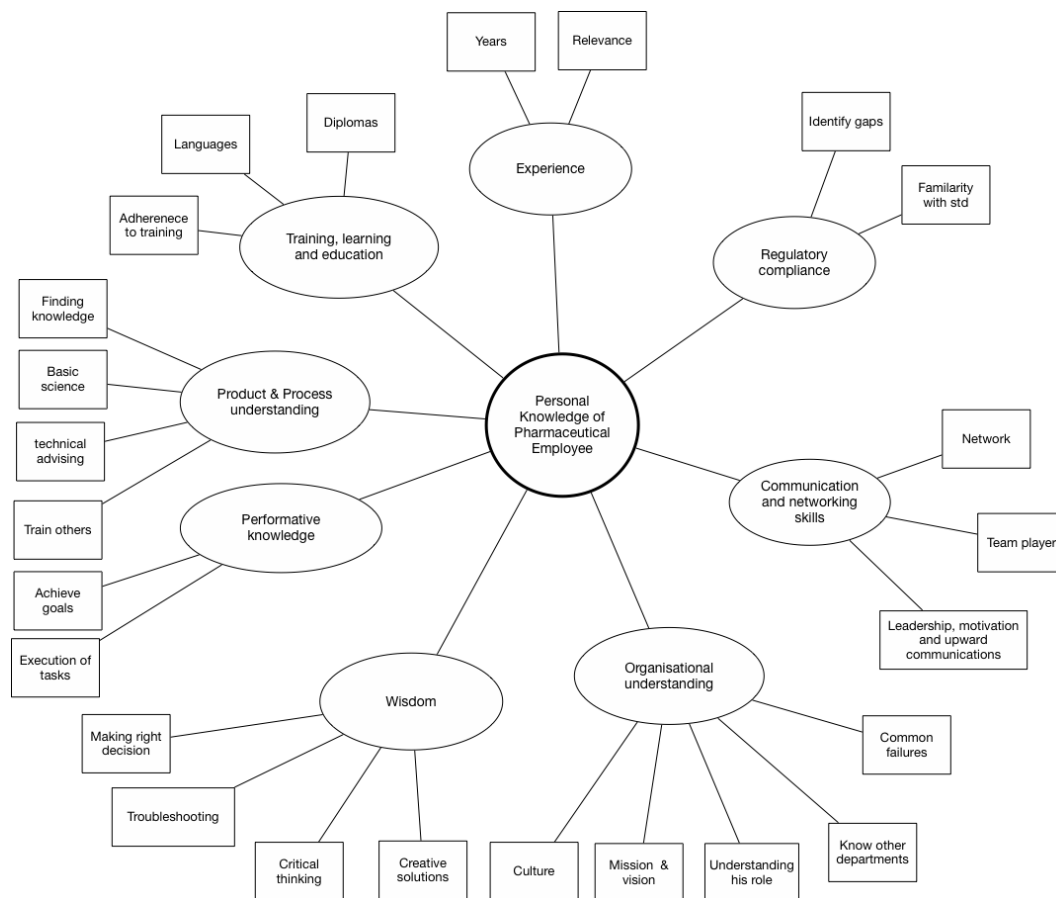


Figure 4-10 Thematic Map

### Step 6: Writing-up

The findings of the thematic analysis are reported in the next chapter (chapter five) and will be used to develop the conceptual framework. The comprehensive discussion of the thematic analysis findings in light of the extant literature is presented in chapter five.

## II. Framework development

The development of the research framework is based on abduction and theoretical re-description of the components of the research phenomenon. This encompasses theories about the social structures and underlying relations united with conceptual thinking. This also reflects how these components appeared and the related causal mechanism (Radulescu et al., 2009). It is worth noting it is a back-and-forth movement between the literature review and thematic

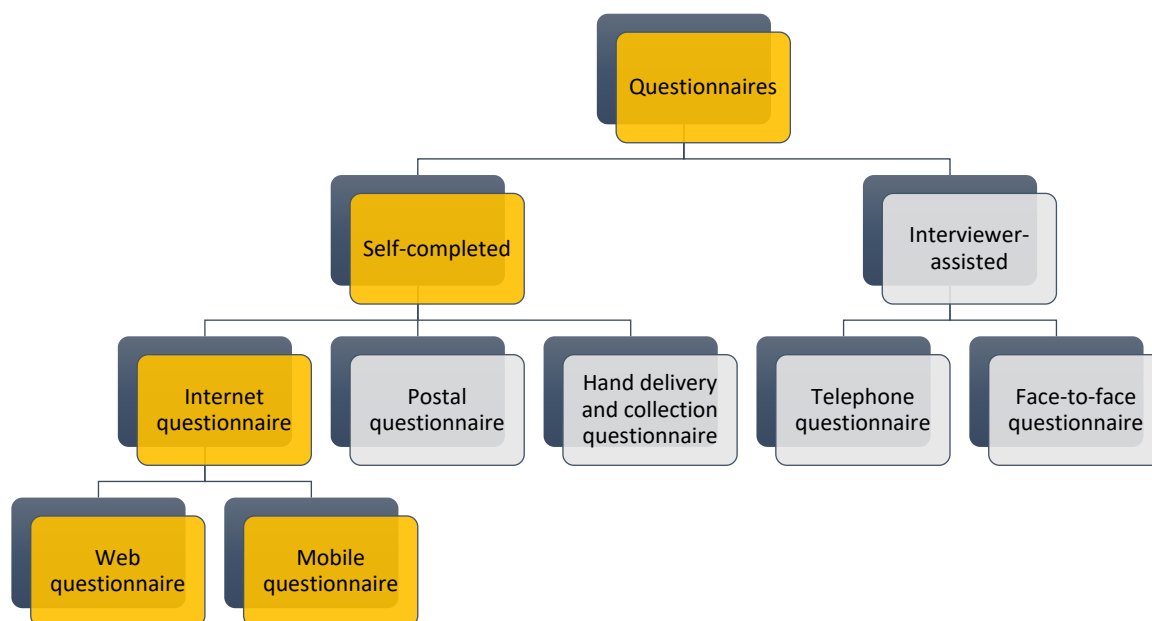
analysis rather than an independent stage. Framework development will be presented in details at the end of the exploratory study chapter.

### III. *Framework optimisation and validation*

After the theoretical grounding of the framework, the next stage is to test and validate the proposed relationships deductively. This stage represents the explanatory study where the relations and underlying factors that explain employee's knowledge are examined. Explanatory research uses data to test theories that have been already grounded and conceptualised including cause-and-effect relationships (Saunders et al., 2008). Mixed methods implied an integration between both open-ended qualitative data and close-ended quantitative responses e.g. questionnaires (Creswell, 2014). The survey is the selected strategy at this stage. Self-completed questionnaires are used for data collection from pharmaceutical industry participants.

#### *(i) Questionnaires*

The questionnaire is a data collection instrument where participants are asked to respond to the same set of questions. It could be self-completed or completed through assistance, e.g. face-to-face or telephone (Saunders et al., 2016). It is a quite common technique when the targeted sample is large (Kothari, 2004). The self-completion interviews are argued to be less costly to administer, less time consuming, free from interviewer effects, less variable and more convenient for participants (Bryman & Bell, 2015). Self-completion questionnaires are the method of choice for data collection at this stage. Regarding the delivery of the questionnaires to the participants (Figure 4-11), web-questionnaire was the selected delivery media.



*Figure 4-11 Types of questionnaires- Adapted from Saunders, Lewis and Thornhill (2016)*

*Note: The selected pathway is highlighted in yellow.*

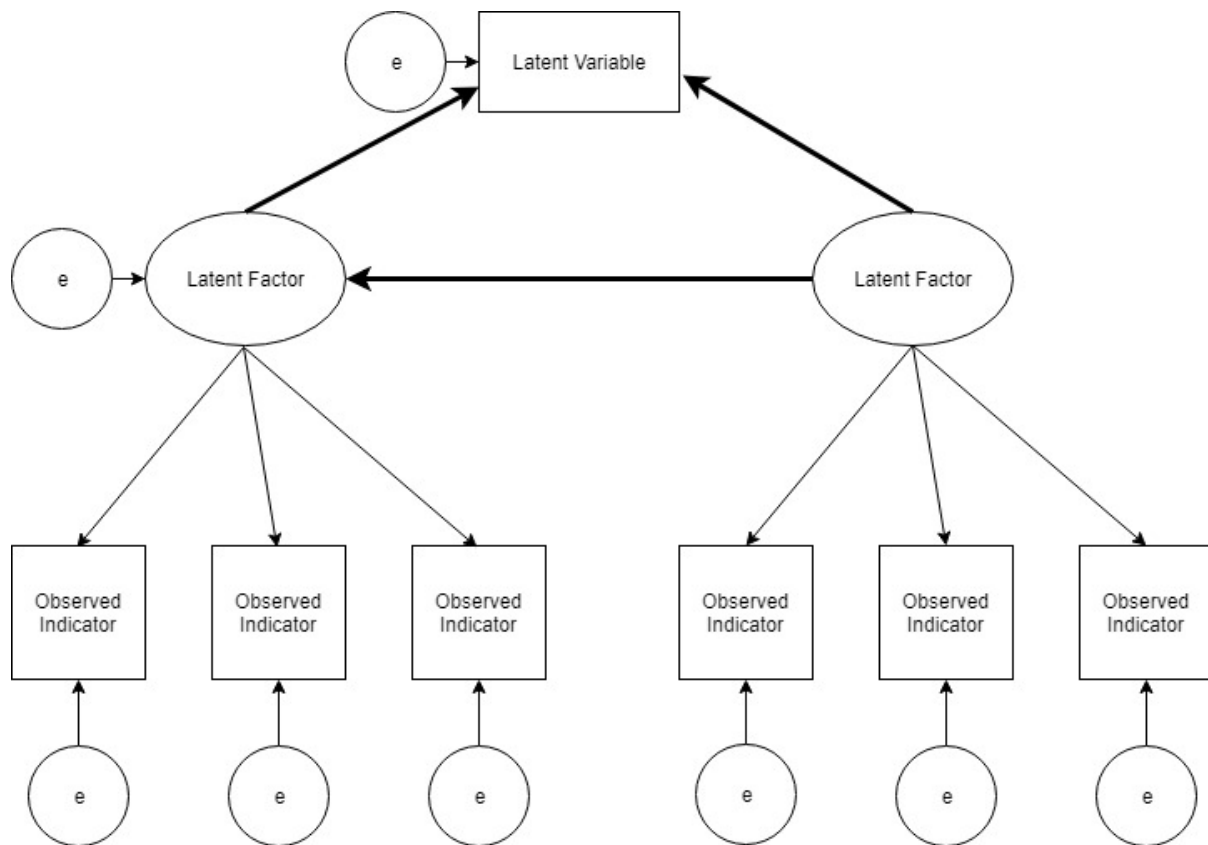
Web questionnaires are often recommended when the research population have ready access to the internet (Kaplowitz et al., 2004) as it provides high confidence that the right person has responded. The method is also argued to result in a reasonable response rate among large samples (Saunders et al., 2016). Moreover, Google forms is the adopted survey tool. This tool is deemed to provide a high level of security and confidentiality as it is password protected and linked to TU Dublin (formerly Dublin Institute of Technology) email system. One more feature is the possibility of making critical questions obligatory or “required” to ensure they are not missed by any of the participants. Screening questions were added at the beginning of the survey to ensure that only relevant participants would participate in the survey. For instance, if the respondent has no experience in the pharmaceutical manufacturing or occupies a support or administrative role (e.g. accounting), he/she will be prompted to submit the form before taking the survey.

### *(ii) Questionnaire design*

The questionnaire is generally divided into two sections. The first section is concerned with the key demographic data such as education, function, position, experience of the participants and data on the level of KM maturity in the participant's organisation. The second section is designed to assess each of the identified personal knowledge indicators of the proposed model (on a Likert scale of seven). One on a Likert scale means "not at all" while seven signifies that the respondent agrees to a great extent with the provided statement. The questions are designed to test the hypothesised theoretical framework using confirmatory factor analysis (CFA) statistics as described in the next section.

### *(iii) Confirmatory Factor Analysis*

Structural Equation Modelling (SEM) is a powerful statistical modelling technique combining Confirmatory Factor Analysis (CFA), regression models and complex path models. It is concerned with latent factors imbedded in theoretical constructs. The argument behind factor analysis is that the covariances between a set of observed indicators can be explained by a smaller number of underlying latent factors (Hox & Bechger, 1998). Latent variables can only be measured indirectly through a set of observed indicators (Skrondal & Rabe-Hesketh, 2007). Observed indicators can be broadly classified into two principal forms: effect (reflective) and causal (formative) indicators (Bollen & Bauldry, 2011). Observed variables can also be called measures or manifests. They are graphically represented by a square or rectangle (Figure 4-12).



*Figure 4-12- Structural Equation Model*

In contrast, unobserved (latent) variables are known as constructs or latent factors and are commonly illustrated as circles or ovals. Measurement component is depicted graphically by a thin line and structural component by using bolded lines (Schreiber et al., 2006). Also, Figure 4-12 shows the measurement errors (e) or residuals in circles. Unlike the latent factors, residual's effect is associated with only one measured variable (Bollen & Bauldry, 2011). In summary, SEM quantitatively tests a proposed theoretical model hypothesised by a researcher outlining how observed indicators define underlying factors and how these factors are related (Schumacker, 2010). Personal knowledge is a latent variable that cannot be directly measured in the organisational context; instead, the underlying factors, as well as the observed indicators (that can be empirically evaluated as a measure of PK), are explained through CFA. SEM is deemed to provide a quantitative explanation of the theoretically grounded PK measurement model hence provides the required validation of the research hypotheses.



### *(iv) Pilot Study*

As a final stage of questionnaire development, the researcher conducted a pilot study before distributing the survey. The pilot study is a pre-testing of the questionnaire that can reveal weaknesses (if any) and provides an opportunity to fix them (Kothari, 2004). The aim of the pilot study was to ensure the clarity and the logical flow of the survey questions and to test the electronic forms in practice. In line with Saunders et al. (2016) recommendations, a non-probability purposive sample was adopted. A total of 14 respondents provided informative feedback and suggestions that were considered sufficient for serving the pilot study. The sample included ten practitioners with different levels of experience in pharmaceutical manufacturing. Table 4-4 provides an overview of the selected pilot study sample. In addition, four academics with experience in quantitative techniques and research methods have participated in the pilot study.

The researcher contacted every participant individually and explained to him/her the purpose of this study and the expected time required to complete the questionnaire. Each participant was asked to provide feedback by filling special fields at the end of each section of the questionnaire. All respondents consented to take part in the study before starting the survey. Ethical considerations (highlighted in section 4.8. at the end of the study) were adopted at all the stages of the research including the pilot study. The researcher reviewed the individual feedback and edited the survey in response. The received feedback was generally positive and helpful. Few corrections in the questionnaire wording were made in light of the pilot study. Also, the screening questions wording was revised due to confusion between R&D and technical services among some participants. Last but not least, although the researcher personally contacted 27 pharmaceutical knowledge workers, only 14 agreed to participate in the pilot study. Therefore, the researcher anticipated a low response rate from the surveyed population.

*Table 4-4 Participants in the pilot study*

	<b>Job title/level</b>	<b>Affiliation</b>	<b>Country</b>
<b>1.</b>	Lecturer	Academic	Ireland
<b>2.</b>	Lecturer	Academic	Ireland
<b>3.</b>	Director	Technical Services	China
<b>4.</b>	Supervisor	QC	Egypt
<b>5.</b>	Specialist	QA	Egypt
<b>6.</b>	Specialist	QC	Egypt
<b>7.</b>	Specialist	QA	Egypt
<b>8.</b>	PhD candidate	Academic	Ireland
<b>9.</b>	PhD candidate	Academic	Ireland
<b>10.</b>	Manager	Production	Egypt
<b>11.</b>	Manager	QA/QC	UK
<b>12.</b>	Manager	Production	Egypt
<b>13.</b>	Manager	QA	Egypt
<b>14.</b>	Manager	Technical Service- QC	Egypt

*(v) Sample size*

The targeted population at this stage is the knowledge workers in the pharmaceutical manufacturing sector. Employees from the production, technical services, warehouse, quality control (QC) and quality assurance (QA) functions are exclusively chosen for the sample. As mentioned previously, the knowledge workers within these functions share the basic qualifications and might have occupied previous positions in one or more of these departments as shown from the profiles of the interviewees (Table 5-1). The sample is not limited to one country as pharmaceutical product and process knowledge and regulations are assumed to be global.

In SEM and CFA, the sample size is an important determinant of stability of parameter estimates. However, a review of the statistical literature reveals that there is no consensus on the minimum sample size. For example, a sample of three to 20 responses per variable are the widely accepted sampling rule (Bandalos, 2018; Mundfrom et al., 2005). It is worth noting that the accepted sample size is also dependent on the developed framework, factor loading (level of communality) and the number of observed variables per factor. The greater the variables to factors ratio (at least three to four) and the higher the level of communality, the smaller the minimum sample size that is required (Bandalos, 2018; Schreiber et al., 2006). Computer

simulation studies of Mundfrom et al. (2005) suggested a minimum sample size of 150 to 180 conditioned that the variables-to-factors ratio is at least 7 even in the case of low communality. Kline (2011) proposes 200 cases as the typical sample size in SEM studies based on the median sample size in published articles in this field. As the variables-to-factors ratio in the proposed framework is close to 7 ( $\frac{41}{6} = 6.8333$ ), a sample size of 180 cases is considered the minimum threshold for this study. At the end of the survey period, the researcher received 190 valid responses.

### *IV. Sample structure and collection*

Due to the lack of a complete sample frame, it was found impossible to conduct a simple random sampling. The researcher considered several options in order to collect a representative sample of the pharmaceutical manufacturing sector including panel survey companies and business mailing list brokers. However, none of them provided appropriate solutions. Cluster sampling was considered a suitable alternative as it is possible to create a comprehensive list of pharmaceutical factories in one country rather than the list of manufacturing professionals. Cluster sample is recommended when it is impractical or impossible to create an inclusive sample frame for all the elements of the population (Creswell, 2014).

In cluster sampling, the whole population is divided into groups called clusters, then a randomly selected cluster(s) is used as the final sample (Taherdoost, 2016). Cluster sampling can be one-stage where all the members of the randomly selected clusters are surveyed or may be two-stage where the elements in the chosen clusters are randomly sampled (Žmuk, 2016). As the researcher had no control over the survey distribution within the participating organisations and due to confidentiality precautions that prevented the full access to full employee lists, two-stage cluster sampling was found suitable for data collection. As the researcher worked for 10 years in the Egyptian pharmaceutical sector and developed a wide network of contacts, Egypt was chosen to commence cluster sampling. It's worth noting that

Egypt is among the largest pharmaceutical manufacturers and consumers in Africa and the Middle East with a market value of EGP 35.6 billion (expected to exceed EGP48 billion by 2020) (Gage Consulting, 2017).

The researcher initially reached out to a random sample of 50 Egyptian pharmaceutical manufacturing firms sourced from Egyptian yellow pages websites and verified individually by checking the company website. Contact was made with senior or middle management from one of the target functions of the research. A rapport was developed, and each contact was asked to distribute the survey to 10 appropriate respondents in their firm. Follow up emails were used to encourage participation. A total of 150 responses were received at the end of the survey period.

The research also reached out to contacts within TU Dublin, the school of chemical and pharmaceutical sciences who supported the distribution of the survey to three part-time master's programmes in which students commonly have current or prior experience in the manufacturing sector:

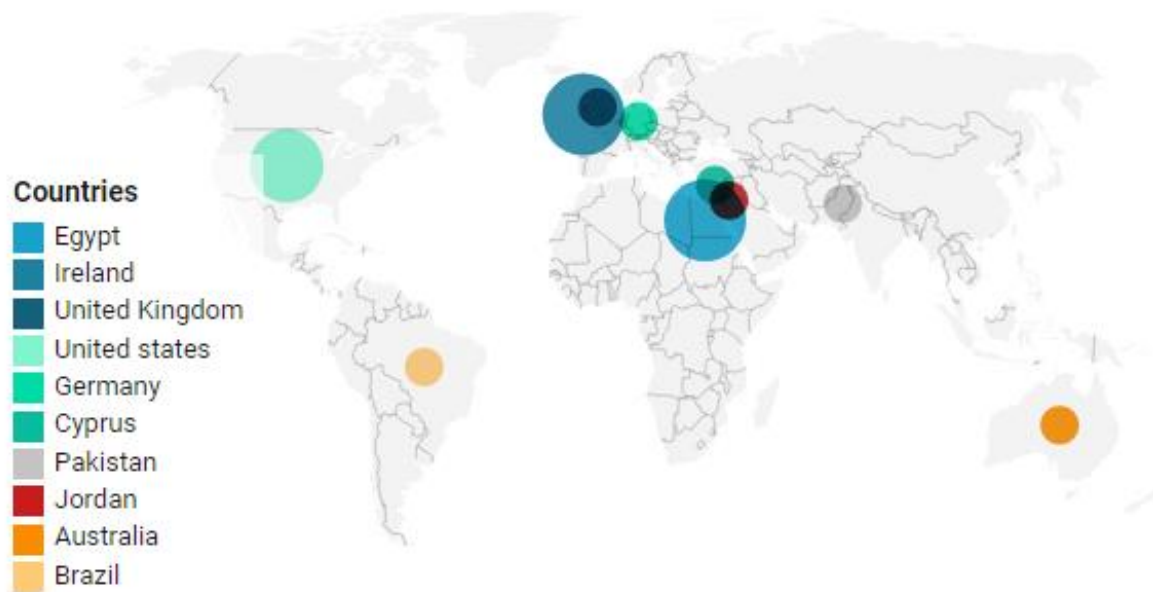
- a. MSc of Pharmaceutical validation technology.
- b. MSc of Pharmaceutical quality Assurance and Regulation
- c. MSc of Pharmaceutical quality assurance & biotechnology

A total of 18 responses were received within three weeks and after sending a reminder email in week two. The researcher also used social media and popular pharmaceutical forums on LinkedIn to communicate with pharmaceutical manufacturing professionals worldwide. The following are the key forums that were used in this study:

- PIC/S GMP Industry Forum (15,277 members).
- Pharmaceutical Microbiology (25,790 members).
- Pharmaceutical Discussion Group (18,795 members).
- Quality Assurance, GMP and ICH Guidelines (76,110 members).

- ISPE Ireland Affiliate (557 members).
- Global Pharmaceutical Contract manufacturing (861 members).

At the end of the survey period, only 22 responses have been received through these forums from six continents as shown in Figure 4-13.



*Figure 4-13 Response per country from social media sample*

### V. *Maximisation of response*

Self-completed electronic questionnaires can provide reasonable response rates (especially when distributed within organisations) (Saunders et al., 2008). Nevertheless, some measures are found necessary to maximise the response rate. Studies reveal that in populations with ready access to the internet, a web survey with a mailed advance notice has a comparable response rate to hard-copy mail survey (Kaplowitz et al., 2004). For this reason, the survey email is accompanied by a pre-contact letter. This letter confirms the confidentiality of the shared data and their exclusive use in research. The cover letter highlights the main objectives of the research and the affiliation of the researcher as well as contact details. Furthermore, the mail is personalised (by identifying the title and name of the contact person) using mail merge or

manually as applicable. Last but not least, follow up emails were sent once after ten days to two weeks after the initial contact to ensure the maximum response.

Regarding the design and language, the researcher uses a clear language, avoids jargons and uncommon vocabulary. All readability and clarity features are examined during the pilot testing of the questionnaire. Literature suggests the use of incentives to enhance the response rate (Faria & Dickinson, 1995; Lorenzi et al., 1988). As an incentive to complete the survey, the participants were informed that the researcher will donate \$1 (one US dollar) per completed survey for the Egyptian National Cancer Institute - Cairo (<http://www.nci.cu.edu.eg/>). The Egyptian National Cancer Institute is a governmental organisation affiliated to Cairo University. After the collection of 150 responses, a copy of the donation receipt was posted on the researcher LinkedIn page as evidence of payment (as promised).

The average response rate for the questionnaire was 18-30% (global vs locally distributed in Egypt) which is a reasonable response from an internet-mediated questionnaire (Saunders et al., 2008). However, it was observed that the promised contribution to charity had an insignificant effect on response rate. This goes in line with previous studies where personal cash incentives (e.g. lottery) significantly increased mail survey returns in comparison with promises of charity contributions (Furse & Stewart, 1982; Hubbard & Little, 2015). It was argued that charity donation is usually associated with philanthropy and might look for some potential participants as an improper incentive for taking part in a research survey (Pedersen & Nielsen, 2016). Similarly, a comprehensive review of 1607 academic articles published between 2000 and 2005 found that the use of incentives is not correlated with the response rate (Baruch & Holtom, 2008).

### *4.8 Ethical Considerations and the Researcher's Role*

Ethics are the principles of right and wrong that individual rely on for making choices and taking decisions (Laudon & Laudon, 2016). The research has to follow certain standards of behaviour to manage his/her relationship with research stakeholders (Saunders et al., 2016). Four ethical issues are commonly encountered in research: harm to participants, informed consent, invasion of privacy and deception (Bryman & Bell, 2015). The researcher acknowledges the research ethics as the top priority through all the stages of this research. All research participants are adults (over 18 years old) with no apparent mental or psychological illness that can influence their free will. In addition, informed consent was obtained at all data collection phases. Before data collection, all participants either in interviews or surveys were clearly informed of the purpose of this study and that all the provided information are used only for research purpose. For interviews, subjects' names and their companies were removed during the transcription process.

Moreover, the final copy of each interview transcript is sent to the participant for a final quality check and to have a second chance to opt out of the interview process if needed. Leading questions are strictly avoided ensuring the objectivity and reliability of the collected data. This guarantees higher consistency as well as trustworthiness of data (Kvale & Brinkmann, 2009). To avoid any stress of psychological harm for interviewees, they were informed at the beginning that they have the right to end the interview at any stage or to refuse to answer any question. The anonymity and confidentiality are also secured for all the survey data. Finally, the author ensured a high level of integrity during the reporting of research findings and accurately referenced all cited authors.

It is noteworthy that the researcher is a pharmacist with more than 10 years of experience in the pharmaceutical manufacturing industry. He held several roles in the quality assurance and technical services. This included managerial and non-managerial roles. This long

experience is believed to familiarise the author with the industry operations, terminology and regulations. The author also utilised his personal network to recruit the interviewed experts from different functions. Also, personal contacts facilitated the distribution of the questionnaire within the identified clusters. This was deemed inevitable to have access to employees within the pharmaceutical manufacturing organisations. Having a practical experience avoids the difficulty of failing to understand the terms and abbreviations commonly encountered in the pharmaceutical industry. In addition, familiarity with the different manufacturing and management processes enabled him to synthesise suitable probing questions during interviews.

However, from a critical realist understanding, the researcher believes that the objective reality cannot be measured with certainty as our perception is influenced by conditions and social factors (Easton, 2010). The critical realism's reality is also stratified and we deal only with outermost level “*the empirical*” (Mingers, 2004). Hence, the reality is not simply what can be empirically perceived as proposed by the positivist. Developing explanatory theories that help identify causal mechanism driving the social events would definitely take us closer to the reality (Fletcher, 2017). The author employed MMR in order to combine both the qualitative and quantitative techniques to enhance the credibility and integrity of research finding (Schoonenboom & Johnson, 2017). This combination of different methods, following structured analysis methodology and deductively comparing the findings with extant literature is deemed to reduce the researcher's bias during data collection and analysis. Also, the researcher utilised the data to explain the underlying social structure (causal mechanisms) behind the personal knowledge (reality). The developed framework of causal factors from the QUAL phase was further tested in a bigger sample of pharmaceutical knowledge workers using CFA where the interference of the researcher became minimum.



### *4.9 Dissemination of Research Findings*

The dissemination of the research findings is planned at each milestone. Two literature review papers have been published in the Knowledge Management Research and Practice (KMRP) Journal. KMRP is one of the key peer-reviewed journals in the KM field. Available online since 2003, KMRP is the first KM journal to gain an impact factor (Thomson Reuters, 2015). Moreover, KMRP was placed third in 2008 then the second in 2013, according to expert survey rankings conducted on a sample of 25 key KM journals (Serenko & Bontis, 2013). In addition, a Scientometric review paper has been presented in the 12th International Forum on Knowledge Asset Dynamics (IFKAD) highlighting the major trends in KM research. The empirical study findings are deemed to be published in a KM peer reviewed journal. A measurement framework or scale for industrial application is another expected outcome from this study.

Furthermore, the researcher was invited to speak about his early findings in the National Pharmaceutical and Life Science Expo in 2018 and 2019. This was another opportunity to disseminate the research findings and obtain direct feedback from industry practitioners. It is noteworthy that the National Pharmaceutical and Life Science Expo is an annual meeting of over 1000 senior managers and speakers from the pharmaceutical and life-sciences sector. It provides a platform to disseminate the latest research updates, best industry practices and the most innovative technology solutions (Premier, 2019).

### *4.10 Write-up: Presenting Research Results*

Proper reporting of a research is of ultimate importance for the reader to judge the adequacy of the research methods and findings. This implies a proper layout of the research thesis to include: A) preliminary pages; B) the main text and C) the end matter (Kothari, 2004). The primary part includes all the tables of content, figures and lists of tables. This part also includes the abstract, the acknowledgements and the declaration. The main text of the thesis consists of

eight chapters that include the literature review, research methodology, exploratory and explanatory studies, discussions and conclusions. The final part includes references and appendices.

### 4.11 *Summary and Conclusion*

This chapter provides an explanation and a justification of the research methodology in this dissertation. It outlines the adopted paradigm, the research paradigm, the research strategy, the scope and the data collections methods. A detailed research plan describes the research journey from literature review until data analysis and conclusion. The next chapter is the first part of the primary data collection where the researcher explores the research phenomenon in the industry context.

## **Chapter 5 : Exploratory Study Findings and Framework Development**

### 5.1 *Introduction*

The aim of exploratory studies is to understand the research phenomena as we explore what happens in the field (Gray, 2013). In other terms, a researcher endeavours to familiarise himself with a certain phenomenon and formulate his hypotheses (Kothari, 2004). This familiarity can be achieved via a literature review and/or communications with industry experts through interviews or focus groups (Saunders et al., 2008). After the extensive literature review in chapter two and three, the exploratory research was undertaken to portray the common practices in the pharmaceutical industry regarding personal knowledge management and measurement. The exploratory study would also examine, in the next sections, the KM maturity in the pharmaceutical manufacturing sector. At the end of this chapter, the conceptual framework will be developed and presented.

### 5.2 *Interviews*

In order to explore the current understanding of the “knowledge” and its management practices among the pharmaceutical industry practitioners, a set of semi-structured interviews were conducted with a selected sample from the pharmaceutical industry experts. The interviews were intended to define the dimensions of the personal knowledge taking into consideration the special nature of pharmaceutical manufacturing. A non-probability sample was considered the most practical choice at the exploratory stage (Saunders et al., 2008). Detailed justification of sampling techniques is described in the methodology chapter (chapter four).

A total of 15 semi-structured interviews were conducted with senior managers from different functions in the pharmaceutical industry. Interviews were conducted over the period from March to September 2018. Interviewees were recruited from the researcher’s industrial network, LinkedIn and by direct invitations during industry related exhibition (the National

Pharma & Life Sciences Expo 2018). Over 29 candidates were suggested for the purposive sample. All the nominated managers comply with the inclusion criteria as mentioned in chapter three (4.7). Furthermore, a ranking system of three levels was utilised to define the priority and relevance of each candidate to the inclusion criteria. Managers who had a superior rank or score (i.e. rank one) were given the priority in the interviewing process. This ranking was based on the position in the organisation and the relevance of experience either the single or multi-functional experience (Table 5-1).

Table 5-1 Interview list

No	Title	Function	Affiliation	Location	Ranking	Scheduled on	Media
1.	QC Manager	Quality	Multinational	KSA	1	02/03/2018	Facebook call
2.	MEA Quality Improvement Senior Manager	Quality	Multinational	Turkey	1	12/04/2018	Skype
3.	Technology Transfer Manager	Quality	International	Cyprus	1	25/04/2018	Skype
4.	QA associate director	Quality	Multinational	China	1	04/05/2018	WhatsApp
5.	Production leader; Consultant scientist	Technical Service; production	Multinational	USA	1	09/05/2018	Facebook call
6.	Enterprise staff supplier quality	Quality	Multinational	UAE	1	10/05/2018	Skype
7.	Production manager	Production	Multinational	Egypt	1	01/06/2018	Facebook call
8.	Manager; Pharmaceutical and molecular biotechnology Research Centre	Research; broad industry experience	Governmental	Ireland	1	12/06/2018	Skype
9.	Associate director technical service	Technical Service	Multinational	China	1	14/06/2018	WhatsApp
10.	Quality Assurance Lead	Quality	Multinational	Switzerland	1	27/06/2018	Facebook call
11.	Consultant	Academia; broad industry experience	Governmental; Multinational	Ireland	1	01/08/2018	Face-to-face

12.	IT Service Manager - Regional	IT	Multinational	Egypt	2	01/08/2018	Facebook call
13.	Validation leader	Quality	Multinational	Egypt	1	28/08/2018	Facebook call
14.	QA and compliance manager;	Quality; Logistics; Production	Domestic (private)	Egypt	2	05/09/2018	Facebook call
15.	QA/QC Manager	Quality; Production	Domestic (private)	Egypt	2	29/09/2018	Facebook call

The sample covered several organisations in nine countries (Figure 5-1) from domestic (private), governmental and multinational sectors in order to shed light on the different KM practices including knowledge measurement where applicable. Eighty percent of the participants are affiliated to multinational companies. The average organisation size is 355 employees (Max =1200; Min= 7). One-third of these organisations are mainly producing biologics and vaccines. Another third described their experience to be in the conventional pharmaceuticals. The rest of the sample is affiliated to organisations producing a mixture of biologics and conventional products as well as medical devices. The median length of interviews is 28 min 2 sec (maximum length= 38 min 36 sec; minimum length= 17 min 47 sec). The interviewees represented a broad range of expertise. Fifty-three percent of the participants were affiliated with the quality unit as a core experience. Production, technical services, logistics, KM consultancy and IT were also represented in the sample. The final sample was intended to cover the key technical functions of the pharmaceutical manufacture with a special focus on the quality unit. The researcher assumed that quality managers would always be familiar with any KM initiative in their organisations where KM is mentioned in quality guidelines and seen as the enabler for the pharmaceutical quality system (ICH, 2009; WHO, 2011b). Last but foremost, 93% of the interviewees are currently affiliated to manufacturing organisations. The research and development participant had also an extensive manufacturing experience.

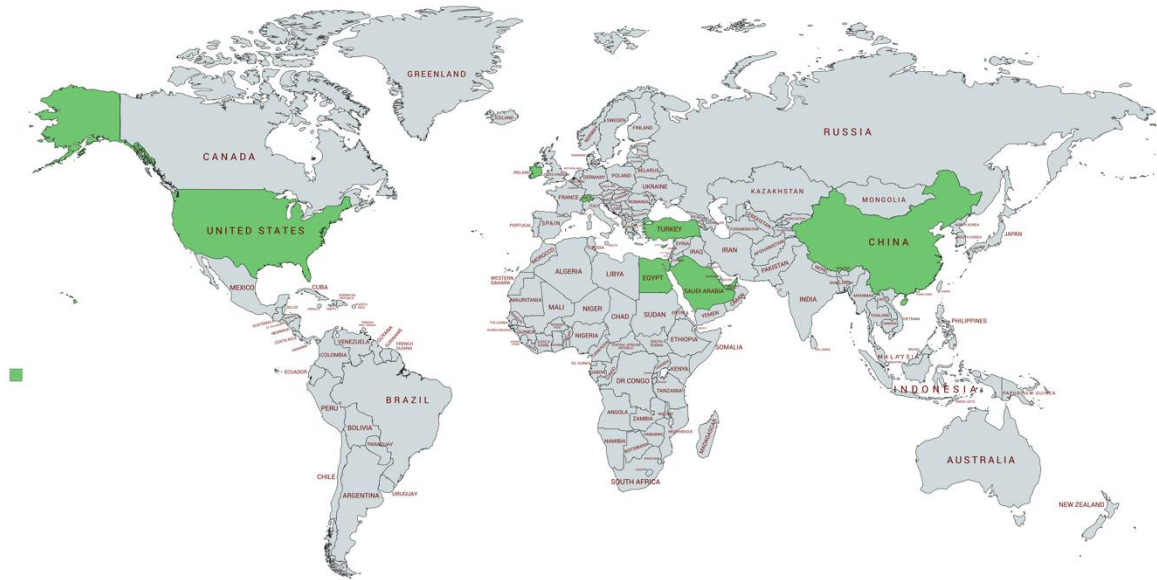


Figure 5-1 Interviews by country map

### 5.3 Understanding knowledge from the Practitioners' Perspective

During the course of interviews, knowledge was described from different angles. Interviewees offered different definitions of knowledge that varied between broad or narrow descriptions. From the narrow perspective, employee knowledge was portrayed as multidisciplinary, job-related, depending on department or having a special definition for every industry and perhaps for every area within the same industry. On the other hand, other interviewees provided broader definitions. For instance, subject 12 defined knowledge as:

*"A very abstract concept. Knowledge ...it is a collective understanding based on practices and experiences that have been developed over the years through execution and implementation".*

It was also described as *"a wide definition"* and *"a diversified aspect"* by subjects two and three respectively. The offered definitions are in line with knowledge definitions in literature where it is gained over time by direct experience and lifelong learning (Hoe, 2006; John Mingers, 2008). Davenport and Prusak (1998) proposed a similar definition of knowledge as a fluid mix of experience, values, contextual information and expert insights. However, the

preliminary definition of knowledge by interviewees limits sources of knowledge to the direct experience or learning by doing.

Participants described two types of knowledge: one that can be found in written documents or drawings “explicit knowledge” and another type which is difficult to articulate “tacit knowledge”. The tacit knowledge is not written, but employees can use it to solve problems (Polanyi, 1966). Moreover, attempts to code the tacit knowledge were recognised. Subject one referred to an initiative to articulate tacit knowledge in his organisation:

*“We have programs like after-action reviews where we try to articulate the learning from every experience.”*

There was an emphasis on the importance of the flow of this tacit knowledge throughout the organisation. Subject 11 explained how current policies of incentivising knowledge holders indirectly encourage knowledge hoarding in the form of Subject Matter Experts (SME’s). Alternatively, the interviewee suggests that firms should spend more efforts to establish a knowledge sharing environment and offer the appropriate incentives to maintain this.

By the same token, there was a consensus among the participants that there is a need to leverage knowledge to improve operations. They elaborated that the efficient use of knowledge could entail a reduction of process cost, optimum utilisation of equipment, decrease time and efforts associated with operations, a better understanding of products and effective implementation of the pharmaceutical quality systems. Subject 11 referred to the ICH Q10 description of KM as an enabler of the pharmaceutical quality systems.

### *5.4 Knowledge Maturity in Pharmaceutical firms*

This study documented several KM initiatives within the participants’ organisations. All interviewees mentioned one or more attempts to capture, leverage or share knowledge in their workplace. These initiatives are argued to overcome (or decrease) the impact of the five main barriers to KM success in organisations i.e. inefficient communication, lack of sharing culture,



lack of competence, lack of incentive and lack of interest from the employee (Oliva, 2014). Some of these initiatives were voluntary actions, while others had a formal firm-wide nature. For instance, ‘after-action reviews’ were used to learn about specific situations, articulate the acquired knowledge in the form of learned lessons and reuse the learned lessons in the future. The interviewees employed document management systems as a secure and reliable method of document retention and control. Other initiatives took the form of a social event for knowledge sharing. Knowledge sharing sessions were one of these events to facilitate an informal meeting of staff where they are encouraged to exchange knowledge about the problems they face. Subject 7 explained his experience with “Lunch and Learning” initiative:

*“something like knowledge sharing lunch when we have once per two weeks... we gather together for lunch and some of the colleagues... one of the colleagues can present something related to his area of experience... his or her area of knowledge to the rest of the team so that they also gain the knowledge and understanding of this topic from the SME who is presenting this during lunch time... is something like informal or less formal knowledge exchange and this is on the level of the small teams and groups”*

Alternatively, the interviews showed that virtual communities and expert finder platforms were used to facilitate knowledge exchange. However, one drawback of this approach is its over-reliance on employee participation (Levy, 2009). The interviewee outlined the significance of regular updates of employee profiles to get the full benefit from this repository. This step was quite challenging for the organisation to find effective ways to incentivise employees to stay active on these platforms. Also, the study found that company-owned social networks were adopted to facilitate knowledge exchange among employees. These networks were a simulation of Facebook or LinkedIn but exclusively within the company. They were used for internal job posting, search for talents, expertise locator or to cover social events within companies, e.g. a visit of the vice president. Microsoft Teams, SharePoint and Yammer are examples of the widely used applications in this area.

In contrast, rudimentary Microsoft Excel spreadsheets were also used to build a knowledge map in relation to product history files (explicit knowledge). There were some individual initiatives to use free technology to enhance knowledge exchange within small teams. For example, subject two explained a personal initiative to use WhatsApp groups to exchange regulatory guidelines and scientific articles with his team. This WhatsApp group was also used to transfer knowledge to other teams within the same company. He pointed out that *“it is not the company initiative”*.

Another approach was to provide a platform where employees can search and find useful technical resources. It is worth noting that it is not part of the training systems but rather a repository of technical resources. Individual employees or groups can contribute to this library of technical media (e.g. successful media fill video record) and they can also improve the quality of its content. This offered means for knowledge and experience transfer within the organisation. Regular conference calls are held where each manufacturing site (in a multinational company) present the contributions to this knowledge repository. Apparently, this demonstrates a form of Wikis addressed in academic literature (Edwards, 2015a; Jones, 2009). Another version of these platforms offered a mobile application. Subject three explained one of these applications in the following paragraph:

*“This application on the mobile is user-friendly and can help us a lot get knowledge and take lecture at home or in your car... at any place you can take your lecture. It is very well selected tool”.*

Supplier Quality Academy was an attempt to transfer knowledge out of the organisation to the suppliers. Through this system, it was possible to share sessions or presentations which is believed to be useful to the suppliers. It was evident that the use of IT solutions was going in parallel with social activities to promote knowledge sharing within these organisations. This combination of technology and social initiatives is argued to support the tacit dimension of knowledge which can hardly be managed using IT tools ( Chatzkel , 2007).

Findings from the interview highlights that KM strategy wasn't well-defined for most of the participants, or they are not aware of its existence. Instead, they mentioned other strategies or policies for training, development or patent disclosure. It was also apparent that KM and training are sometimes confused among practitioners in the pharmaceutical industry. Subject seven assumed that they might have KM strategy but under a different name:

*“No, I didn't hear the exact terminology... KM development but I think it is already in practice, but we have different terminology”.*

Despite that, some of the knowledge processes were managed through formal procedures, e.g. knowledge transfer. In fact, WHO has dedicated the annex 7 of TRS961 guideline for technology transfer. This explains the relative maturity of knowledge transfer for production and quality control processes as appeared in the interviews.

The perception of KM maturity varied among the practitioners. Some described the current KM practices as “*very immature*” as we are on “*the very early days*” of KM. For others it was described as a well-established system. The level of maturity of KM systems was also described as “*patchy*” i.e. it is different from one organisation to another or even among departments of the same organisation. Subject 12 clarified his expectations of KM in the following paragraph:

*“I think my expectations are a little bit higher for knowledge management. I think the pharmaceutical industry has established the first part very well which is the instructor-led training, basic foundations to the discipline, even highly specialised discipline where they give additional training in that aspect is it's very well developed but is it where we need to be? No. I think there is a level of knowledge lost through attrition of people's leaving the company for retirement or who developed a lot of learning over the years that is easily lost because we don't have a way of documenting those experiences and sharing learnings.”*

Training is an educational activity. It aims to accumulate knowledge and skills needed for better performance of an employee in his/her current role or as a preparation for another position within the organisation (Scurtu & Neamtu, 2013). Part of the observed controversy is

due to the unclear distinction between training systems and KM in the studied organisations. The mechanism of implementing KM away from training is not clear and underdeveloped. Also, the participants described a lack of suitable effectiveness checks within the traditional training systems. This means there is no guarantee that knowledge is effectively transferred after training is completed. They argued that knowledge can be acquired through self-learning and employees were allowed to independently interpret what they read on some occasions. Another source of confusion is the lack of differentiation between document control systems and KM. While these systems can transfer and track changes that happen in processes and systems, subject 11 highlighted that organisations expect to have information systems that can manage firm's knowledge in a way similar to electronic document management systems. However, almost half of the firm's knowledge is contained in people's brains (tacit knowledge) while the rest is stored in documents and electronic systems (cited in Liao, 2005). Both training and document control were traditionally seen as a compliance activity rather than a knowledge transfer process.

“Traditionally training wasn't seen as a knowledge transfer activity was seen as a compliance activity where you have to do X amount of training and X amount of qualifications in order to do X amount of tasks”

*Subject 11.*

Moreover, the interviews discovered a high attention to data protection among interviewees. Use of data cloud or public servers raised doubts and fears among interviewees. It is believed that these doubts about confidentiality and protecting proprietary data might hinder KM initiatives in pharmaceutical organisations (Wang, 2006). For instance, subject nine expressed his sceptical opinions about the security of social networks as they might rely on public cloud computing platforms. In contrast, the fear of reputation damage after a data breach encouraged decision makers to enforce data access controls and to adopt information security management systems, e.g. ISO 27001. In line with finding from a recent study of Durst & Zieba (2019),

those fears portray the participants' reactions to cybercrimes and other technological risks of KM with possible negative consequences on business, reputation and patients' health.

### 5.5 Knowledge sharing and transfer

The interviews shed light on another reason of inefficient flow of knowledge in the pharmaceutical organisation. The interviews suggest that employees get their basic training on the IT systems by the vendor then each department start coding the knowledge into this new repository in its own way, using their own terminology and implementing their taxonomy of data. Over time, the organisation ends to a group of individual silos or isolated islands that benefits a little from each other's knowledge. Subject 11 illustrates this situation in the following quote:

*“So, you end up with a system that's impenetrable. You've actually created locked-in syndrome within the silos because nobody sat down to think about how might we architect this forever? So that everyone can have access to it and it's not just relying on this tree structure.”*

Similarly, the interviews highlighted a lack of systematic process for knowledge sharing and transfer among employees. This often leads to hoarding of knowledge among subject matter experts and project managers who see knowledge as power as they are in this position because they have something not with everyone. Ultimately, others have little chance to learn and when these persons leave, the knowledge loss is quite substantial. The subject 12 exemplifies this phenomenon in the next paragraph:

*“It is like construction project managers. They maintain their position throughout their career as the construction project person because it is a positive feedback loop in which they do a project they learn from it so they become more careful of doing projects so they're chosen to do more projects, and then they learn from that too and become more capable and it goes on and on and on until that person requires that information is lost they have a continuous influx of people of at different stages of their career so that when that happens that when someone does retire he'll have people who are at different levels of capability in which they can cover that person leaving the company”.*

It was noted that the knowledge sharing is not often a part of the formal roles and responsibilities. Management doesn't usually dedicate time (during working hours) to allow employees to share their knowledge systematically. These findings supports the lack of knowledge management strategy as explained in (5.4 ).

### *5.6 The value of knowledge measurement from the practitioners' perspective*

The findings of the exploratory study suggest a consensus among the participants on the great value of the knowledge measurement. One of the proposed applications of knowledge measurement is employee appraisal. Subject three suggests the evaluation of employees not only on performance but also on their level of knowledge and how they improve it. He also added this could work as a motive for continuous learning. He provided a real example of applying this initiative in the scientific office of his company. However, this does not contradict with the delimitation of knowledge measurement and the traditional performance appraisal that has been outlined in chapter two. In fact, the design of a performance appraisal system can be complex and can involve multiple dimensions (Bayo-Moriones et al., 2019). Another suggested value of measurement was to assess the effectiveness of any KM initiative within the company on the employees' knowledge or in other words the return on investment. Subject 12 said in that respect:

*“So, yes. This short answer is it would be very helpful for the organisation. It would make sure that we don't lose much money in executing initiatives and systems that are not helping the organisation in retaining knowledge.”*

The interviewed experts added it could offer a lot of help, especially as a selection criterion during the recruitment and retention of employees. It can also predict the outcome of the employee based on the level of knowledge he/she holds. It can define the minimum requirement for each job. Moreover, it can be used as a way to check the knowledge acquired after training or over a certain period. Others referred to the potential impact on business cost due to lack of knowledge, e.g. the cost of rework. Similarly, they emphasised that it would save

money by retaining knowledge within the organisation. It was also described as crucial for business success and for decision-making process as explained by subject 11:

*“How good we are using what we know as an organization to inform our decision-making processes.”*

Embracing Drucker’s Management by Objectives approach (Greenwood, 1981), knowledge measurement can drive the development plans of the employees in different functions as explained below:

*“I don't want to repeat myself but easy way to see the value would be if I have indicator that tell me if my department is much higher than the average knowledge or just at the average or below the average. This might drive my plans for my people. So, if it is much higher this means I have to focus on the execution rather than the knowledge building or the awareness. If I am at the average I need to work side by side. If I am much lower, it might indicate that I need to change the team to get more experienced people or knowledgeable people or to do something to leverage the knowledge of the team to be an average of a bit higher.”*

*Subject one*

This notion was further highlighted by subject 11. She clarified while an employee might use company resources to enhance their CVs rather than obtaining relevant training and development, having a comprehensive knowledge measurement and management strategy would generate knowledge goals for each employee that can benefit both the employee and the organisation. She said also:

*“When you look at the individuals themselves they've got specific goals and drivers for their career that are not just linked around “I hope I can get that black belt training on Six Sigma next year on my CV [...] So, I think a tool such as that would be invaluable because again it helps start thinking about twisting the coin. It's not about building the CV; it's about enhancing the organizational capacity.”*

An additional value of the individual knowledge measurement was to prognosticate individual strengths and weaknesses. Subject nine argued that a measurement tool could show him/her what is needed for the development of each employee in his area. This can help deploy the employees in the right positions and get the best out of them. Subject seven explicate this

application of individual knowledge measurement tool in the following:

*“I think if we have a structured tool which can give us an overview, not an overview ... a deep understanding, strong and fair assessment of the amount of knowledge our people or talents have I think this will be important in setting how do we deploy these talents and these knowledgeable.”*

On the other hand, findings suggest that having a knowledge measurement system in place would build trust in the company decisions. This can provide an advantage during audits or inspections. The reason behind this, it would provide the auditors with objective evidence that only qualified persons take decisions that might impact patient health. Subject ten clarify this notion in the following quote:

*“So, auditor has come into companies and they start looking at pharmaceutical development and you know - defining what we had made that were made and so on and they start asking questions: why did you know if you're doing risk assessments why did you use...? why did you come up with these? this risk assessment... how did you come to these conclusions and then the obvious question is: are you qualified to actually make those decisions? Okay, what's your background?”*

The measurement tool is claimed to influence the whole corporate not only from a quality and regulatory perspective but also at the business level. Subject eight argued that this tool allows the decision-maker to know who has more knowledge objectively and in turn assign new projects and responsibilities to the suitable person. This is deemed to improve the quality and business outcome. This supports the notion that the organisational ability to exploit existing knowledge is a determinant of its success and competitiveness (Matoskova, 2016). By the same token, subject 12 speculated that *“the aggregates of the individual speak for the performance of the site”*. As a result, he continued *“it starts by individual. If every individual is capable consequently the whole organisation is strong and healthy”*. The findings suggest that the outcome of the personal knowledge measurement can reflect the knowledge level within the whole department or even the whole organisation. This also endorses that HC is a unit-level resource and the measurement must be conducted at the individual level (Moliterno & Ployhart,



2011). Subject 11 believes that these efforts help link value to knowledge. In turn, when decision makers see the contribution of knowledge to value creation, this will build maturity in KM practices in the organisation.

However, one-third of the interviewed managers referred to some potential barriers hindering the systematic measurement of the employee knowledge within their firms. One of these barriers is the availability of alternatives. For instance, it is not always possible to have several employees who have the necessary knowledge about a niche product or a particular process. In this situation, measuring employee knowledge would offer no more options as the organisation might not have the luxury to assign a more knowledgeable worker to support this process.

Subject 14 mention this barrier in the following quote:

“If you go to the detailed technical point you don't have the luxury to have 2, 3, 5 persons able to support in this area [...] let's have an example. I have now an issue related to XX manufacturing for example. you have a specific person, he is educated to support this. He is a global XX steward and he's supporting this molecule. So, it won't be helpful anyway if I'm gonna assess his knowledge. What else! I don't have options!”

Similarly, some other firms have a one-year contract of employment policy. This doesn't allow the company to take any corrective actions after knowledge measurement. It might not have a formal performance review process either. By the time the organisation takes any action based on the measurement process, these employees won't be there anymore. Subject ten asserted:

*“You know by the time you actually take your corrective action the person's contract will have expired”.*

In addition, it is not always possible to find a standard or a reference to assess the knowledge against (Borgatti & Carboni, 2007). This is quite apparent in innovative and research-related activities. The employee is doing a certain task for the first time and nobody knows if this is the right way to do it or not. Subject ten demonstrated this in the following quote:

*“The work we're doing is research and so the samples there has no history or no and no one has tested it before. So, we're the first people looking at this particular measurement and so it's you know it's there is no reference.”*

Poor understanding of the KM and PKM is another barrier to implementation. Interviews revealed that management are not always aware of the benefits of the personal knowledge measurement and in turn, they might not support such initiatives in their organisations. Indeed, the existence of a knowledge-oriented leadership encourages the development and use of KM and consequently enhances innovation (Donate & Sánchez de Pablo, 2015). In addition, subject 11 asserted that management often looks at the employees' knowledge in a very static way where seniority and/or the number of qualifications or certificates are the only ranking criteria rather than real capabilities. Based on this understanding, they have a wrong assumption that proper knowledge measurement activities have been already in place.

### *5.7 The knowledge measurement practices in the pharmaceutical industry*

Interviewed managers emphasised the regulated nature of the pharmaceutical industry. This is coupled with the expectation of high-quality standards in all operations. This also implied a need to have the proper knowledge before involvement in any process in such a controlled environment (WHO, 2014). The interviews reveal that the pharmaceutical industry has a global nature where practitioners are speaking the same technical language and refer to the same global standards. However, some participants argued that albeit there is still a lot to learn from other sectors such as automotive, nuclear sector, aeronautics as well as oil and gas in the field of KM. According to subject 11, KM is still “immature” in the pharmaceutical industry.

There is a consensus among the participants that the knowledge measurement practices in the pharmaceutical industry are still informal activities. Managers might evaluate the knowledge of their subordinates in a qualitative way missing any objective criteria. The process is described as a managerial skill which is based on the manager's personal experience, and it

varies from one to another.

Direct managers can assess the subordinate knowledge through daily interactions and performance. Over one third of responses linked the knowledge measurement with the recruitment process. During this process, the manager often evaluates the knowledge of the applicants through technical questions. Another form of interviews takes place after major deviations to ensure that workers hold the required knowledge and can apply it. The operational managers also have open discussions with employees during Gemba walks, and this offers another opportunity to assess their level of knowledge qualitatively. However, the participants expressed their need to measure the knowledge of their employees in a formal way. They are looking for a formal and standardised knowledge scale. This would standardise the assessment process. Subject 12 and one respectively emphasised this meaning in the next paragraph:

*“Yeah we need to know [...] how you know you have a gap if you cannot measure. That is why I said we need to be able to measure it.”*

*“I don't know the way. I mean if it is true that we have a way to say " in this department the collective knowledge of employees hit this bar which might be high standard one...this means this gives great confidence that this department can make decisions in (desirable) way and if it didn't hit the bar or was significantly below this bar it might also indicate that something needs to be improved in the knowledge of the organisation so it might be a priority to improve.”*

Nevertheless, seven out of 15 interviewees showed scepticism about the possibility of having an objective measurement scale of employee's knowledge. Statements such as “*assess, I am not sure!*”, “*you cannot give it a rating*” or “*I don't see we can do it*” reflects the feelings of uncertainty in light of the current practices.

Talent management can be described as a relatively established process in at least one-third of the participating organisations. The process aims to acquire knowledgeable people from the market and to retain them in the company (Somaya & Williamson, 2011). The findings show

that talent acquisition starts from the direct manager who nominates the potential talents and ends with senior management, e.g. the site head who approves these choices. Talent management, in the studied organisations, is also part of the succession planning where talented workers are prepared for leading positions. Despite that the talent is not only the knowledge but also the skills and abilities (Nijs et al., 2014), subject seven affirmed that knowledge is an important part of the talent. He stated:

*“We have a system...the system is supported by IT tool for talent management, and very important part of talent management is the knowledge... the person knows, the strengths of this person, in which parts this person is very strong, and how can we develop the person in this strength knowledge. Further, how can we compensate for the absence of this person in case of retirement, lay off, rotation to a different job or whatever?”*

The paragraph above illustrates the management awareness of the significance of knowledge loss. People who leave their jobs or retire take their knowledge out of the organisation. This would also increase the turnover cost when the organisation tries to replace the lost knowledge holder as subject 14 mentioned below:

*“So, if you for example... if you have a very experienced scientist and for some reason, you will lose this person, and this will cost you a lot to get somebody else to start over what he used to do.”*

Forgetting is another mechanism of losing knowledge (Holan & Phillips, 2004; Watanabe Wilbert et al., 2019). The interviews reveal that when the organisation fails to document the experiences and to share the learnings, it is usually not possible to avoid repeating the mistakes the person who has retired had already faced in the past. Subject matter experts who are retiring are seen by participants as another threat to the pharmaceutical organisation. There is still no clear process to transfer their knowledge or to systematically document it in a way that allows retrieval in the future.

Thus, the findings reveals that when knowledge holders leave and the knowledge hasn't

been well documented (or shared), the organisation faces challenges with process and product related information especially with legacy products and products acquired from other companies. It has been argued that decision-makers would hardly be able to make the right decisions, and they could resist any changes as they are not sure about the possible consequences. Even wrong decisions can be made due to the lack of knowledge and months might be wasted to discover the root causes of the generated problems instead of using the current resources for continuous improvement. This supports the notion employees leave the organisation with the critical knowledge that supports the business leading to negative impacts on productivity, performance and organisational knowledge base (Massingham, 2018; Parise et al., 2006).

In this chaos, the study records some attempts (eight out of 15 interviewees) to plan existing resources and human capital. However, the first challenge they have is that it is not always possible to identify the knowledge holders. Sometimes management face a particular problem, and it needs a certain knowledge to solve it, but it is not possible to know exactly who has this knowledge or skill. As there is no formal process for this, it is totally reliant on manager's interactions with his team. Subject ten provide an example of that from his organisation in the following quote:

*“For example, if a problem comes in and requires ion chromatography as an example, you know, do I know anyone here with Ion chromatography experience probably not- maybe just people that I can go and ask about it, but I don't know that I have that expertise. We don't do that... hard to do... but we should do.”*

Four of the participants referred to the organisational endeavours to plan their Human Capital through the identification of knowledge gaps among staff. This process is limited by the lack of consist knowledge measurement tool too. This notion was endorsed by subject 12 as he said:

*“How do you know you have a gap if you cannot measure? That is why I said we need to be able to measure it. You could have a problem with your knowledge of your organisation and not know. And the only way to know is to measure.”*

One of the used approaches (in two interviews) is to ensure that each critical area is covered by a backup person(s). The backup person holds all the necessary knowledge, and this ensures the operation will not be interrupted due to the absence of the needed knowledge holders. However, interviewees asserted this approach is not always possible especially with highly technical and specialised roles as it is not possible to have a substitute.

In one of the interviews, the Skills Matrix was introduced as a practical application of both human capital planning and backup person allocation. It was described as an annually used tool to assess and manage skills in a function or department. Also, the training and recruitment needs are determined based on this matrix. It starts by analysing the process into tasks or steps. The matrix consists of two axes. The first is the processes or tasks to be done in a certain unit or department. The other axis contains the names of the workers in this area. Each employee receives a score from one to five based on his capabilities. If the worker cannot undertake the job at all, he/she receives one. He/she receives two or three if they can complete it without supervision. The worker receives five when he/she is able not only to undertake the job but also to train others on it. Despite that, this scoring is still a subjective activity totally dependent on the supervisor or direct manager's opinion as shown in the next quote from subject eight:

*“It depends on the supervisors' knowledge and the manager knowledge about employees, and this is built through the experience of the whole year, and this matrix is updated. So, of course, you have seen many situations during the year that build your knowledge about the employee in this task.”*

### *5.8 The personal knowledge of the pharmaceutical employee*

The following section illustrates the key antecedents and measures of employee knowledge in the pharmaceutical manufacturing sector that have been discovered in the interviews. The

interviewed managers explain these measures based on the common practices and their industrial experience. Eight main themes and their underlying subthemes are explicitly discussed showing the current practices of industry practitioners to assess the personal knowledge of individual employees.

### 5.8.1 Regulatory compliance

#### *I. Ability to identify compliance gaps*

In such a regulated industry, the ability to understand and interpret regulatory standards to identify implementation gaps is seen as a measure of knowledge of regulations. Subject seven refer to this in the following paragraph:

*“...understanding and the capability to interpret the quality standards from different bodies and from different countries is the key knowledge factor.”*

This ability to interpret the guidelines can be envisaged in employee compliance to these regulations in his area and/or his ability to identify implementation gaps (e.g. gap analysis) as well. Subject four stated:

*The gaps you put in your final report [...] give us an indication for how much you are updated with the new requirements... the main gaps you find...*

#### *II. Familiarity with relevant regulatory standards*

In addition to employee's ability to interpret regulatory standards, seven of the interviewed managers expressed their concern of their employees' familiarity with the recent requirements or expectations of the regulatory bodies. They emphasised the importance of employee's knowledge of current Good Manufacturing Practices (cGMP) in addition to the internal company standards. The knowledge of the latest updates of relevant standards is necessary to be able to achieve compliance.

*“If the reference of the health authorities- we are dealing with- is the ICH or the WHO then what are the latest updates in the ICH or WHO (standard) and the level of knowledge you have related to this standard.”* Subject four

### 5.8.2 Product and process understanding (mastership)

#### *I. Finding knowledge (know-where and know-who)*

The ability to find knowledge about the process, product or equipment is one of the suggested predictors of his/her personal knowledge. As it is impossible to know everything, findings from five interviews show that it is highly appreciated if the employee knows where to search to find knowledge. Subject two provide his explication as follow:

*“He shouldn't know the info when I asked him for example but should know where to search where to find”.*

The knowledge can be available somewhere in a computer or a server, and it must be retrievable to be used. Part of the knowledge lost when a person leaves the organisation is the Know-Who (Jennex, 2014; Parise et al., 2006). Thus, besides the need to know where to find knowledge, there was an emphasis on the need to know who to go to and who not to go to. In other words, another important part of process knowledge would be the knowledge of the “*go to person*” for each process.

*“We'd better if you could just go to someone who had expertise in the area or working... does know who to go to, who not to go to”.* Subject ten

Interviews uncovered some of the KM initiatives that facilitated knowledge findings by electronic systems such as expertise locators and social networks. Indeed, the existence of informal personal networks to connect knowledge holders can compensate for the deficiencies of the formal organisational arrangements (Grabher & Ibert, 2006).



### *II. Working without supervision (Skills Matrix)*

The application of skills matrix to assess the employees' knowledge about the process is explained in detail under (4.8). It relies on the ability to work without direct supervision or have the knowledge to train others on a certain task as a proxy indicator of the level of process understanding.

### *III. Technical knowledge*

Two thirds of the participants advocated that knowledge holder should understand and explain the underlying theories of processes, product and equipment in his/her area. Understanding of the principles underlying phenomena is described as Know-why (Raghu Garud, 1997). This reveals the management concerned with employees' knowledge in basic science and other technical details of formulation and/or analysis. They argued that a manufacturing employee must maintain a certain level of knowledge about the scientific background of processes and product in addition to full awareness of risks and precautions. This includes also the modern technologies employed in manufacturing.

*".. Even if it is molecule related, or substance  
related or the technology itself about the equipment..."*

Subject 3

Two of the interviewed managers used technical questions as a knowledge assessment tool during the recruitment of their subordinates. The technical questions are related to the part of the operations he/she supports. It might be about the analysis techniques, formulation, or commissioning and qualification activities. Subject two explains this in the following quote:

*"We ask some questions in our industry for the employee to understand if he has a knowledge about our industry, our guidelines, all the rules which is covering or which is covering our industry during the normal work."*

However, the findings suggest that explicit technical knowledge is more appreciated for junior employees and operational managers rather than senior employees as explained by case 13.

### *IV. Technical advising*

The interviews revealed a form of technical knowledge sharing among employees. This can take the form of formal assignment of a Subject Matter Expert (SME) or Molecule Steward based on his/her outstanding process/ product knowledge. Knowledge holder can also be informally perceived as “*the go-to person*” by his/her colleagues. However, the improper use of those SME’s and lack for proper incentives for knowledge sharing might lead to knowledge hoarding among few of employees who try to protect their knowledge privilege in the organisation. Subject 11 clarified this in the following quote:

*“Subject matter expert and then that gives them maybe an extra 10% in their pay package or something. So, the incentive for them is actually to hoard their knowledge right so they become the expert the go-to person rather than the incentive being the other way of identifying where their knowledge is where their current knowledge bases what knowledge gaps they have and where they might be to fill those and then getting them to share that knowledge as part of the incentive package.”*

Finally, knowledge is acquired by participation and involvement (Bakken & Dobbs, 2016) were contributing to process design, development and improvement can demonstrate a proxy indicator of personal knowledge.

### 5.8.3 Performative knowledge

Performative knowledge refers to the skills needed to be able to do something (Mingers, 2008). Management used the performance as a predictor for employee knowledge. In other words, if the employee holds the required knowledge to do a certain task, management will expect superior performance and outcomes out of this task. Knowledge holders understand the process they are responsible for and knows exactly how to do the job from start to end. It is

about the know-how of the product or the process. Performance is characterized in terms of “efficiency” and “effectiveness” (Ajith Kumar & Ganesh, 2011) as explained in the following sections.

### *I. Achieve the organisational/departmental goals (effectiveness)*

Interviews asserted that knowledge can enable the achievement of firm goals and objectives. Knowledge here is assessed through its outcome. Outcome and deliverables are measures of employee knowledge.

*"If you need to conduct or to make a specific task you can assess from the outcome and the deliverables of this task how much knowledge about this task and how much knowledge about the requirements and expectations of industry this person has though the deliverables of the task and this is entire year of performance" Subject 7.*

Keeping this in mind, subject 9 nominated productivity as another predictor of knowledge. Knowledgeable employees are deemed to meet their productivity targets and achieve company goals. In other words, deliverables are the result of employee knowledge. On this ground, performance reviews measure the contribution of employees over one year including his level of knowledge and development plans. It measures if the employee is capable of achieving a certain number of goals that have been tightly linked to departmental and organisational goals. Performance appraisal was presented as another indicator of personal knowledge in the following quote by subject seven:

*"If you are talking about the assessment of knowledge of persons, I think it is very core part of the performance review... the semi-annual and annual performance review and each employee within the company is assessing the amount of knowledge that key participants are having and how much knowledge is necessary to perform his job is in place."*

### *II. Execution and implementation of tasks (efficiency)*

Management interprets the way employees interact and execute their job as a proxy indicator for their knowledge. They referred to these interactions by “day to day

activities” and “day to day interactions”. Subject eight explains his approach to assess his subordinates’ knowledge:

*“This is not a direct way to (measure knowledge) ... I'm not sitting down with an employee just to assess their knowledge... It is observed due to day to day work or tasks performed day to day.”*

The involvement of employees in the execution of different processes, holding proper knowledge to improve product or process and the quality of doing this job reflects how much knowledge he/she has. This improvement in the performance is summarised by subject two:

*“I believe that people whose knowledge is higher, perform better, perform faster.”*

Timeliness of doing a task was also linked to employee knowledge. If the employee is experienced with a certain process, he is expected to be able to do it faster and within the planned timeline. This can be explained that the employee can use his/her prior experiences if he did a similar job before and in turn would do it faster.

*“It’s more related to the way he is executing his job because the level of knowledge you have facilitates the job execution. If you participated before in the job, then when you are trying to validate it would be very easy for you to execute or to start the protocol or to conclude a report the gaps you put in your final report”.*

Another measure of execution and implementation of tasks is the ability to do it right the first time. The findings affirm the role that knowledge has to make “doing the job right first time” possible. This is illustrated in the following quote from subject two:

*“When this employee, for example, will have this knowledge, he will do the right thing, he will take a solid decision, he will do his work right this is a reason this is a reason for to know this knowledge.”*

On top of that, doing the job right first time can be also linked to getting reproducible results. Knowledgeable employees are argued to maintain the minimum (non-process related) variability. This can be verified once the same or nearly the same results are obtained when the job is repeated by different persons. In the case of analytical labs, their results can be even

compared to the results of an experienced analyst or neutral standards. The following quotes represent the practitioners' insights about this point:

*"So, I guess we will consider someone to be successful if they've got reproducible results." Subject ten*

*"We need to work more on this part to minimise individual variability." Subject 14*

### 5.8.4 Wisdom, problem-solving and decision making

Wisdom is the last layer of the knowledge pyramid (Bernstein, 2011). It was used by practitioners to describe the judgemental capabilities and the problem-solving capacities of employees.

#### I. *Making the right decisions*

An important effect of wisdom is the readiness to take critical decisions and use knowledge properly (Thomas et al., 2017). Interviewees portrayed knowledge as an enabler of right decision making. In addition, the level of maturity in decision making (e.g. the factors considered to make a decision) was indicative of the quality of the decision making. One of the interviewed senior directors (subject one) outlined how knowledge-based on the understanding of company processes and governmental regulations enables "*calculated risk-taking*" and "*better decisions*". Another manager (subject two) explicitly referred to the role of knowledge in decision making:

*"...he can take the right decision; this shows that he has a lot of knowledge."*

Subject 12 emphasised the quality of the decision-making process and the need to consider the basis upon which the decisions are made. The decision-making skills were presented as a 'must-have' capability for each employee to handle his/her job duties. Starting from onboarding training program confirmed this skill. Management knowledge was also seen as another enabler to right decision making:

*"I think better decisions when the management has good knowledge ...decision-based knowledge can be very effective in taking decisions based on knowledge. So, I believe it is a very important tool to be used in taking decisions." subject three*

### II. *Trouble shooting*

Trouble shooting and problem solving were also highlighted by one third of participants as a measure of personal knowledge. This was depicted by the ability to close gaps or solve problems on daily work. The knowledgeable pharmaceutical employee is believed to be familiar with the possible failure modes of his process and possible solutions. This was seen as an indicator of knowledge stock and the ability to use this knowledge.

*"Understanding of failure modes that may be present in each analysis..."*  
*Subject 3*

It also implies the analytical skills necessary to explore vague situations and come with the right solutions. It was even considered a comparative advantage among individual employees.

*"I think this is the knowledge we can assess in employees and compare between individuals" subject nine*

Additionally, accumulated experiences about specific types of problems and the most effective solutions save both time and effort. Subject ten demonstrated his experience in solving client companies' problems with biologics in the following quote:

*"When a company comes to us with a new problem; it's a new problem for them, but it's something that we've seen before. So, we can dip into previous work that we've done and kind of look at it and say okay we're gonna use that same approach."*

### III. *Critical thinking*

As mentioned before in the previous section, taking the right decision needs both a proper use of knowledge and analytical skills. The employees are informally assessed for their ability to think critically, apply solid criteria for decision, react well in difficult situations, interpret the results and finally come with the right decisions or solutions. They have to illustrate this

clear and rationale way to solve work problems. A senior director (subject 12) expressed his expectations of his team in the following quote:

*“Basis on which the decisions were made[...] what level of maturity they have when they make those decisions what do they factor-in what do they not factor-in [...] do they underestimate certain things; how do they communicate them that information how they communicate that decision; are we leaning towards alt conservatism or are we more taking a more risky approach that we should? Those are things that I debate through today those are the kind of knowledge expectations that I want them to reach.”*

#### IV. *Applicable and creative solutions*

The fourth element to be considered for problem-solving is the ability to think outside the box. Personal knowledge is often reflected as creativity and self-expression (Bhatt, 2002). Knowledge was believed to allow employees to introduce new ideas to improve the process or product. This can be in the form of business cases or suggestions of improvement initiatives.

*“How he can introduce new ideas to the process or the organisation; how he can present business cases or suggestions to improve the process.”*

Subject six

#### 5.8.5 Organisational Understanding

The findings advocate that the personal knowledge of employee is not limited to the technical aspects. Pharmaceutical industry employees are expected to know about their organisation mission, vision, operations, functions, culture and values.

##### I. *Organisational culture*

The first component of organisational understanding is organisational culture and values. Culture refers to shared assumptions or values which are learned within organisations to solve their adaptation and integration problems (Schein, 2004). The findings show that employees need to embrace company values and abide with certain ethical rules. From this perspective,

the employee must know what is right and what is wrong within a specific organisational context. The code of conduct of every organisation might define some of these values that should be promoted among workers. These may include and not limited to integrity, transparency, respect for people, etc. Employees understand the underlying assumptions in their organisational culture to take the right decisions. Subject 13 explained the importance of company values as shown in this quote:

*“We are calling “Credo”. Credo is our values and one of the very important point... law is the values that we are committing our customers our consumer. For that, everyone in the company needs to know or have knowledge of the credo and have a commitment of this.”*

The employee’s understanding of the organisational jargon and technical terminology is indispensable for the proper understanding of the organisational culture and dynamics. Nevertheless, this jargon may vary from one manufacturing site to another even within the same company. The induction training for new employees introduces those terms to new employees as explained by subject 12.

*“So, it is basically to understand the terminologies that are you within the company's world worldwide and site-wide.”*

Subject 12

### II. *Organisational mission and vision*

Once a new employee joins the pharmaceutical company, he/she commences the necessary orientation or induction training about the company. This would include the awareness of key operations in addition to the organisational objectives, mission and vision.

*“So, you can know the person who is really knowledgeable about what we are doing.”*

Subject 5



### III. *Understanding his role in the organisation*

Participants pointed out that the employee should be aware of his/her role in the organisation along with the relationship with other teams and functions. Consequently, the employee's roles and relationships would be aligned with the organisational goals and objectives.

This can be exemplified by this quote from a senior director (subject seven):

*“We assess also the organizational knowledge, how the person understands the organisation, how the person understands his position in the organisation, how the person understands the correlation between him or her and their team with the organization alignment with organizational objectives”.*

### IV. *Knowledge about other departments*

The interviewees described other elements of knowledge on the organisation including awareness of other operations and activities in other functions particularly in cases of partnership or involvement with cross-functional project teams.

### V. *Common failures*

This includes familiarity with historical failures and repetitive out of specifications (OOS) results. This can be important for understanding the process trends and history of recurrent issues. Subject three enumerated several actions that were taken to share this type of knowledge among employees through the use of visual management tools.

*“So, we try to make it very simple with pictures just to share the knowledge most of the analysts fail in.”*

#### 5.8.6 Communication and networking skills

During the course of interviews, there was repeated emphasis that business is not only in need of technical skills but also other social competencies. This agrees with the notion that knowledge is not just a thing or a process but it can be envisaged as a personal network (Chatti, 2012) and knowledge work is increasingly social (Wright, 2005). Engagement with the team,

taking the lead, effective communication and motivation of peers are some of the skills expected by interviewees from the workforce. To achieve this, certain characters were endorsed by interviewed industry experts, e.g. openness and transparency, practical and pragmatic.

### I. *Team player*

Certain skills and competencies are expected by the interviewed experts from the pharmaceutical employee to undertake his job effectively. The employee needs to work with teams, take the required actions and maintain a good relationship with team members. In other words, he/she should be a team player who shows high levels of engagement in the assigned activities.

*“The main knowledge is what I want to evaluate is the ability to be team player” Subject five*

This can be understood in light of the high level of maturity in project management in the pharmaceutical firms (Wakefield, 2005) which requires engaged teams.

### II. *Leadership, motivation and upward communications*

Participants advised that an employee is required to know how to take the lead in organisational initiatives. They stated this type of knowledge or skill is even of more significance at the senior level. It implies also the capability to motivate co-workers and team members. Participants affirmed that individuals could have a gross impact on team spirit. Consequently, they need to know how to manage this.

On the other hand, interviewed managers required their employees to know the right way of dealing with and influencing top management. This comes from their experiences with escalation and bottom-up (upward) communications. In other words, they need to know how and when to escalate and use this effectively to communicate with or even influence senior management.

### III. *Internal and external network*

The personal network is an important determinant of the flow of knowledge in the organisation (Chatti, 2012). This network can be internal or in other words consisting of friends from the workplace, perhaps colleagues from the same or different functions. It can also be an external network where the employee has access to what is called the communities of practice (COP) (Bolisani & Scarso, 2014). This also requires good communication skills with co-workers which is necessary for a manufacturing role. These behaviours that signify openness and transparency and effective communication are necessary for a successful business. Subject 11 demonstrates types of behaviours which are appropriate for the manufacturing organisation:

*“We look at behavioral specialisms as well. So that we're looking at the types of behaviors that were nominated as being appropriate in our organisation and knowledge transfer and sharing would be one of those Ummm...you know, openness and transparency and communications and things like that.”*

#### 5.8.7 Learning and education

Formal education is still a prerequisite for many pharmaceutical manufacturing roles. During recruitment, each role usually specifies the required qualifications. Participants showed that it can be even used for comparison between people's knowledge in the form of “*how many qualifications do you have?*”. Likewise, other participants asserted that certificates can also become a prerequisite before getting a promotion or being qualified for certain jobs.

With regard to training, two sub-themes were discovered: adherence to training and training effectiveness. Companies develop training programs, and they expect employees to adhere to this program. Completing 100% of the assigned training courses is the expectation. Companies use both internal and external training resources. Interviews revealed also that well-known training companies might supply external training. Also, special training and qualification are required for critical processes. Training programs start with induction training for new

employees. There is periodic training and on the job training. Employees might also be trained on historical issues and OOS. Last but not least, training was confused by some participants with knowledge sharing or knowledge measurement as shown in the following quotes:

*“When they receive a kind of knowledge sharing or knowledge transfer techniques like the training, for example, they need to be assessed for how much understanding they get from the training?” Subject seven*

*“I think I have answered this question before through the qualification training program. I think that is the only way we have to ensure knowledge transferred correctly.” Subject eight*

*“They need to be assessed for how much understanding they gain from this knowledge” Subject seven*

The lack of discrimination between training and knowledge sharing was observed multiple times with several participants particularly when they discussed training effectiveness. They described how they measure the knowledge acquired by their employees after training through training effectiveness checks. The interviewer was aware of this confusion but he didn't interfere not to guide the interviewees and to minimise bias in the results. In terms of the effectiveness criteria, it was primitive and not well-developed for regular training. It was described as a simple quiz usually taken after reading the relevant standard operating procedure. Then the trainee is required to solve these questions to be certified for that training. However, critical tasks have extensive testing under what is called “qualification programs”. This includes a quiz, essay, oral discussions, presentation, monitoring programs and certification. Subject 13 clarify this in the following quote:

*“I mean if it's something critical to the consumer health, we will have not only an SOP it will be like guidance, SOPs, standards plus presentation plus you know like quizzes plus certification that this guy has a completed the stuff and so on.”*

Similarly, subject eight and 12 respectively added:

*“This is mandatory and oral discussions are not accepted anymore, so we have to prove that knowledge transfer is done in a satisfactory manner.”*

*“We do have ways to assess those people and their learning through either questions or some kind of assessment that are done depending on the level or criticality of the information that being transferred to that person and we can very well characterize their level of understanding based on those challenges and those questions and those on that assessment.”*

Another type of education highlighted in the interviews includes soft skills and languages (e.g. English). In fact, the global regulatory guidelines by WHO, FDA, ICH are published in English. Furthermore, multinational companies have employees from different nationalities and learning a foreign language can be necessary for communication and knowledge sharing. This can explain the value of learning foreign languages in particular the English language.

The willingness to learn was also seen as an antecedent of knowledge. This was explained that people gain knowledge in their areas of interest. Indeed, the ability to assimilate and use knowledge (Absorptive Capacity) at an individual or organisational level is dependent on the prior knowledge of a closely related discipline (Cohen & Levinthal, 1990). According to this notion, if the employee is interested in a particular discipline (e.g. following certain regulatory guidelines, reading particular books, communicating with industry experts in this field, etc.), this can be an indicator of his knowledge in this field or a similar field. The next quote can exemplify this idea from subject one:

*“You can see that the people's interests. So, definitely staff or employees who are interested in following annexes or some different ICH chapters or looking about those things. This might be an indicator that he is building or he fed his knowledge.”*

Likewise, subject six added:

*“you can find someone who always has more knowledge more than at the task he is performing at the moment; he always has a need to learn and read about the process [...] I think this is the way I can manage I can assess the knowledge ..can measure the knowledge of the employee.”*

### 5.8.8 Experiential knowledge

Experiential knowledge refers to personal prior experiences particularly about people, places, events or feelings (Mingers, 2008). This type of knowledge was described by

interviewees as the knowledge that develops over time. It is usually measured by the years of experience or job tenure. Moreover, ICH Q10 outlines the prior knowledge and experiences as one of the sources of pharmaceutical knowledge (ICH, 2008). However, relying on seniority, length of experience, the number of training courses or qualifications as a sole measure of knowledge received a lot of criticism from some participants. It is claimed that pharmaceutical organisations are busy measuring the explicit potential causes of knowledge which are not always associated with a high level of tacit knowledge. Subject 11 explained the current process of assessing or comparing employee knowledge as follow:

*“You know, and very often they tend to be around seniority rather than capabilities. you know how many years of experience do you have how many qualifications do you have, how many training courses have you been on. So, in my experience is still that are our training organizations that tend to capture our qualifications and our capabilities... focus more on again those explicit outcomes rather than that tacit (knowledge) sharing.”*

Moreover, the value of experience is seen related to the level of relevance to the current job. Technical jobs have prerequisite requirements of relevant experiences. This means the employee spends a certain period doing this job or similar job. The reason behind this, as explained by a validation leader in one of the multinational pharmaceutical organisations, the level of performance is proportional to the experience. If the employee did a particular job before, it would be easier for him to repeat it. Experience facilitates task execution as shown below:

*“Because the level of knowledge you have facilitates your job execution if you are participated before in the in the job then when you are trying to validate it would be very easy for you to execute or to start the protocol or to conclude a report on the gaps.”*

The same idea was mentioned by another manager who explained how his team solve industry problems for their clients using their experiences and pretested solutions as shown in the following quote:

*“It's a new problem for them, but it's something that we've seen before [...] we're gonna use that same approach.” Subject ten*

Over and above, interviewees used the experience to differentiate between two types of knowledge: explicit knowledge coming from books and documents versus tacit knowledge (Polanyi, 1966) acquired by socialisation and experience.

*“You can learn from documents like research or books or something you can get out of a library and knowledge based on experience that they have to develop over time.” Subject 12*

### 5.9 Framework Development

This study adopts an abductive approach engaging both of the extant literature and the primary data to develop the research framework (Saunders et al., 2016). The outcome of the exploratory phase is utilised to develop a measurement framework to identify and measure the personal knowledge of the pharmaceutical industry employees. The framework consists of observed indicators (measures or manifestations of the personal knowledge) together with the underlying latent factors. The proposed framework design is in line with the theoretical assumptions of Second-Order Hierarchical Confirmatory Factor Analysis (CFA) (Kline, 2015). The proposed framework identifies 41 personal knowledge measures (observed variables) reflecting six latent factors describing the main latent variable of the study i.e. the personal knowledge of knowledge workers in the pharmaceutical manufacturing. Because knowledge and its underlying factors are latent variables that cannot be measured directly (Bollen & Lennox, 1984), the research used both primary data from the thematic analysis as well as the literature when applicable to define the observed measures of the personal knowledge. The six hypothesised factors are: regulatory compliance, performance, wisdom, organisational understanding, product and process understanding (mastership) besides communication and networking skills (Figure 5-2; Table 5-2). Education, KM maturity of organisation, type of organisation, employee experience, training and job level will be studied as controls.

The first control is the education level starting from high school and up to PhD level. KM maturity included four levels of maturity based on Lotti Oliva (2014) framework. The four levels of KM maturity start from the lack of awareness of KM, the lack of formal KM processes, isolated implementation of KM to the top level where KM becomes a part of the holistic organisation strategy. Type of organisation compared domestic, international and multinational enterprises. Employee experience was included as the total number of years in the pharmaceutical industry (total experience) and the experience in the current role (current experience). Training was basically assessed by the percentage of compliance to the training plan. Finally, the job level included five levels starting from the entry-level or student and up to senior management.

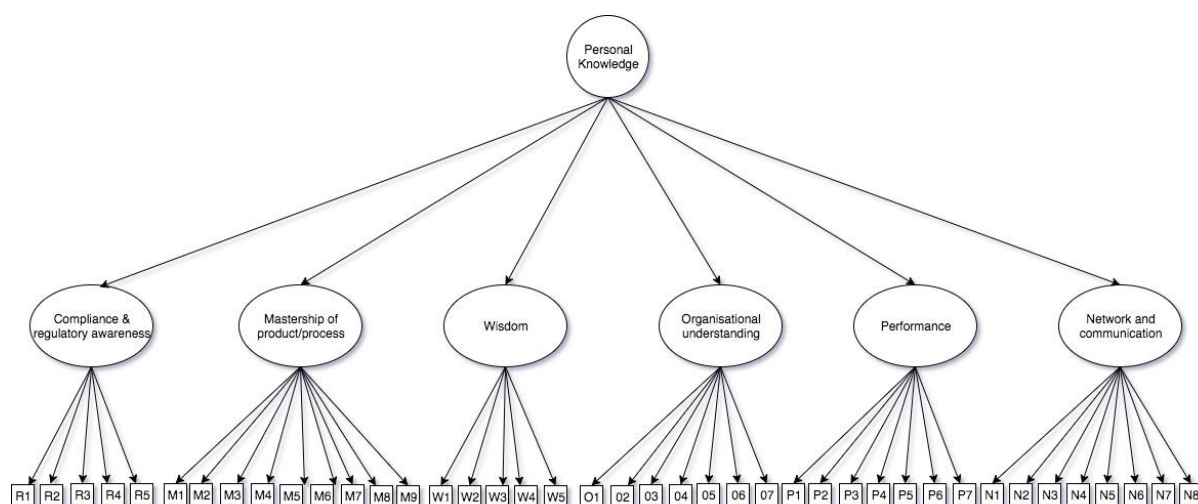


Figure 5-2 The conceptual framework

Table 5-2 PK measures and the underlying factors

Factor	Measures	Code
Compliance and regulatory awareness	Identify compliance gaps/deviations in your area/process	R1
	Associate compliance gaps to a specific clause in a standard, SOP or a Pharmacopeia	R2
	Find relevant standards or regulatory guidelines	R3
	aware of updates to regulatory standards, specifications and SOPs	R4



Factor	Measures	Code
	Involved in the development and improvement of standards and specifications in your organisation	R5
Mastership of product/process	Locate relevant process and product related information	M1
	Carry out assigned responsibilities without supervision	M2
	Contribute to the design and development of processes/products within your function	M3
	Train others in relation to your current role	M4
	Complete relevant records/forms (including electronic records) associated with products or processes in your department	M5
	Explain to colleagues the scientific basis and precautions of processes in your area	M6
	Explain to colleagues the technology utilised in machinery and equipment in your area	M7
	Are involved in the design, validation, control and continuous improvement of products/processes in your function	M8
	Technical advising (colleagues seeks one's technical advice)	M9
Wisdom	Think critically (clearly and rationally) to solve work problems	W1
	Solve daily work problems efficiently	W2/W3
	Other people believe you solve daily work problems efficiently	
	Other people believe you make the right decisions in work	W4
	Your out of the box suggestions are implemented within your organisation	W5
Organisational understanding	Understanding his role	O1
	Familiarity with processes in other departments of the organisation.	O2
	Understand the terminology used in your organisation	O3
	Understand the values of your organisation	O4
	Understand the vision, mission and goals of your organisation	O5
	Abide by the values of your organisation	O6
	Explain the historical Out of Specifications (OOS), failures and/or any weaknesses in your area	O7
Performance	Achieve departmental/organisational goals successfully	P1
	Play a key role in successful projects in your area	P2
	Complete assigned tasks "right first time"	P3
	Complete assigned tasks in a consistent manner	P4
	Complete assigned tasks on time	P5
	Meet or exceed the required targets	P6

Factor	Measures	Code
	Achieve a strong positive evaluation in annual appraisal by management (performance management)	P7
Network and communication	Identify the appropriate person to obtain information relating to a specific product/process	N1
	Communicate effectively with co-workers to get the job done	N2
	Communicate effectively with senior management	N3
	Motivate others to achieve organisational goals	N4
	Lead others to achieve organisational goals	N5
	People see you as a team player	N6
	have a wide network of contacts within your organisation	N7
	have a wide network of contacts outside your organisation (pharmaceutical and non-pharmaceutical)	N8

### 5.10 Summary and Conclusion

This chapter demonstrated the findings of the exploratory study and the outcomes of the thematic analysis. Fifteen interviews were conducted with pharmaceutical industry experts from nine countries. The interviews explored the practitioner's definitions of knowledge and how it is managed in the pharmaceutical manufacturing sector. The study shed light on the level of KM maturity in the pharmaceutical sector. The chapter discussed the value of the personal knowledge measurement for the pharmaceutical firm. Finally, personal knowledge measurement practices and indicators were explored and explained. In light of the thematic analysis and literature review, the conceptual framework was abductively developed. The next chapter is data analysis of the quantitative survey in an attempt to confirm and optimise the proposed conceptual framework.

## **Chapter 6 : Quantitative Data Analysis**

## 6.1 Introduction

This chapter focuses on the analysis of the data obtained from the questionnaire. The design and distribution of the questionnaire is outlined in chapter four. In total, 190 valid responses were received using Google forms for data collection. The chapter provides the details of the respondents and their organisations before focusing attention on the analysis of the framework using CFA tools.

## 6.2 Sample demographics data

### 6.2.1 Descriptive statistics

At the end of the quantitative data collection phase, 190 valid responses were received including participants' self-assessment of their personal knowledge. The questionnaire included 41 questions (based on Likert scale) representing the proposed 41 observed indicators of personal knowledge. Table 6-1 demonstrates the descriptive statistics of the selected scores on Likert scale. The results show that the selected ratings ranged between 1 and 7. Based on sample mode, (5, 6 and 7) were the most selected scores. However, the mean score is positively shifted (between 4.9 and 6.2). Sample kurtosis and skewness will be discussed in section 6.3.1 "data preparation".

*Table 6-1 Descriptive statistics*

Variable	Total Count	Mean	SE Mean	TrMean	StDev	Variance	Minimum	Q1	Median	Q3	Maximum	Range	Mode	N for Mode
<b>M1</b>	190	5.6	0.08	5.7	1.1	1.3	2	5	6	6	7	5	6	61
<b>M2</b>	190	5.6	0.11	5.8	1.5	2.1	1	5	6	7	7	6	7	63
<b>M3</b>	190	5.5	0.10	5.6	1.4	2.0	1	5	6	7	7	6	7	57
<b>M4</b>	190	5.9	0.08	6.0	1.1	1.3	2	5	6	7	7	5	6	69
<b>M5</b>	190	5.8	0.09	5.9	1.2	1.4	1	5	6	7	7	6	6	73
<b>M6</b>	190	6.0	0.07	6.1	1.0	1.1	2	5	6	7	7	5	6	73
<b>M7</b>	190	5.7	0.08	5.8	1.1	1.3	1	5	6	7	7	6	6	65
<b>M8</b>	190	5.6	0.09	5.7	1.2	1.5	1	5	6	7	7	6	6	67
<b>M9</b>	190	5.8	0.07	5.8	1.0	1.0	2	5	6	6	7	5	6	81
<b>N1</b>	190	5.7	0.09	5.8	1.2	1.5	1	5	6	7	7	6	7	58

Variable	Total Count	Mean	SE Mean	TrMean	StDev	Variance	Minimum	Q1	Median	Q3	Maximum	Range	Mode	N for Mode
N2	190	6.0	0.07	6.1	1.0	1.0	1	6	6	7	7	6	6	79
N3	190	5.9	0.08	6.0	1.0	1.1	2	5	6	7	7	5	6	75
N4	190	5.7	0.08	5.8	1.1	1.2	2	5	6	6	7	5	6	68
N5	190	5.8	0.08	5.9	1.1	1.2	1	5	6	7	7	6	6	75
N6	190	6.0	0.07	6.0	1.0	1.0	2	5	6	7	7	5	6	76
N7	190	5.9	0.08	6.0	1.1	1.2	2	5	6	7	7	5	6	68
N8	190	5.6	0.09	5.7	1.3	1.6	2	5	6	7	7	5	6	59
O1	190	6.2	0.06	6.3	0.9	0.8	3	6	6	7	7	4	7	87
O2	190	5.8	0.07	5.8	1.0	1.1	2	5	6	7	7	5	5	64
O3	190	6.1	0.06	6.2	0.9	0.8	3	6	6	7	7	4	6	74
O4	190	6.0	0.08	6.1	1.0	1.1	3	5	6	7	7	4	7	71
O5	190	5.7	0.08	5.8	1.2	1.4	1	5	6	7	7	6	6	68
O6	190	5.7	0.09	5.7	1.2	1.4	1	5	6	7	7	6	6	62
O7	190	5.4	0.10	5.5	1.3	1.8	1	5	6	6	7	6	5	54
P1	190	5.9	0.07	5.9	1.0	1.0	1	5	6	7	7	6	6	91
P2	190	6.0	0.07	6.1	1.0	0.9	3	5	6	7	7	4	6	72
P3	190	5.8	0.07	5.9	1.0	1.0	3	5	6	7	7	4	6	82
P4	190	6.0	0.07	6.0	0.9	0.8	3	5	6	7	7	4	6	81
P5	190	5.9	0.07	6.0	1.0	1.0	1	5	6	7	7	6	6	75
P6	190	5.9	0.07	6.0	1.0	1.1	2	5	6	7	7	5	6	74
P7	190	5.9	0.08	6.0	1.2	1.4	1	5	6	7	7	6	6	79
R1	190	5.2	0.11	5.2	1.5	2.3	1	4	5	6	7	6	5, 6	50
R2	190	4.9	0.12	5.0	1.7	2.8	1	4	5	6	7	6	6	51
R3	190	5.7	0.09	5.9	1.3	1.7	2	5	6	7	7	5	7	65
R4	190	5.7	0.08	5.8	1.1	1.2	1	5	6	7	7	6	6	68
R5	190	5.5	0.09	5.6	1.3	1.6	1	5	6	6	7	6	6	65
W1	190	6.0	0.07	6.1	0.9	0.8	2	6	6	7	7	5	6	81
W2	190	6.0	0.06	6.1	0.9	0.7	3	6	6	7	7	4	6	86
W3	190	5.9	0.07	6.0	0.9	0.8	3	5	6	7	7	4	6	78
W4	190	5.9	0.07	5.9	0.9	0.8	3	5	6	7	7	4	6	81
W5	190	5.1	0.09	5.2	1.3	1.6	1	4	5	6	7	6	5	62

### 6.2.2 Respondents

The review of sample statistics shows that more than two-thirds (70%) of respondents are males while female respondents represent only 26% of the sample with 4% of respondents failing to provide this information. The responses reflect the gender imbalance in the manufacturing sector. According to the statistical office of the European Union, males are

overrepresented in the manufacturing sector (79%) in comparison to females (Eurostat, 2020). The sample also includes 49 responses from quality assurance and 50 responses from quality control constituting 52% of all responses. In addition, 40% of responses were from production, packaging and technical services. The remainder of respondents is affiliated to other functions including supply chain, operation excellence and project management roles (Table 6-2). Figure 6-1 depicts the level of education of the respondent. While more than half of the sample received at least university education, 73 respondents completed postgraduate studies with ten of the respondents hold a PhD degree.

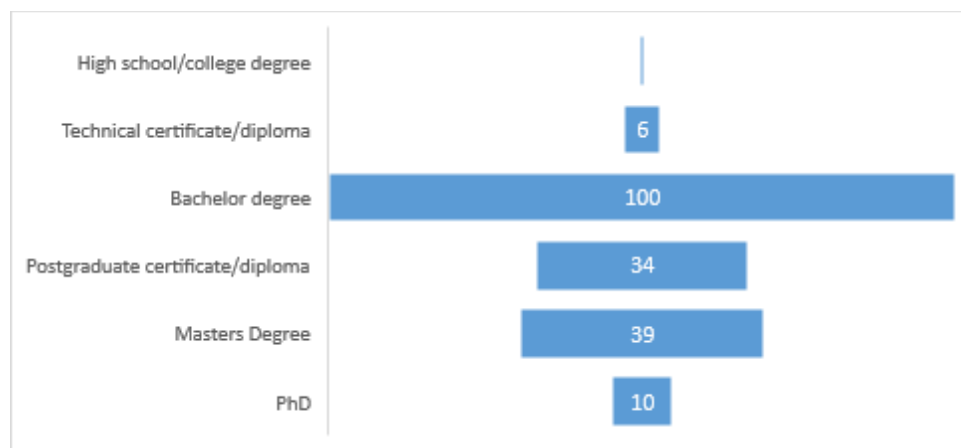


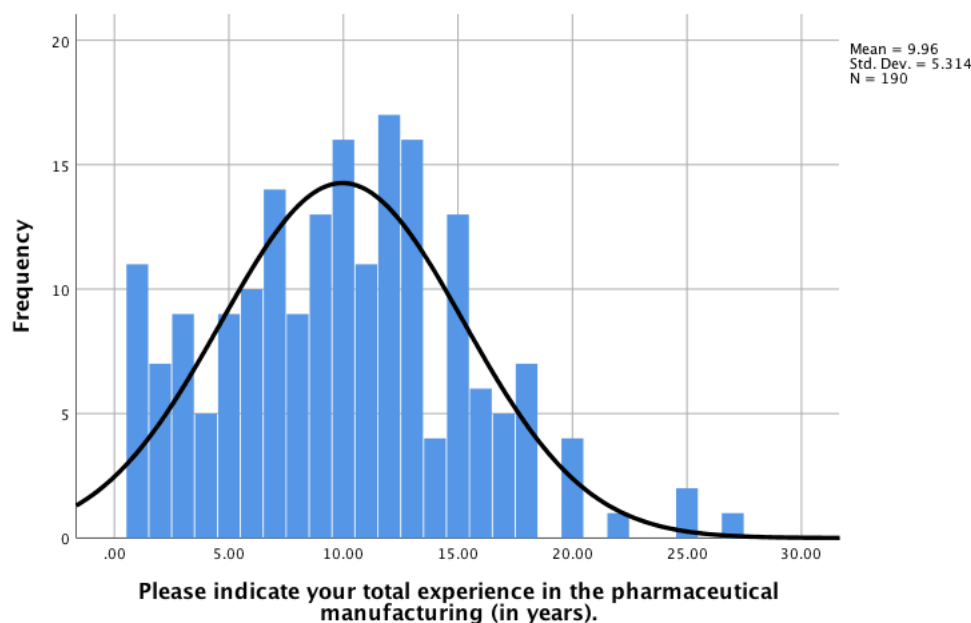
Figure 6-1 Level of Education

Table 6-2 Participating Functions

	Frequency	Percentage
Quality Assurance	49	26%
Production or packaging	39	21%
Quality Control	50	26%
Technical services	37	19%
Other	15	8%
<b>Total</b>	<b>190</b>	

Furthermore, the average length of experience of participants from the manufacturing sector ranged from one year and up to 27 years with an average of approximately 10 years (standard deviation = 5.314 years). Figure 6-2 depicts the distribution of the number of years of

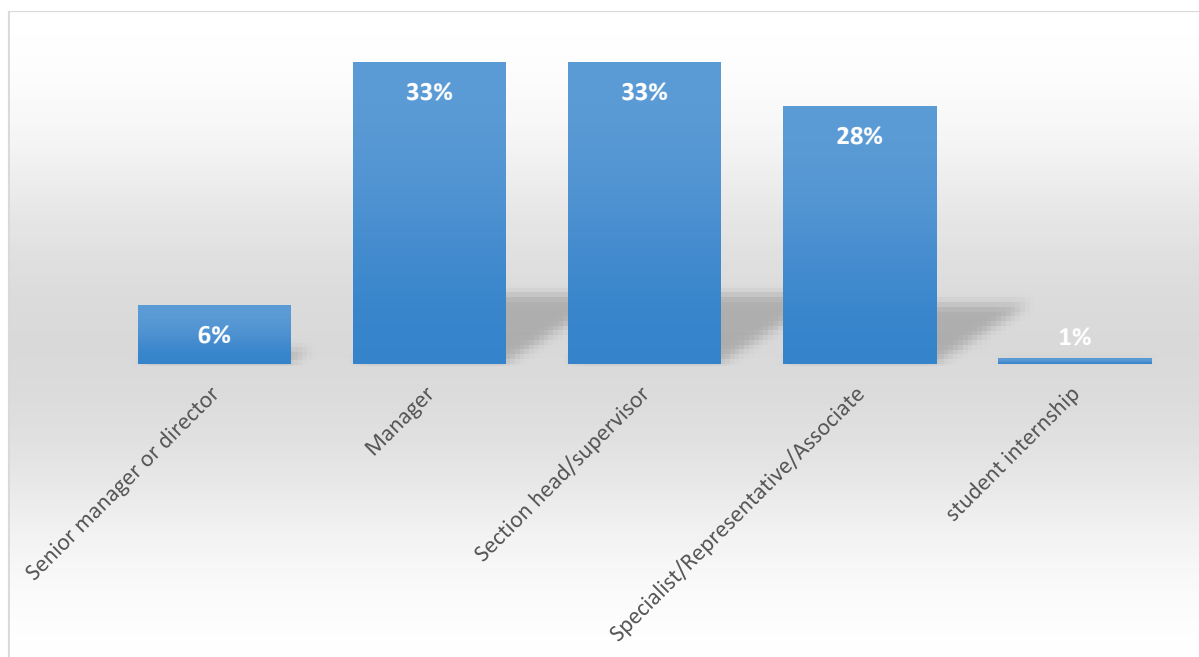
experience of respondents. On average, 72% of the participants' tenure was at the current function. However, only 51% of the tenure was at the current employer. This reflects the mixed experiences held by respondents at different functions and different organisations. The sample varied also at the depth of experience at one department or function ranging from totally new up to 18 years at the same department.



*Figure 6-2 A histogram depicting the experience range of respondents*

The sample represented different job levels in the organisation. However, it can be noticed that middle and senior managers constitute 39% of the sample (Figure 6-3). This relative over-representation of managers may be attributed to the design of the two-stage cluster sampling where contact persons (can be more than one per organisation), who were selected from managers and senior managers, were solely responsible for distributing the survey within their organisation. However, some managers provided only a single response per organisation and apologised that it is not possible to share the survey link within their organisation due to fear of company's data breach. Another potential reason for the over-representation of managers is that the survey was not designed to be distributed to every member of the organisation. Operators and technicians were out of the scope of this survey. As a result, the survey was

distributed among fewer professional levels where managers may make a significant portion of them.



*Figure 6-3 Job Level*

As the questionnaire language was in English, it was found necessary for data validity purposes to ensure that participants are able to understand the questions and select the most accurate answer. Three main language skills were self-assessed by respondents. With regard to reading skill, 98.4% of respondents described themselves as intermediate, advanced or native. Despite that English reading skill are the most relevant skill required to complete the questionnaire properly, other language skills were evaluated too. The survey shows that over 96% of respondents possess intermediate to advanced speaking and listening skills (Table 6-3).

*Table 6-3 English Language Fluency*

	Reading	Speaking	Listening
Beginner	1.6%	1.6%	3.2%
Intermediate	12.1%	35.8%	27.9%
Advanced	71.6%	49.4%	55.8%
Native or bilingual	14.7%	13.2%	13.2%



### 6.2.3 Organisations

More than half of the participants are affiliated to well established pharmaceutical organisations operating for more than 20 years. Conversely, two percent of responses came from relatively new firms operating for less than five years (Table 6-4Table 6-4).

*Table 6-4 Age of organisation*

	<b>Frequency</b>	<b>Percent</b>
Less than 5 years	4	2.1
From 5 to 10 years	22	11.6
From 11 to 20 years	59	31.1
From 21 to 50	60	31.6
More than 50 years	45	23.7
<b>Total</b>	<b>190</b>	

The European Commission defines small enterprises as an enterprise that employs less than 50 employees while medium enterprise employs more than 50 but less than 250 (EC, 2003). Forty-four respondents were affiliated to medium size enterprises while only 6 worked for small enterprises (Table 6-4). Chi-Square test of independence (Table 6-6) revealed a significant association between the organisation size and age (Pearson Chi-Square =78.059; df=16; P< 0.000).

*Table 6-5 Size of organisation*

	<b>Frequency</b>	<b>Percent</b>
Less than 50 employees	6	3.2
From 50 to 249 employees	44	23.2
From 250 to 500 employees	33	17.4
From 500 to 1000 employees	28	14.7
More than 1000	79	41.6
<b>Total</b>	<b>190</b>	<b>100.0</b>

Table 6-6 Chi-Square Test: Organisation size vs age

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	78.059	16	.000
Likelihood Ratio	88.865	16	.000
N of Valid Cases	190		

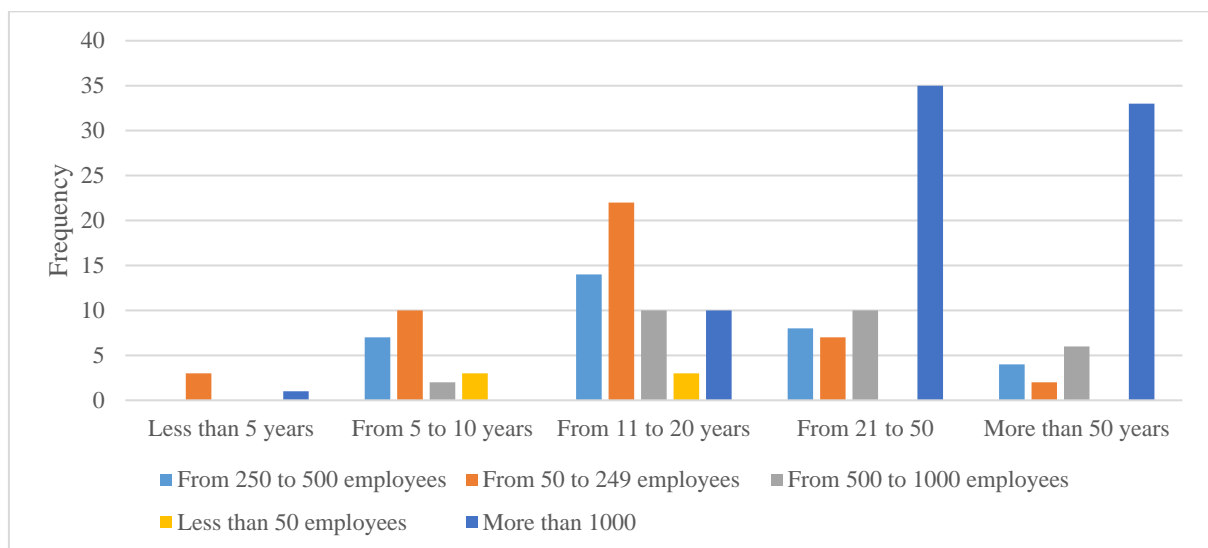


Figure 6-4 Organisation size vs age

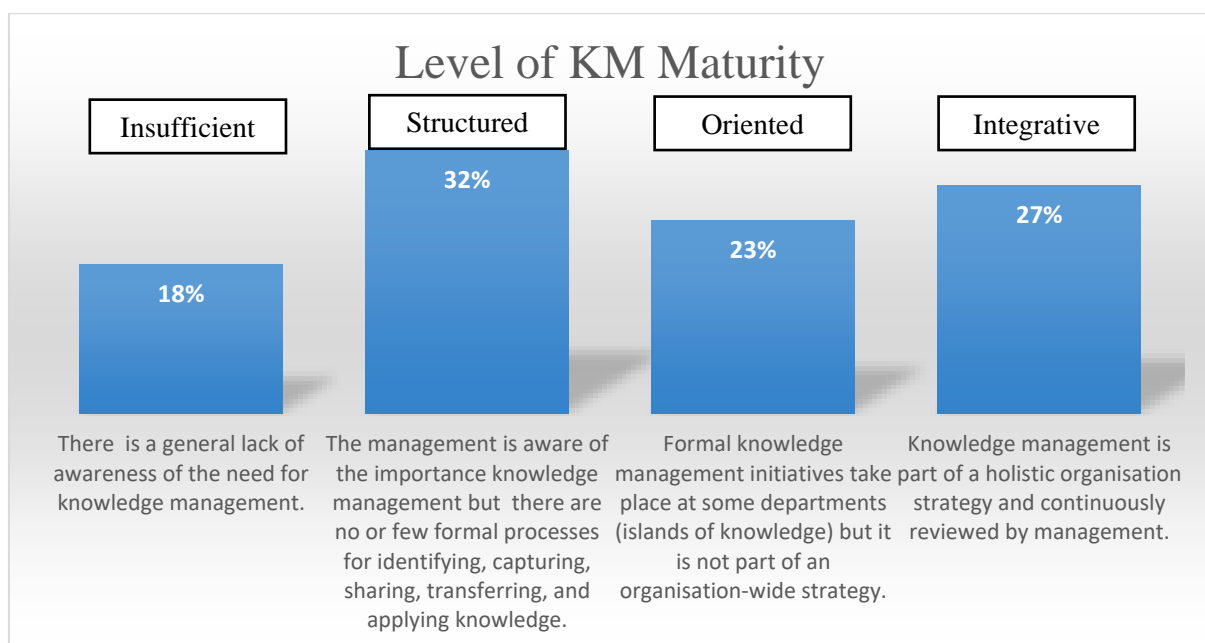
Four levels of knowledge maturity were recognised among the organisations of participants based on Oliva (2014) framework that identified four levels of KM maturity: insufficient, structured, oriented and integrative (Figure 6-5). Approximately one-third of participants' organisations belonged to the structured KM maturity level. Only 18% of respondents referred to a lack of awareness of the need to KM in their organisations. Interestingly, Chi-Square test of independence showed (Table 6-7) no association between organisational size and the level of KM maturity (Pearson Chi-Square= 18.357; df=12; P=0.105). Similarly, the test (Table 6-8) demonstrated a lack of association between the organisation age and the level of KM maturity (Pearson Chi-Square=19.310; df=12; P=0.081).

*Table 6-7 Chi-Square Test: organisation size vs KM maturity*

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	18.357	12	.105
Likelihood Ratio	20.171	12	.064
N of Valid Cases	190		

*Table 6-8 Chi-Square Test: organisation age vs KM maturity*

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	19.310	12	.081
Likelihood Ratio	19.309	12	.081
N of Valid Cases	190		

*Figure 6-5 KM Maturity levels in the sample organisations*

Forty-nine percent of respondents described their manufactured product as conventional pharmaceuticals. Fourteen percent produced biologics and 24% have mixed portfolios. The remainder of participating manufacturers is specialised in other pharmaceutical products such

as medical devices, veterinary product or active pharmaceutical ingredients (API). It should be emphasised that more than 52% of responses were received from multinational and international enterprises (Table 6-9). Also, 93.2% of the respondents are affiliated to private sector organisations while the remaining 6.8% work for governmental firms.

*Table 6-9 Type of participants' organisation*

	Frequency	Percent
Multinational or global	100	52.63 %
International	1	0.53 %
Domestic/local	89	46.84 %
Total	190	100.0 %

Finally, almost two-thirds of participants completed more than 80% of their technical and GMP training plan at the time of filling the survey (Table 6-10).

*Table 6-10 Compliance to training plan among participants*

	Frequency	Percent
Less than 40%	6	3.2
40-50%	8	4.2
51-60%	4	2.1
61-70%	15	7.9
71-80%	32	16.8
81-90%	60	31.6
More than 90%	65	34.2
Total	190	100.0

## 6.3 Confirmatory Factor Analysis

### 6.3.1 Data preparation

The data was prepared for further analysis. This included the analysis of missing data, outliers, data normality and reliability. Data organisation and coding of the variables was required to prepare them for CFA. Variable codes are presented in chapter five (Table 5-2). Both SPSS 26 and IBM AMOS 26 were used for data analysis at this stage.

### *I. Missing data and outliers*

The risk of incomplete surveys or in other words missing data was mitigated by making the 41 model questions required. However, an initial analysis of the data identified a small percentage of missing data (less than 1%) as the first ten responses were received before making all the model questions required (not more than one missing response per variable). Estimate means and intercepts option in AMOS was selected to compensate the few missed entries (less than 1%). No further action was taken.

Multivariate outliers are cases whose variables show a pattern of values different from other cases in the sample. Although there is no consensus on the best action to be taken to deal with outliers, multivariate outliers possibly caused by data entry mistakes or random responding can be omitted (Bandalos, 2018). Mahalanobis Distance test in SPSS 26 was used to identify outliers in the sample. Twelve multivariate outliers were identified in the dataset ( $P < 0.001$ ). The researcher chose to compare the model estimation and goodness of fit with and without those outliers. A small and insignificant improvement in model fit was observed after omitting the outliers from the data. Based on this observation, a decision was made to retain multivariate outliers.

### *II. Normality of variable distribution*

One of the basic assumptions of CFA is data normality. According to the probability theory, normal or Gaussian distribution is a type of continuous probability distribution where the characteristic bell curve can be defined by the population mean and standard deviation (Lucey & Lucey, 2002). Reporting the skew and kurtosis indices of all continuous variables is a recommended practice (Kline, 2011). It has been recommended that the skewness index should not exceed  $| 2.0 |$ . However, more liberal standards have accepted kurtosis up to  $| 7.0 |$  (Bandalos, 2018).

As outlined in Table 6-11, skewness and kurtosis values are less than | 2.0 | and | 7.0 | respectively suggesting acceptable data normality. It is noteworthy that all skewness values are negative. This is in line with Dunning-Kruger effect on self-evaluation of personal knowledge (Schlösser et al., 2013) which will be discussed in the next chapter. Last but not least, the data presented in the form of a Likert scale from one to seven. The literature suggests a negligible bias in parameter estimates can be achieved when the Likert scale is five or more categories as the data can be treated as continuous (Bandalos, 2014).

*Table 6-11 Data Skewness and Kurtosis*

	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis	
					Statistic	Std. Error	Statistic	Std. Error
M1	2	7	5.61	1.125	-.660	.176	.230	.351
M2	1	7	5.61	1.464	-1.161	.176	.811	.351
M3	1	7	5.49	1.421	-.890	.176	.326	.351
M4	2	7	5.90	1.134	-1.077	.176	.810	.351
M5	1	7	5.82	1.201	-1.325	.176	2.160	.351
M6	2	7	5.97	1.028	-1.058	.176	1.074	.351
M7	1	7	5.70	1.122	-.885	.176	1.049	.351
M8	1	7	5.63	1.225	-1.085	.177	1.525	.352
M9	2	7	5.77	1.010	-1.053	.177	1.952	.352
N1	1	7	5.68	1.245	-1.005	.177	1.062	.352
N2	1	7	5.98	1.008	-1.306	.176	2.876	.351
N3	2	7	5.89	1.041	-.944	.176	.733	.351
N4	2	7	5.68	1.081	-.916	.176	1.361	.351
N5	1	7	5.77	1.083	-1.167	.176	2.325	.351
N6	2	7	5.96	.988	-1.050	.177	1.406	.352
N7	2	7	5.88	1.097	-1.105	.176	1.392	.351
N8	2	7	5.55	1.283	-.817	.176	.225	.351
O1	3	7	6.24	.875	-1.354	.176	2.353	.351
O2	2	7	5.75	1.027	-.761	.176	1.058	.351
O3	3	7	6.10	.888	-.793	.176	.143	.351
O4	3	7	5.97	1.038	-.882	.176	.218	.351
O5	1	7	5.73	1.163	-1.040	.176	1.350	.351
O6	1	7	5.65	1.187	-.972	.177	1.378	.352
O7	1	7	5.42	1.330	-.865	.176	.679	.351
P1	1	7	5.86	1.000	-1.345	.176	3.314	.351
P2	3	7	5.98	.970	-.801	.176	.194	.351
P3	3	7	5.83	.988	-.786	.176	.334	.351
P4	3	7	5.98	.900	-.674	.176	-.021	.351
P5	1	7	5.89	1.018	-1.033	.176	1.909	.351
P6	2	7	5.87	1.031	-.973	.176	1.183	.351
P7	1	7	5.87	1.171	-1.732	.176	4.314	.351

	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis	
					Statistic	Std. Error	Statistic	Std. Error
<b>R1</b>	1	7	5.17	1.527	-.724	.177	-.290	.352
<b>R2</b>	1	7	4.89	1.672	-.638	.177	-.535	.352
<b>R3</b>	2	7	5.75	1.289	-1.017	.176	.345	.351
<b>R4</b>	1	7	5.74	1.082	-.892	.177	1.260	.352
<b>R5</b>	1	7	5.48	1.274	-1.030	.177	1.442	.352
<b>W1</b>	2	7	6.04	.908	-1.028	.176	1.674	.351
<b>W2</b>	3	7	6.04	.863	-.820	.176	.718	.351
<b>W3</b>	3	7	5.89	.905	-.617	.177	.310	.352
<b>W4</b>	3	7	5.86	.900	-.608	.177	.336	.352
<b>W5</b>	1	7	5.13	1.266	-.620	.176	.497	.351

### III. Reliability

Cronbach's alpha  $\alpha$  was used to assess instrument reliability. Cronbach's alpha is a widely used measure of the reliability of such multi-item indices (Bonett & Wright, 2014; Cronbach, 1951). The test depends on the number of items  $k$  and their intercorrelation  $\bar{r}$ .

$$\alpha_{\text{standardised}} = \frac{K \bar{r}}{(1 + (K-1)\bar{r})}$$

A high value of Cronbach's alpha implies a high level of reliability or low response variance. On the other hand, a small value may be an indicator of low instrument reliability or can indicate that the items do not really measure the same construct (Groves et al., 2004).

As pointed out earlier, the number of test items, item interrelatedness and dimensionality affect the value of alpha. The commonly acceptable values of alpha range from 0.70 to 0.95 (Tavakol & Dennick, 2011). The calculation of Cronbach's alpha coefficients for the different factors ranged from 0.738 to 0.886 indicating acceptable internal consistency between questions and answers as seen in the table below (Table 6-12).

Table 6-12 Cronbach's alpha

Factor	Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items
Mastership of product/process	.859	.863
Wisdom	.823	.840
Organisational understanding	.846	.854
Performance	.881	.886

Network and communication	.858	.866
Compliance and regulatory awareness	.738	.738

---

### 6.3.2 Model Specification

The specified model consists of 41 reflective (effect) indicators (Bollen & Bauldry, 2011) and six underlying latent factors creating a second-order hierarchical CFA model. Hierarchical models present the hypotheses in such a way that the higher-order factors have a presumed direct causal effect on the lower order factors (Kline, 2011). The relationship between the latent variable and the reflective indicators is theoretically grounded based on the conceptual framework presented in chapter five and considered as the manifestations of the personal knowledge of pharmaceutical manufacturing employees. Each of the 41 observed indicators has a unique variance as shown in Figure 6-6. Unique variance accounts for the measurement error or the unreliability in a specific indicator in contrast to the common variance (communalities) accounted for the latent variables in the model (Kenny, 2006). Similarly, each latent factor of the first order variables has a residual which accounts for the variance unexplained by the higher-order construct (Kline, 2011). Personal knowledge is a latent variable that doesn't have its own observed indicators. Instead, it is indirectly measured by the observed indicators measuring the first-order constructs (Byrne, 2016).



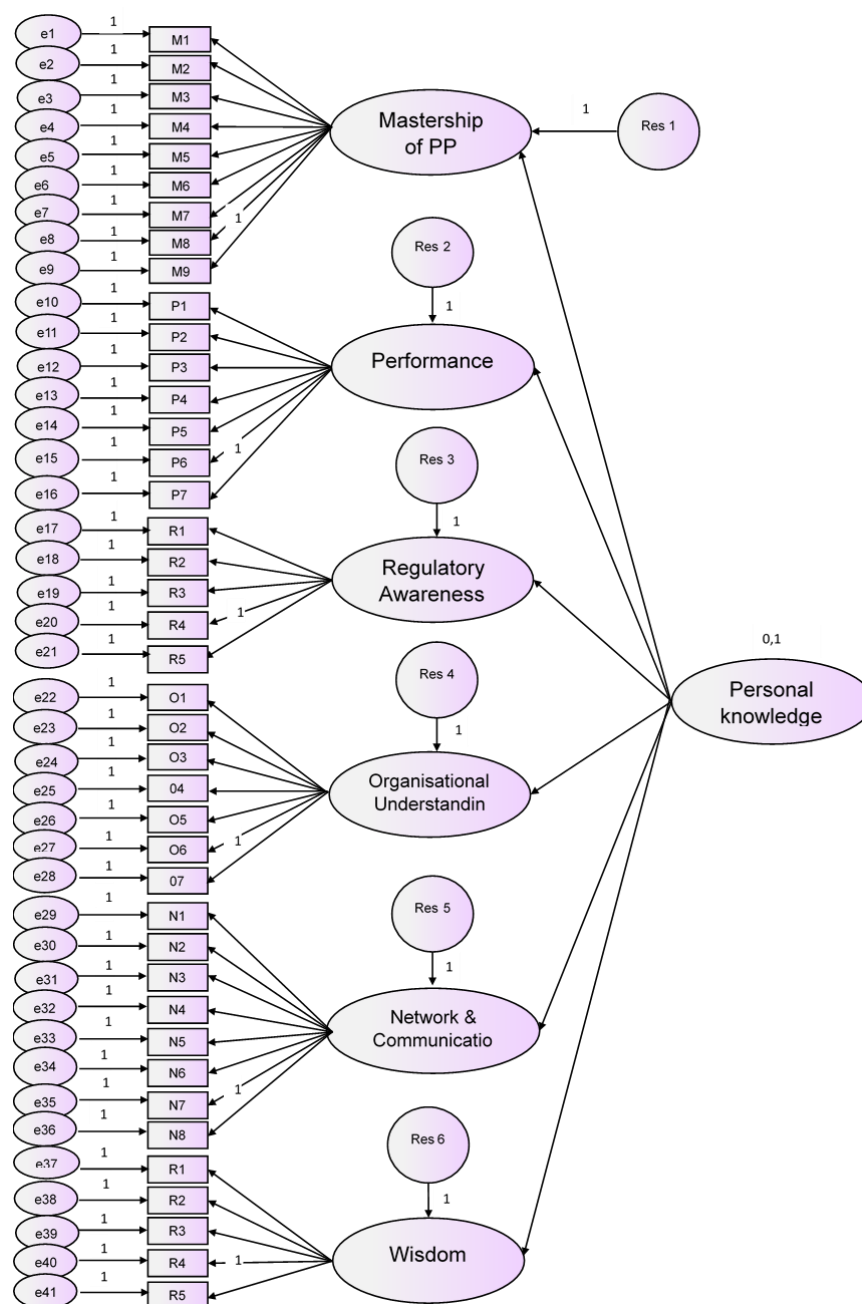


Figure 6-6 Specified full model one

For graphical representation, rectangles were used to refer to the observed variables, while oval shapes referred to the latent variables. Straight arrows describe the direction of the causal relation in the model. IBM Amos 26 offers three methods for model specification: programming, graphics and table interface (Byrne, 2016). Amos Graphics user interface was utilised to specify the model instead of the traditional programming (coding) interface. This method was found more convenient and poses a lower risk of coding errors. For reasons related

to model identification, the researcher constrained the regression path of one observed indicator per each of the six first order constructs to the value of one. Because the impact of the latent variable (personal knowledge) on the lower order construct and measures is the main interest of this study, the researcher constrained the variance of personal knowledge to one leaving the second-order factor loadings freely estimated. All measurement error and residual variables have a constrained regression coefficient of one. Based on the theoretical background of this model, cross loadings are fixed to zero.

### 6.3.3 Model identification

Bollen (1989) suggested three conditions for model identification:

- Three or more observed variables must load on each latent construct.
- Measurement error variances are not correlated.
- Each variable loads on one latent construct.

As shown in the model specification section, all three conditions are met. In CFA, a model must be either just identified or over-identified (recommended) but cannot be under-identified. In other words, the number of variance/covariance elements must be equal or more than the parameter values to be estimated (Bandalos, 2018). The following formula calculates the number of covariances in the model:

$$\frac{v(v + 1)}{2} = \frac{41(41 + 1)}{2} = 861$$

Where v is the number of observed variables. The total number of variances (41) and covariances = 41+861 =902. The number of parameter values to be estimated in this model can be enumerated as follow:

- 41+6 -6 =41 loadings/regression weights for first and second-order variables excluding 6 constrained regression weights that have been fixed to one.

- 41 measurement error variances.
- 6 residuals variances.
- 41 intercepts

For a grand total of distinct parameters to be estimated =  $(41+41+6+41) = 129$  which is less than 902 (degrees of freedom =  $902-129 = 773$ ). A positive degrees of freedom means that the model is over-identified and can be estimated (Byrne, 2016) as will be explained in the next section.

#### 6.3.4 Model estimation

Maximum Likelihood (ML) method was chosen for the model estimation. ML is the default estimation algorithm in IBM AMOS 26 with assumptions of continuous and normally distributed data. It is a widely used method offering unbiased, consistent, and efficient results (Bandalos, 2018). The results of the initial model indicate an average regression weight of 0.7, the maximum loading equals 0.95 and the minimum loading is 0.4. However, 94% of the loading values are above 0.5 and 55% are above 0.7 which indicates a moderate to high correlation with the underlying latent constructs and the latent variable (personal knowledge). It is argued that moderate to high correlation is a desirable situation when dealing with effect indicators in a model (Bollen & Lennox, 1984) such as the specified model in this study. Moreover, all loading values are statistically significant ( $P < .001$ ) as shown in Table 6-13.

*Table 6-13 Model one standardised and unstandardised regression weights*

Variables			Standardised estimates	Unstandardised estimates	S.E.	P
Performance	<---	PK	.923	.651	.076	***
Regulatory	<---	PK	.783	.592	.083	***
Organisational	<---	PK	.813	.572	.083	***
Network	<---	PK	.931	.481	.087	***
Wisdom	<---	PK	.946	.585	.087	***
Mastership	<---	PK	.882	.492	.066	***
M9	<---	Mastership	.554	1.000		

	<b>Variables</b>	<b>Standardised estimates</b>	<b>Unstandardised estimates</b>	<b>S.E.</b>	<b>P</b>
M8	<--- Mastership	.524	1.148	.195	***
M7	<--- Mastership	.677	1.359	.194	***
M6	<--- Mastership	.748	1.375	.185	***
M5	<--- Mastership	.678	1.456	.208	***
M4	<--- Mastership	.771	1.563	.207	***
M3	<--- Mastership	.703	1.786	.249	***
M2	<--- Mastership	.580	1.519	.240	***
M1	<--- Mastership	.583	1.174	.185	***
P7	<--- Performance	.605	1.000		
P6	<--- Performance	.739	1.077	.131	***
P5	<--- Performance	.690	.993	.127	***
P4	<--- Performance	.821	1.043	.118	***
P3	<--- Performance	.716	1.000	.124	***
P2	<--- Performance	.828	1.135	.128	***
P1	<--- Performance	.705	.997	.125	***
R5	<--- Regulatory	.594	1.000		
R4	<--- Regulatory	.627	.897	.138	***
R3	<--- Regulatory	.695	1.182	.171	***
R2	<--- Regulatory	.563	1.243	.207	***
R1	<--- Regulatory	.502	1.013	.184	***
O7	<--- Organisational	.530	1.000		
O6	<--- Organisational	.695	1.171	.173	***
O5	<--- Organisational	.770	1.271	.178	***
O4	<--- Organisational	.821	1.209	.164	***
O3	<--- Organisational	.642	.809	.125	***
O2	<--- Organisational	.592	.863	.140	***
O1	<--- Organisational	.704	.875	.128	***
N8	<--- Network	.404	1.000		
N7	<--- Network	.670	1.417	.271	***
N6	<--- Network	.723	1.378	.257	***
N5	<--- Network	.812	1.696	.305	***
N4	<--- Network	.767	1.601	.293	***
N3	<--- Network	.787	1.581	.287	***
N2	<--- Network	.764	1.485	.272	***
N1	<--- Network	.454	1.091	.248	***
W5	<--- Wisdom	.490	1.000		
W4	<--- Wisdom	.711	1.032	.161	***
W3	<--- Wisdom	.714	1.040	.162	***
W2	<--- Wisdom	.798	1.111	.164	***
W1	<--- Wisdom	.825	1.208	.176	***

Table 6-14 shows the unique variances (measurement errors and residuals) in the model. It can be observed that the variance of the second order latent variable (personal knowledge) has been fixed to one. All other variances were left unconstrained.

*Table 6-14 Unique Variances*

<b>Variables</b>	<b>Estimate</b>	<b>S.E.</b>	<b>P</b>	<b>Variables</b>	<b>Estimate</b>	<b>S.E.</b>	<b>P</b>
<b>PK</b>	1.000			<b>20</b>	.708	.086	***
<b>Res1</b>	.069	.021	***	<b>19</b>	.854	.114	***
<b>Res2</b>	.074	.023	.001	<b>18</b>	1.903	.221	***
<b>Res3</b>	.221	.065	***	<b>17</b>	1.736	.195	***
<b>Res4</b>	.167	.048	***	<b>28</b>	1.265	.136	***
<b>Res5</b>	.036	.015	.018	<b>27</b>	.723	.084	***
<b>Res6</b>	.040	.018	.023	<b>26</b>	.548	.068	***
<b>9</b>	.702	.076	***	<b>25</b>	.350	.048	***
<b>8</b>	1.081	.116	***	<b>24</b>	.461	.052	***
<b>7</b>	.678	.076	***	<b>23</b>	.681	.075	***
<b>6</b>	.464	.055	***	<b>22</b>	.384	.045	***
<b>5</b>	.775	.087	***	<b>36</b>	1.369	.143	***
<b>4</b>	.519	.063	***	<b>35</b>	.660	.073	***
<b>3</b>	1.015	.116	***	<b>34</b>	.462	.052	***
<b>2</b>	1.415	.154	***	<b>33</b>	.399	.049	***
<b>1</b>	.831	.090	***	<b>32</b>	.479	.056	***
<b>16</b>	.865	.093	***	<b>31</b>	.409	.049	***
<b>15</b>	.480	.055	***	<b>30</b>	.421	.049	***
<b>14</b>	.539	.060	***	<b>29</b>	1.223	.129	***
<b>13</b>	.263	.032	***	<b>41</b>	1.212	.128	***
<b>12</b>	.474	.053	***	<b>40</b>	.398	.045	***
<b>11</b>	.294	.037	***	<b>39</b>	.399	.046	***
<b>10</b>	.500	.056	***	<b>38</b>	.269	.033	***
<b>21</b>	1.045	.124	***	<b>37</b>	.261	.034	***

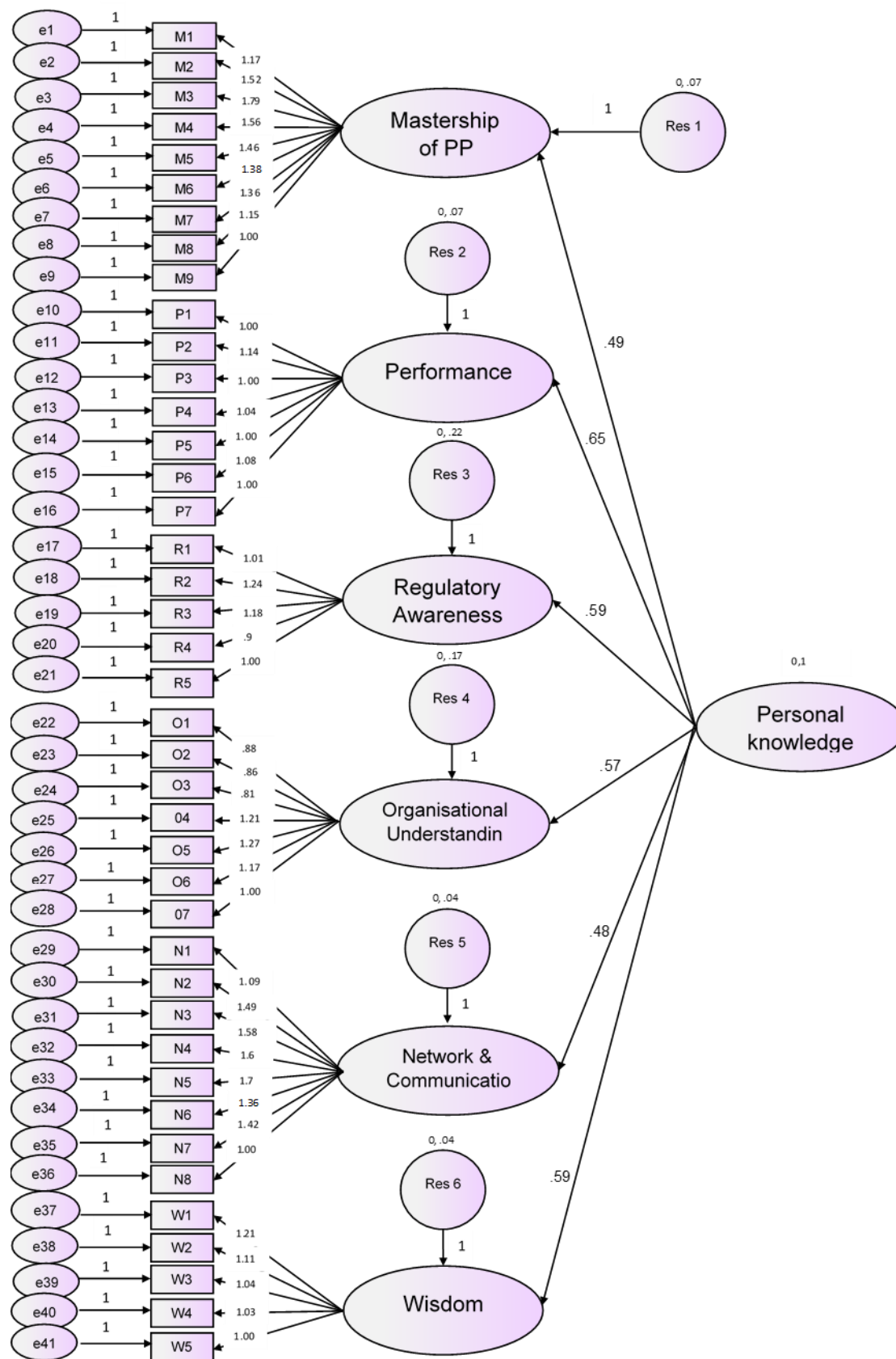


Figure 6-7 Model one with unstandardised estimates

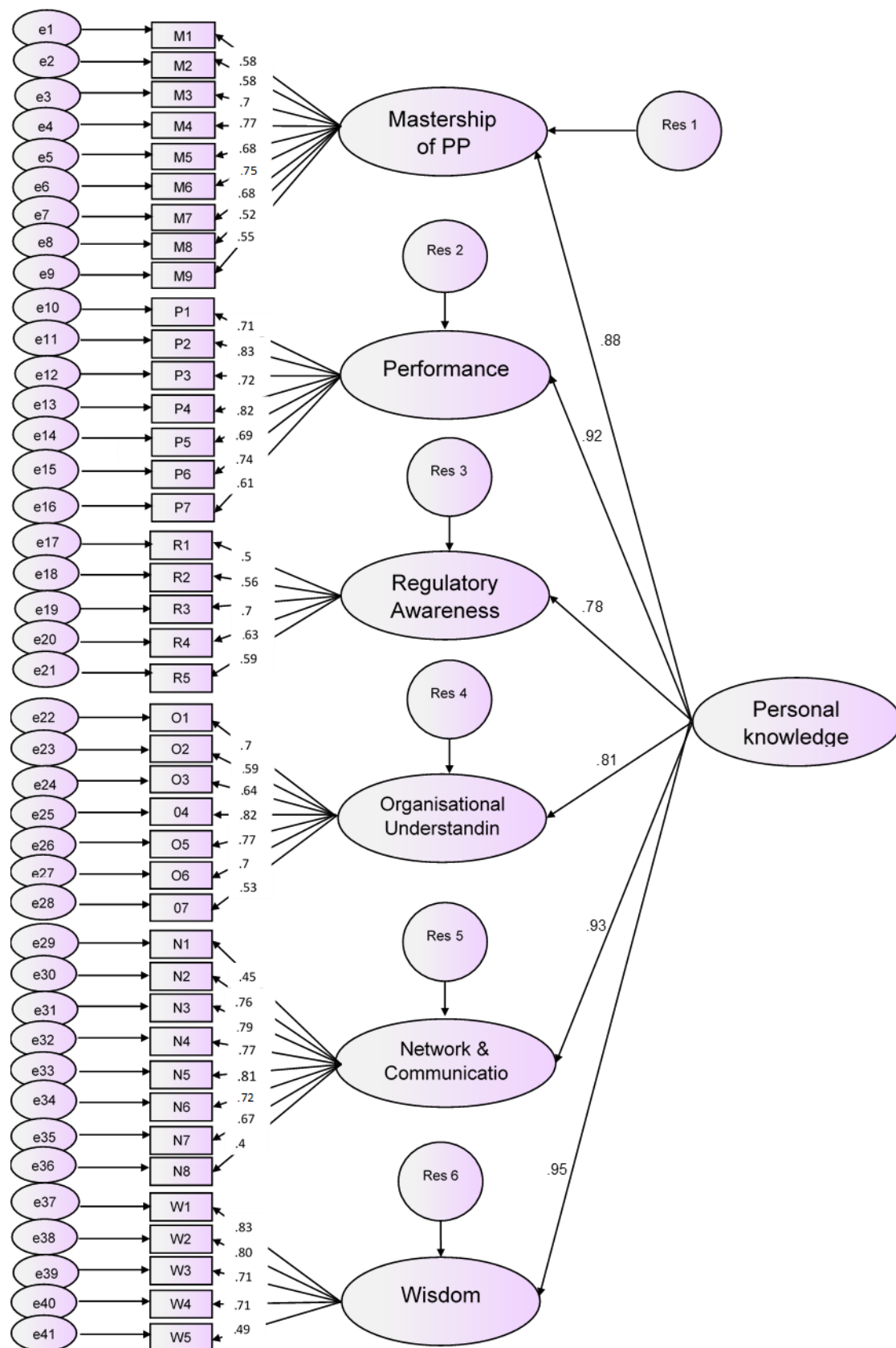


Figure 6-8 model one with standardised estimates

## 6.3.5 Model testing “goodness of fit”

The model that well fits the data as explained in the SEM literature should be able to match and reproduce the actual covariances among the variables in the study sample (Bandalos, 2018). A survey of the literature reveals that methodologists have proposed many fit indices. Model chi-square ( $\chi^2$ ) is one of the most popular indices of the overall model fit. Significant chi-square at 0.05 threshold implies a poor model fit. However, this method was criticised for being over-sensitive to sample size (Hooper et al., 2008). Table 6-15 shows a significant  $\chi^2$  test results ( $P < .05$ ) as an indication of poor model fitting (for model one). However, the literature shows no consensus on  $\chi^2$  test as a sole indicator of the overall model fit. In fact, SEM researchers emphasised that significant  $\chi^2$  test results don't necessarily entail model rejection but further exploration in light of the theories underlying the proposed model (Bandalos, 2018; Crede & Harms, 2019). In order to mitigate the effect of sample size, the relative or normed chi-square ( $\chi^2 / \text{DF}$ ) was proposed as an alternative to chi-square test where a value of five or less indicates good fit (Tabachnick & Fidell, 2007; West et al., 2012).  $\chi^2 / \text{DF}$  equals to 2.668 (Table 6-15). The first row of the table below refers to the model under test (model one), while the two rows beneath handles the saturated and the independence models. The independence model can be described as a hypothesised model in which the correlations between its variables equal to zero. In contrast, the saturated model has the number of parameters to estimate equal to the variances and covariances of the observed variables and is the least restricted (Byrne, 2016).

*Table 6-15  $\chi^2$  Test results for model one*

<b>Model</b>	<b>No. of Parameters</b>	<b><math>\chi^2</math></b>	<b>DF</b>	<b>P</b>	<b><math>\chi^2 / \text{DF}</math></b>
<b>Default model</b>	129	2062.208	773	.000	2.668
<b>Saturated model</b>	902	.000	0		
<b>Independence model</b>	41	5694.069	861	.000	6.613



In addition to  $\chi^2$ , two other popular fit indices were consulted. The root mean square error of approximation (RMSEA) (Steiger, 1980) and the comparative fit index (CFI) (Bentler, 1990). RMSEA is considered as an error of approximation index that can assess the level of model fit in the population. The test assesses the non-centrality parameter which equals zero when the model fit is perfect (Kenny, 2006). Literature suggests that RMSEA score between 0.08 and 0.10 indicates a mediocre fit while scores above 0.10 reflect poor fit. However, it is recommended to have an RMSEA score below 0.08 to guarantee a good model fit (Hooper et al., 2008). The specified model has a RMSEA score of 0.094 signifying a mediocre model fit.

Comparative Fit Index (CFI) is a modified version of the normed fit index (NFI) adjusted to avoid the underestimation of model fit when the sample size is small (Bentler, 1990). Similar to RMSEA, there is no consensus on the cut-off point differentiating good fit from poor fit. In general, CFI values closer to 1.0 demonstrates better fit. However, a value of  $CFI \geq 0.90$  or 0.95 is widely recognised as an indicator of a good fit. The CFI value for the model one is 0.733 suggesting mediocre fit results.

The model fit indices were recalculated without the 12 outliers identified by Mahalanobis distance test as mentioned before. A slight improvement was observed where the RMSEA score decreased to 0.09, CFI value increased to 0.758 and chi-square = 1874 with df = 773 at  $P < 0.001$ . In order to investigate the underlying causes of the modest fit of model one, the next section will discuss model alterations that were carried out with a resulting improved model fit.

#### 6.3.6 Model respecification / optimisation

A revised abbreviated model was assessed based on the original model (model one). The second model is based on five factors instead of six where the regulatory awareness (having the lowest loading) is merged with the Mastership of product and process. The revised model

assumed that the regulatory awareness e.g. the ability to identify gaps in the process or system is an integral part of product and process understanding. In other words, the awareness of specifications and the ability to identify the gaps between the practice and the standard/specification is a basic part of the Mastership of the process/product. If an employee is unable to identify non-conformances in his/her work area or unaware of them, this may reflect a deficiency in his/her product and process knowledge. By the same token, ICH Q10 emphasises that the corrective actions and preventive actions (CAPA) resulting from the investigation of product/process non-conformances should enhance product and process understanding (ICH, 2008).

It is worth noting that all the observed measures in the specified model one are reflective indicators which implies that the observed indicators of each factor are interchangeable (Bollen & Bauldry, 2011; Kline, 2015). Based on this understanding, interchangeable measures showing low loading were omitted and the model was re-estimated. Model two (Figure 6-9) below was generated taking a conservative approach through omitting any reflective indicator with a loading value  $\leq 0.5$ . It was also considered to maintain three measures per factor as required for model identification (Byrne, 2016; Schumacker, 2010). Table 6-15 enumerates standardised and unstandardised regression weights of model two. It can be observed that all standardised regression weights are greater than 0.63 and significant at  $P < 0.001$ .

*Table 6-16 Model two standardised and unstandardised regression weights*

Variables			Standardised estimates	Unstandardised estimates	S.E.	P
Performance	<---	PK	.850	.629	.066	***
Organisational	<---	PK	.670	.605	.077	***
Network	<---	PK	.840	.814	.069	***
Wisdom	<---	PK	.954	.545	.061	***
Mastership	<---	PK	.747	.631	.074	***
M7	<---	Mastership	.754	1.000		
M6	<---	Mastership	.844	1.025	.098	***
M4	<---	Mastership	.717	.961	.104	***
P5	<---	Performance	.729	1.000		

	Variables		Standardised estimates	Unstandardised estimates	S.E.	P
P4	<---	Performance	.920	1.115	.094	***
P3	<---	Performance	.769	1.024	.100	***
O6	<---	Organisational	.763	1.000		
O5	<---	Organisational	.822	1.057	.096	***
O4	<---	Organisational	.860	.986	.087	***
N5	<---	Network	.897	1.000		
N4	<---	Network	.862	.959	.062	***
N3	<---	Network	.737	.789	.066	***
W4	<---	Wisdom	.636	1.000		
W2	<---	Wisdom	.835	1.259	.137	***
W1	<---	Wisdom	.844	1.338	.144	***

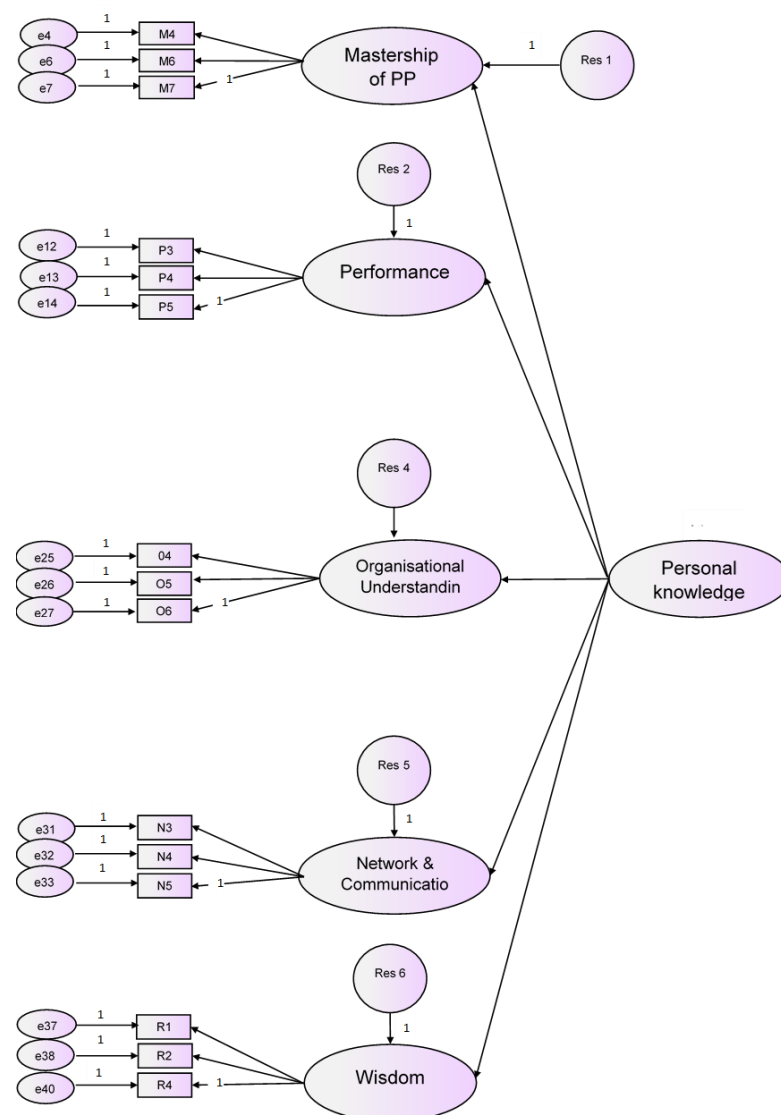


Figure 6-9 Respecified model (two)

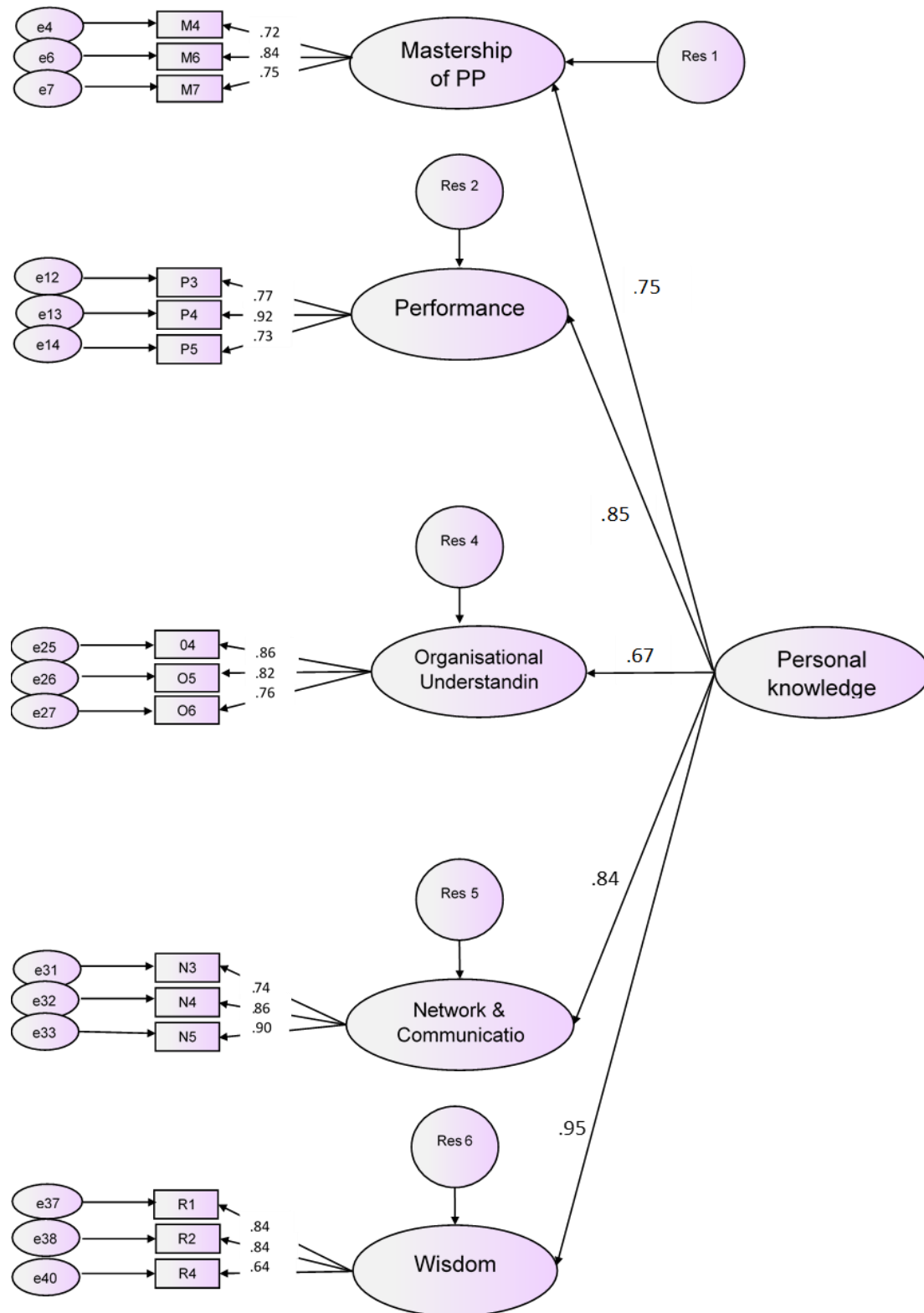


Figure 6-10 Model two standardised estimates

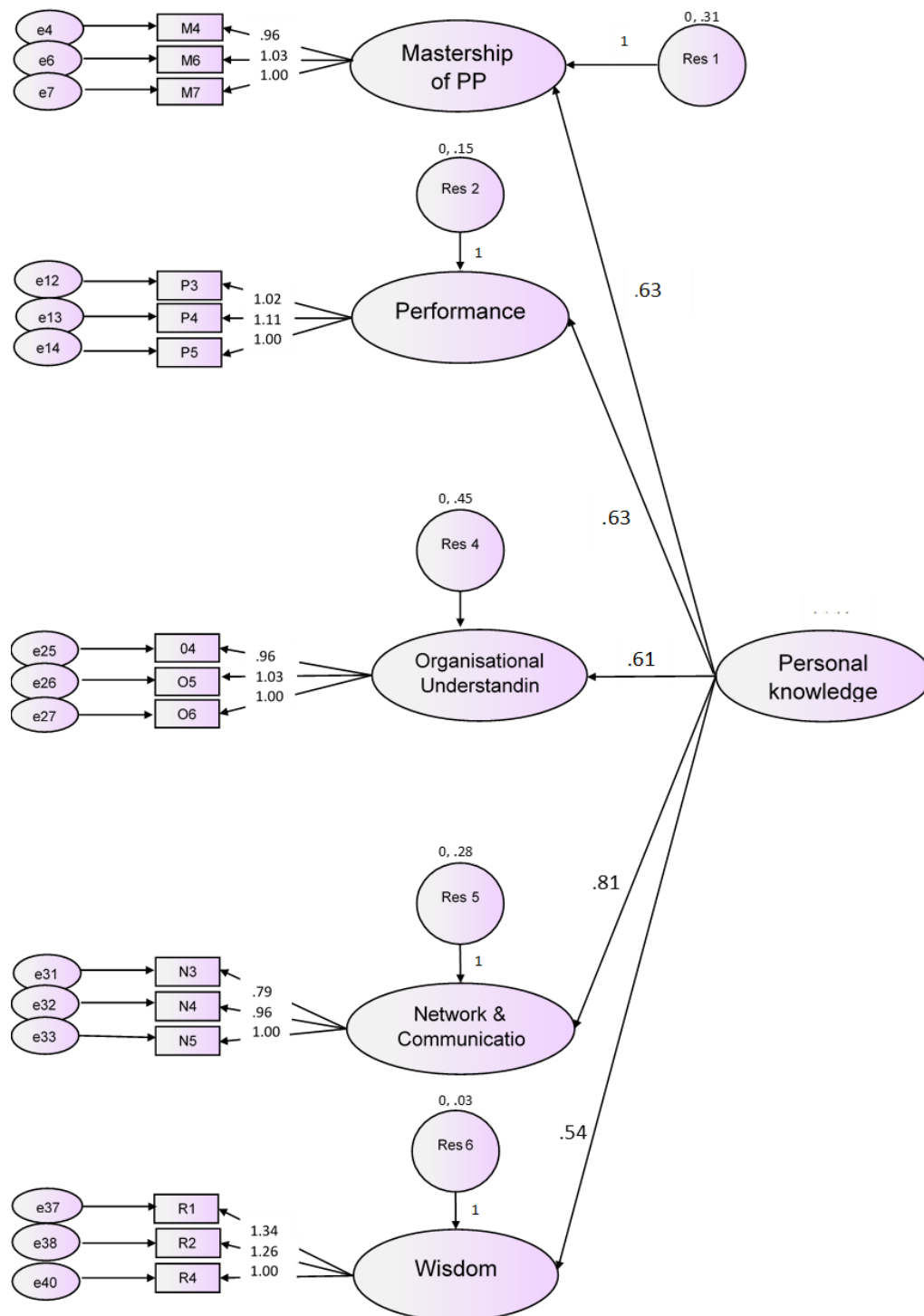


Figure 6-11 Model two unstandardised estimates

Model fit indices were reassessed for the new model showing a significant improvement. CFI value for model two equals 0.949 (approx. 0.95), RMSEA value equals 0.074, chi-square test result equals 172.32 with df=85 ( $P < 0.001$ ) and  $X^2/df$  equals 2.027 (Table 6-16; Table 6-18). The revised results suggest a good model fit.

*Table 6-17  $\chi^2$  Test results for model two*

Model	No. of Parameters	$\chi^2$	DF	P	$\chi^2/DF$
<b>Default model</b>	50	172.320	85	.000	2.027
<b>Saturated model</b>	135	.000	0		
<b>Independence model</b>	15	1820.665	120	.000	15.172

*Table 6-18 Unique variances- model two*

	Estimate	S.E.	P		Estimate	S.E.	P
<b>PK</b>	1.000			<b>12</b>	.397	.049	***
<b>Res1</b>	.315	.067	***	<b>27</b>	.586	.077	***
<b>Res2</b>	.152	.036	***	<b>26</b>	.436	.067	***
<b>Res4</b>	.448	.085	***	<b>25</b>	.280	.051	***
<b>Res5</b>	.277	.056	***	<b>33</b>	.228	.043	***
<b>Res6</b>	.029	.017	.088	<b>32</b>	.300	.046	***
<b>7</b>	.540	.074	***	<b>31</b>	.492	.058	***
<b>6</b>	.303	.057	***	<b>40</b>	.480	.054	***
<b>4</b>	.622	.079	***	<b>38</b>	.224	.032	***
<b>14</b>	.483	.057	***	<b>37</b>	.235	.035	***
<b>13</b>	.124	.032	***				

Table 6-18 presents the unique variances (measurement errors and residuals) in the revised model -two. All variances have significant values ( $P < 0.001$ ) except residual 6 associated with wisdom construct ( $P < 0.1$ ). Based on the results above, model two is the preferred model with superior fit and loading values compared with model one (Table 6-19).

*Table 6-19 Model fit indices of two models*

Model	$\chi^2$	DF	P	CFI	RMSEA
One	2062.208	773	.000	0.733	0.094
<b>Two</b>	<b>172.320</b>	<b>85</b>	<b>.000</b>	<b>0.949</b>	<b>0.074</b>

### 6.4 Covariates (controls)

Covariates are a form of variables in the measurement model to control and minimise potential bias in estimating the relationship of latent and observed variables that could happen if covariates were not included. However, covariates are not necessarily measures or causes of the latent variable (Bollen & Bauldry, 2011). The researcher studied the influence of sample demographic data on the estimation and fit of the model one (complete 41 measures) and model two (best fit 15 measures). Seven variables extracted from the sample demographic data (Education, KM maturity of the organisation, type of organisation, employee experience, training and job level) were selected as controls - explained in Section 5.9.

*Table 6-20 Model one: controls loadings*

	<b>Controls</b>	<b>Standardised estimates</b>	<b>Unstandardised estimates</b>	<b>S.E.</b>	<b>P</b>
PK <---	Education level	.054	.057	.075	.444
PK <---	KM Maturity	.287	.278	.070	***
PK <---	Type of organisation	.002	.003	.076	.973
PK <---	Total experience	.189	.039	.014	.007
PK <---	Training percentage	.131	.323	.174	.063
PK <---	Current experience	-.069	-.017	.017	.324
PK <---	Job level	-.024	-.028	.082	.731

*Table 6-21 Model two: controls loadings*

	<b>Controls</b>	<b>Standardised estimates</b>	<b>Unstandardised estimates</b>	<b>S.E.</b>	<b>P</b>
PK <---	Total experience	.188	.038	.015	.011
PK <---	Current Experience (current role)	-.055	-.013	.018	.448
PK <---	Type of Org	-.014	-.015	.078	.846
PK <---	Job level	-.039	-.045	.084	.594

	<b>Controls</b>	<b>Standardised estimates</b>	<b>Unstandardised estimates</b>	<b>S.E.</b>	<b>P</b>
PK <---	Training percentage	.115	.280	.178	.116
PK <---	Education level	.012	.013	.077	.869
PK <---	KM Maturity	.261	.250	.071	***

Table 6-20 and Table 6-21 illustrate the standardised and unstandardised loadings of the described controls. Five out of seven controls showed insignificant relationships in both model one and model two. Knowledge management maturity exhibits a weak to moderate positive (approx. 0.3) relationship with personal knowledge. This signifies that organisations with well-developed KM systems attract and retain knowledge holders. The total experience in terms of the number of years (job tenure) shows a weak positive relationship at a significance level of 0.05. Figure 6-12 and Figure 6-13 demonstrate the unstandardised estimates of model one and model two with the covariates. A slight reduction in model fit was observed after the introduction of the covariates. CFI value for model two equals 0.834, RMSEA value equals 0.091, chi-square test result equals 2636.519 with  $df=1074$  ( $P < 0.001$ ) and  $X^2/df$  equals 2.455. CFI value for model one equals 0.694, RMSEA value equals 0.088, chi-square test result equals 526.351 with  $df=204$  ( $P < 0.001$ ) and  $X^2/df$  equals 2.58. This can be attributed to the five covariates of the insignificant relationship as well as the limited sample size.



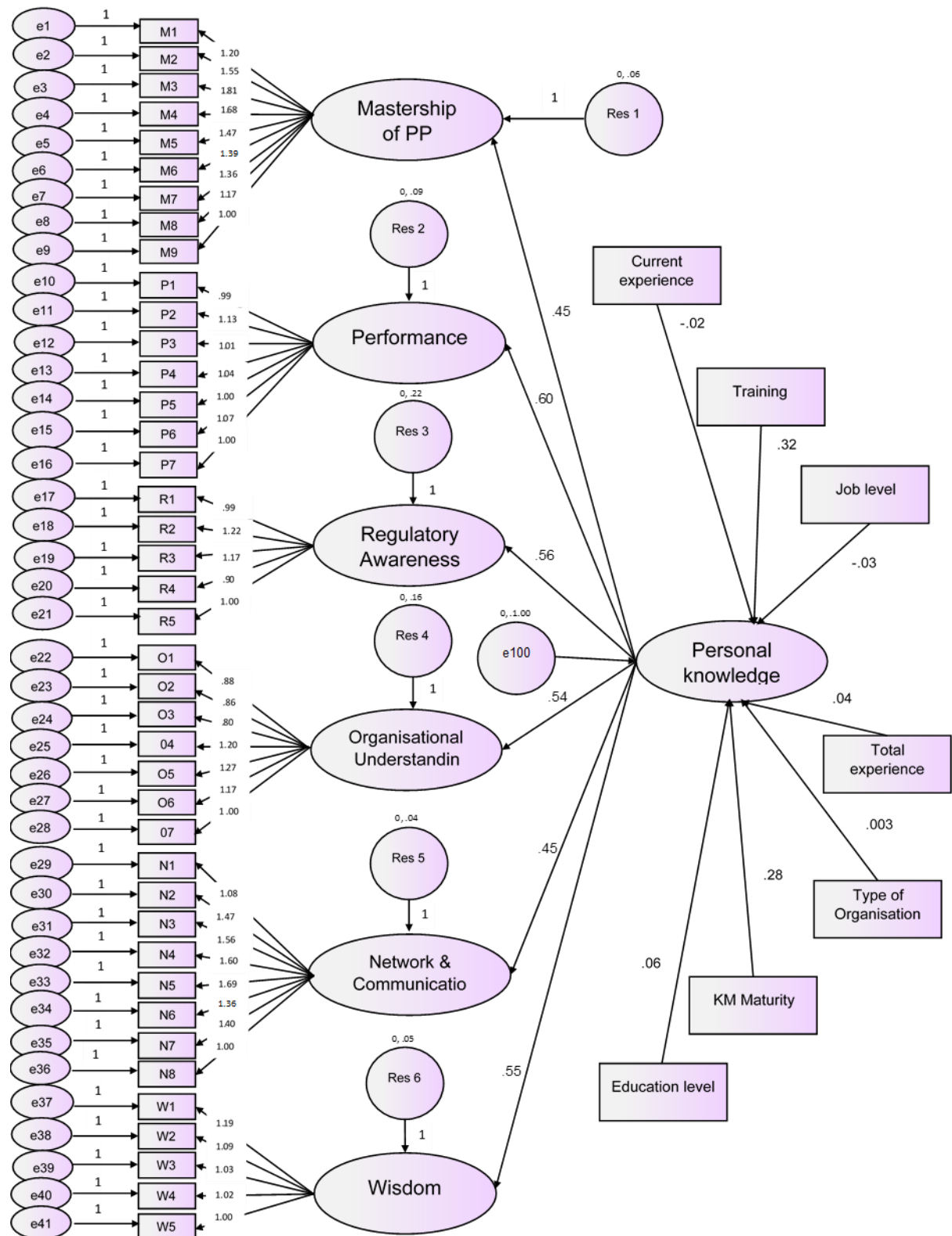


Figure 6-12 Unstandardised estimates of model one with covariates

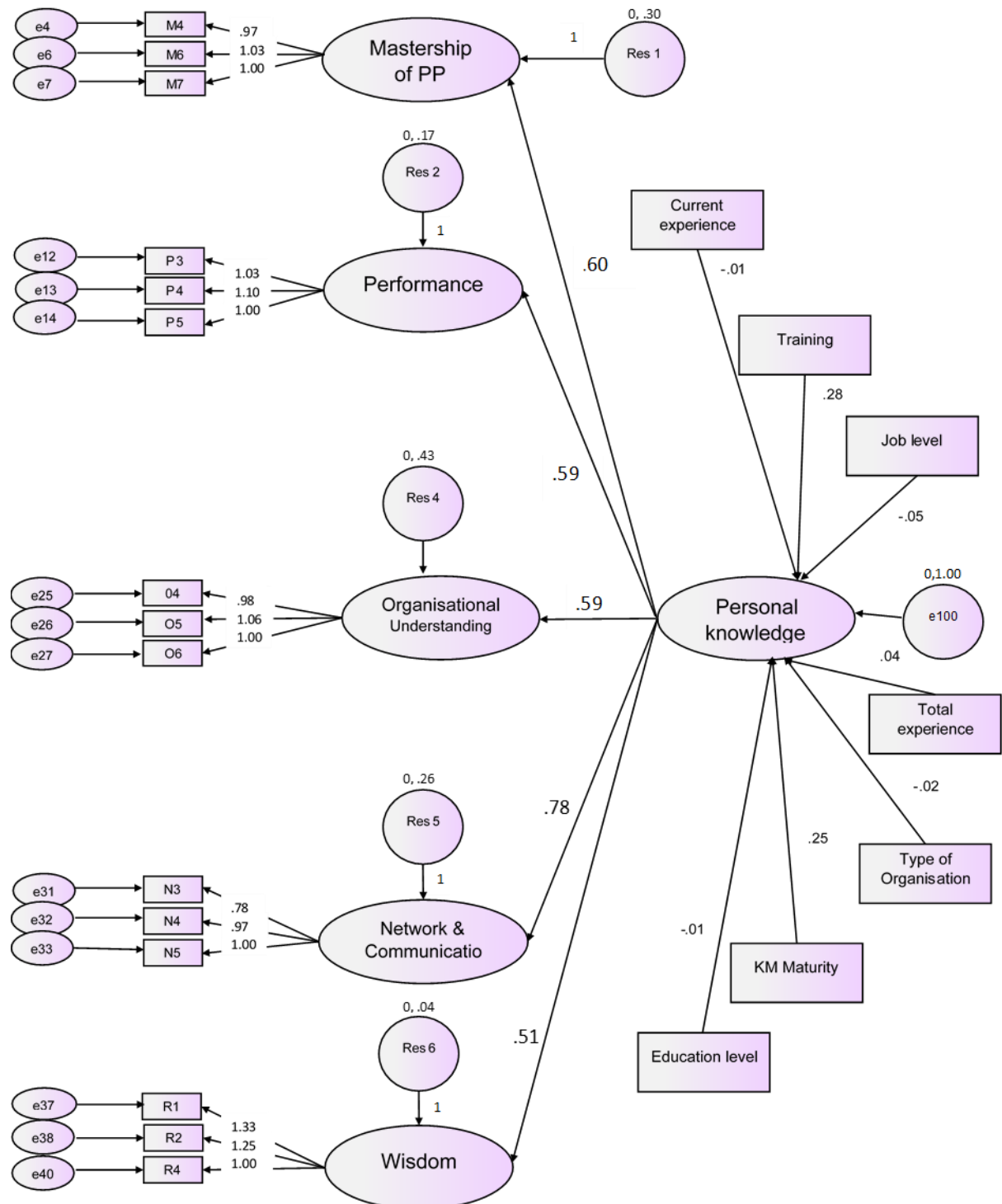


Figure 6-13 Unstandardised estimates of model two with covariates

### *6.5 Summary and Conclusion*

In this chapter, the researcher analysed the quantitative data extracted from the survey responses. Two main phases of data analysis can be distinguished in this chapter: descriptive statistics and confirmatory factor analysis. Descriptive statistics aimed at the review of respondents' demographic data to highlight how it represented the targeted population of the study. Thereafter, the developed model of personal knowledge was tested and optimised employing CFA tools. CFA encompassed six steps starting by data preparation, model specification, model identification, model estimation, model testing of fit then finally model optimisation. At the optimisation step, an alternative model was proposed as a modification of the original model one. The final model (two) is the preferred model that showed good fit and high loadings of all the measures of personal knowledge. Also, the model propounded a reasonable number of personal knowledge measures facilitating its potential use as a tool for personal knowledge assessment in the organisational context. Finally, the influence of seven control variables was assessed where only total experience and KM maturity expressed significant weak to moderate relationships with the personal knowledge suggesting that organisations with mature KM systems retain and attract knowledge holders. The outcome of the quantitative data analysis will be thoroughly discussed and compared to the extant literature in the next chapter offering a comprehensive explication of the research results.

## **Chapter 7 : Discussion**

### *7.1 Introduction*

This chapter presents the discussion of the research results that have been demonstrated in the previous chapters. The researcher adopted sequential mixed methods research (Creswell & Clark, 2018) starting with a qualitative exploratory phase followed by a survey of pharmaceutical manufacturing employees to validate the developed framework. The outcome of the qualitative phase was the development of a theoretical framework of 41 measures of personal knowledge of pharmaceutical manufacturing employee. The model was tested and validated using CFA (Schoonenboom & Johnson, 2017) to identify the best fit model describing the key manifestations of the personal knowledge in a pharmaceutical manufacturing context.

### *7.2 Personal Knowledge Management in the Pharmaceutical Manufacturing*

The researcher received 190 valid responses from more than 50 organisations that presented all drug product categories (conventional, biologics, devices, etc.) in multinational and domestic corporates and in the private and governmental sectors. The sample was intended to cover both genders and all the professional job levels in the organisation and within the functions specified in the study scope. The KM maturity of the pharmaceutical organisation was explored during the exploratory study as well as during the explanatory phase. The results revealed that over 80% of the participant organisations had a form of structured KM system and 27% had integrated KM with the corporate strategies. This agrees with the findings of (Oliva, 2014) that knowledge management is typically implemented in all major corporates.

Since 2008, ICH Q10 depicted KM as an enabler of the pharmaceutical quality system (ICH, 2008). However, the highest percentage of the surveyed companies are still struggling in the second stage of KM maturity where formal KM strategy is not established. Likewise, the qualitative phases addressed several initiatives for knowledge sharing and acquisition that

were widely applied in the pharmaceutical industry. The use of information technology was commonly adopted as an enabler of KM even though it is not sufficient without a supporting culture (Chatzkel, 2007). Evidence from the qualitative and the quantitative studies points to varied levels of KM maturity in the surveyed companies. Also, the survey results agree with the qualitative study findings as personal knowledge measurement activities were informal and unstructured. Nearly all the interviewed industry experts confirmed the lack of KM strategy in their organisations. The Chi-Square test of independence denied any statistically significant association between KM maturity and either organisation size or age. These results build on existing evidence that the pharmaceutical industry haven't developed mature KM capabilities (Calnan et al., 2018).

### *7.3 Personal Knowledge Measurement*

A slightly negative skewness (on average -0.96) was observed in all the variables assessed by the questionnaire. In other words, the most frequent self-assessment scores are higher than the mean and median. Also, the mean was shifted towards the positive side of the scale. This shifting was partially attributed to Dunning-Kruger effect (Kruger & Dunning, 1999) and the nature of the sample. The Dunning-Kruger effect shows that incompetent people would overestimate their capabilities in self-assessments due to their doubled curse being unskilled and unaware (Schlösser et al., 2013). The literature suggests that the only intervention to make participants more accurate in self-assessments is to educate them to be more competent (Kruger & Dunning, 1999).

However, it is believed that the Dunning-Kruger effect has a limited impact on the results of this study aiming to identify personal knowledge measures and the underlying factors rather than assessing the actual knowledge of participants. In the organisational context, this kind of knowledge measurement should be conducted as a 360-degree survey to minimise the bias due

to self-assessment. The other potential factor behind the positive shifting of scoring is the relative over representation of middle and senior managers constituting 39% of the sample (Figure 6-3). This relative over-representation may be attributed to the design of the two-stage cluster sampling as explained in the previous chapter. However, all job levels were represented in the surveyed sample.

### *7.4 Testing and validation of PK framework*

Two second-order CFA models were specified and theoretically grounded on the basis of the conceptual framework. The initial model included six underlying constructs (first-order) while the other model (five-factor model) excluded regulatory awareness as an independent construct. Instead, regulatory awareness was either merged with the Mastership of product and process. It is worth noting that regulatory awareness had the smallest regression weight in relation to personal knowledge. Model two was the optimised model that retained only the measures showing the highest loading values and had the best model fit indices. In all models, personal knowledge was the second-order latent variable. The revised five-factor model had better loading values and model fit indices compared to the six-factor original model (Table 6-18).

Model one shows that the regulatory awareness is the underlying construct of five measures of personal knowledge:

- The identification of compliance gaps/deviations in worker's area/process (R1).
- The association of compliance gaps to a specific clause in a standard, SOP or a Pharmacopeia (R2).
- Finding relevant standards or regulatory guidelines (R3).
- Awareness of updates to regulatory standards, specifications and SOPs (R4).

- Involvement in the development and improvement of standards and specifications in your organisation (R5).

Although regulatory awareness was a theme fully independent of product and process understanding in the thematic analysis study, a closer review of the measures of regulatory awareness highlights the communalities. Prior knowledge of product and process specifications, standard operating procedure or manufacturing process details is a prerequisite for identifying any practice to standard gaps. Moreover, the ICH guidelines accentuated that the adopted corrective or preventive actions to address any potential compliance gap should enhance product and process understanding (ICH, 2008).

### *7.5 Measures of Personal Knowledge*

The review of measurement models shows medium to high correlation with the underlying latent constructs and the personal knowledge (all regression weights above 0.4). In model one (which included all the hypothesised measures of personal knowledge), 94% of the loading values were above 0.5 and 55% are above 0.7 which indicates a moderate to high correlation with the underlying latent constructs and the latent variable. Moreover, the respecified model two (five-factor model) showed a noticeable improvement in model fit. Overall, results suggest that it can provide efficient, reliable, and valid assessment of the personal knowledge. Five factors were identified as the measures of personal knowledge in the pharmaceutical manufacturing context as shown in Table 7-1.

Regarding the applicability of the model in the pharmaceutical sector, three items per factor or a total of 15 measures were found to achieve the required balance between reliability and speed (see model two). Model two was favoured as it has offered both of these criteria by retaining only three measures per each factor and achieving best model fit. Unlike formative measures which cause the underlying latent variable, reflective measures are the effect of the



underlying latent variable and are known to be interchangeable (Kline, 2015). The measurement models used reflective observed variables (measures) to reflect the effect of the underlying factors and latent variable (Bollen, 1989). Consequently, reflective measures under each of the factors can replace one another.

To create the abbreviated model two, measures that have shown the highest correlation with the underlying factors were retained to create the optimum model (model two). The items for the optimised model were chosen balancing concerns for reliability, internal structure, and content representativeness (representing the five constructs). For convenience, the optimised PK framework (model two) will be referred to as the Pharmaceutical Personal Knowledge Framework or the 2P-K Framework.

*Table 7-1 The 2P-K Framework (model two)*

Factor	Measures	Code
Mastership of product/process	Train others in relation to your current role	M4
	Explain to colleagues the scientific basis and precautions of processes in your area	M6
	Explain to colleagues the technology utilised in machinery and equipment in your area	M7
Wisdom	Think critically (clearly and rationally) to solve work problems	W1
	Solve daily work problems efficiently	W2
	Other people believe you make the right decisions in work	W4
Organisational understanding	Understand the values of your organisation	O4
	Understand the vision, mission and goals of your organisation	O5
	Abide by the values of your organisation	O6
Performance	Complete assigned tasks "right first time"	P3
	Complete assigned tasks in a consistent manner	P4
	Complete assigned tasks on time	P5
Network and communication	Communicate effectively with senior management	N3
	Motivate others to achieve organisational goals	N4
	Lead others to achieve organisational goals	N5

#### 7.5.1 Mastership of product and process

The ICH Q10 presents product and process understanding as the core of KM activities and the outcome of applying scientific approaches across the product lifecycle (ICH, 2008). The estimation of the 2P-K framework shows regression weights of 0.75, 0.72, 0.84 and 0.75 for

the mastership factor and the three observed measures respectively reflecting a moderate to high correlation with personal knowledge. In other words, Personal knowledge explains 56% ( $0.75^2$ ) of variations in the mastership construct. The Mastership of product and process knowledge was measured by three items reflecting what can be generally described as technical advising. Interviews revealed that knowledgeable workers are not only capable of doing their jobs without supervision but also are able to pass their technical knowledge to others. Due to the unstructured and subjective nature of tacit knowledge, coaching and mentoring are essential to pass it to other employees. This includes the transfer of subjective understanding, know-how, know-why, job-specific and expert's knowledge (Mohajan, 2016).

The transferred knowledge through training can take several forms. While training can simply imply reading (self-study) what has been explicitly articulated in a document. Mentors or coaches are often required to transfer the heuristics they unconsciously use (tacit knowledge) to perform a certain task in a process (Gorman, 2002). Understanding the underlying theoretical and technology basis of product and process is described as the epistemological knowledge explaining why things are as they are. This type of knowledge normally goes beyond how things happen (performative knowledge) to why they happen (Mingers, 2008). Although sharing product and/or process knowledge with co-workers may be limited by factors such as personality traits, level of trust and other individual and organisational barriers (Pirozzi & Ferulano, 2016; Roos et al., 1997; Sveiby, 2010; Tobin, 1969), the ability to pass technical knowledge to others in the form of formal or informal training as well as to explain the knowledge beyond certain process can be seen as manifestations of deep knowledge. By the same token, Mohajan (2016) enumerated several ways for tacit knowledge transfer including but not limited to: training successors, sharing accumulated knowledge from prior role and other forms or coaching.

### 7.5.2 Wisdom

Three manifestations of personal knowledge were categorised as a reflection of the underlying latent construct of wisdom: critical thinking, problem-solving and proper decision making. The estimation of the 2P-K framework shows regression weights of 0.95, 0.84, 0.84 and 0.64 for wisdom factor and the three observed measures respectively reflecting a moderate to high correlation with personal knowledge. In other words, personal knowledge explains 90% ( $0.95^2$ ) of variations in the wisdom construct. Wisdom is a special type of judgement that requires prior knowledge to critically reflect on and question prevailing mental models (Gorman, 2002). Wisdom is depicted as the summit of knowledge hierarchy and as a result of the underlying knowledge (Ackoff, 1989). It enables the person to anticipate the long-term consequences of his/her actions (Bernstein, 2011). This can be interpreted in the form of a long-term vision, deep thinking, rationalism and coping with complex uncertain events (Ekmekçi et al., 2014). Indeed, multidisciplinary PKM approaches emphasise the use of knowledge for effective decision making and problem-solving (Pauleen, 2009; Wright, 2005). Problem-solving involves understanding of the problem through relevant information, generating alternatives and finally judgement or selecting the most appropriate solution (Wright, 2005). That is to say, holding the necessary tacit and explicit personal knowledge about the product and process is a prerequisite to solving problems which is the core of PKM (Agnihotri & Troutt, 2009).

### 7.5.3 Organisational understanding

Knowledge workers are expected to use their knowledge to make decisions that affect the performance of their organisations (Agnihotri & Troutt, 2009). However, values and contextual information are an integral part of knowledge as defined by Davenport & Prusak, (1998). In other terms, knowledge workers make their decisions in light of their understanding of their organisational culture, values, mission and vision. Three manifestations of personal knowledge were presented as a reflection of the underlying latent construct of the organisational

understanding: understanding company's values, understanding its mission, vision & goals and finally abiding by these values. The estimation of the 2P-K framework shows regression weights of 0.67, 0.86, 0.82 and 0.76 for organisational understanding factor and the three observed measures respectively reflecting a moderate to high correlation with personal knowledge. That is to say that the personal knowledge explains 45% ( $0.67^2$ ) of variations in the organisational understanding construct.

### 7.5.4 Performance

The literature suggests that personal knowledge is required for better performance of job tasks (Tajedini et al., 2018). By the same token, the interviewed industry experts proposed that the personal knowledge of employees can be assessed by the outcome of knowledge i.e. performance. Performative knowledge (also called procedural or know-how) is the form of practical knowledge, skills and competencies which enables us to do something (Gorman, 2002; John Mingers, 2008). Hence, it can be evaluated by success to do something. Three manifestations of personal knowledge were presented as a reflection of the underlying latent construct of performance: completion of a task right first time, in a consistent manner and on time. The estimation of the 2P-K framework shows regression weights of 0.72, 0.77, 0.92 and 0.73 for performance construct and the three observed measures respectively reflecting a moderate to high correlation with personal knowledge. That is to say, the personal knowledge explains 72% ( $0.85^2$ ) of variations in the performance construct. Performance can be understood as the outcome of job activity within a certain period. It is associated with personal knowledge, experience, self-esteem and motivation (Tabata et al., 2016).

### 7.5.5 Network and communication

The fifth construct in 2P-K framework is the network and communication measures. This includes the effective upward communication with senior management, motivation of co-

workers and leadership to achieve the organisational goals. Knowledge is not just a thing or a process, but rather a personal network (Chatti, 2012). Moreover, knowledge work is increasingly depicted as a social activity (Wright, 2005). Personal network in terms of strength of ties and the number of contacts was positively related to performance in knowledge-intensive jobs due to transfer of complex knowledge between contacts (Taba et al., 2016). The estimation of the 2P-K framework shows regression weights of 0.84, 0.74, 0.86 and 0.90 for the communication construct and the three observed measures respectively reflecting a moderate to high correlation with personal knowledge. That is to say that the personal knowledge explains 70% ( $0.84^2$ ) of variations in the communication and networking construct. It is important to note that social networking requires “know-who” form of knowledge (Jarrahi et al., 2019) which is a predominately tacit knowledge impeded in the fluid personal interactions in the organisation (Grabher & Ibert, 2006).

### *7.6 Controls*

The quantitative study assessed the influence of seven covariates on personal knowledge: education level, KM maturity, type of organisation, total experience, current experience, training (percentage completed) and Job level. Five out of the seven control showed an insignificant relationship with the measurement framework. While KM maturity showed a weak to moderate correlation (approx. 0.3) with the personal knowledge, total experience (job tenure) was weakly correlated (approx. 0.2) to personal knowledge and its manifestations. The results suggest that the surveyed organisations which have developed stronger KM systems also employed the most knowledgeable employees. As lifelong employment is no longer the norm in modern organisations, continuous learning throughout the career has become the responsibility of employees in an ever-changing environment to stay competitive (Thornley et al., 2016). It is argued that mature knowledge processes play a potential role in enhancing

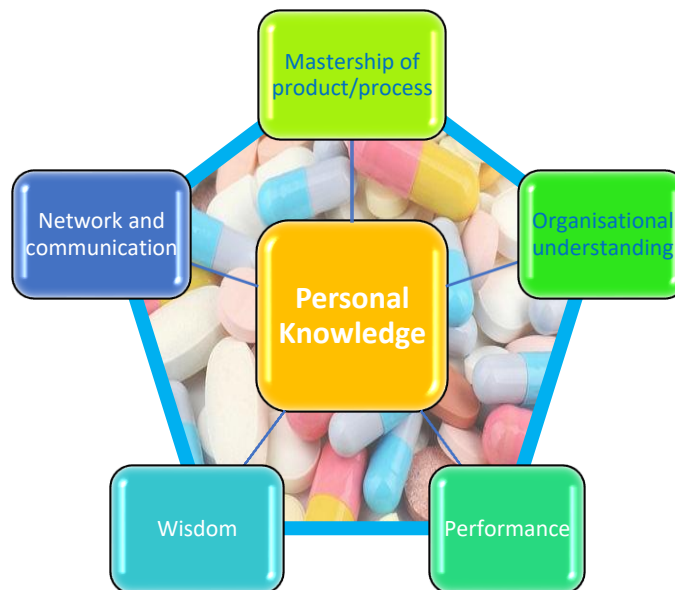
organisational learning and expanding the learning culture (Chinowsky & Carrillo, 2007; Thepthepa & Mitsufuji, 2016). In other terms, this prevalence of learning culture in KM mature organisations can justify the association of KM maturity and personal knowledge.

The job tenure was used as a proxy for employee experience. The available evidence seems to suggest that experience is necessary for problem-solving and proper decision making (Mittelmann, 2016). The qualitative study showed that prior experiences help employees find efficient solutions to problems that had faced the organisation before. The cross relationships between the length of experience and the knowledge management maturity at one side and personal knowledge at the other side is consistent with the notion that time is crucial for knowledge accumulation over a long period through direct experiences and lifelong learning (Hoe, 2006; John Mingers, 2008).

### *7.7 Theoretical Implications*

Successful PKM implies better use of the knowledge of individual employees (Razmerita et al., 2009b). Therefore, the intellectual output of an organisation is reliant on the personal knowledge of its employees (Hine et al., 2008). In order to manage this sort of knowledge predominately stored in people's brain (Thornley et al., 2016), better understanding and measurement of the personal knowledge is prescribed. An empirical study of the personnel knowledge in the pharmaceutical manufacturing sector resulted in the development of the Pharmaceutical Personal Knowledge (2P-K) framework (the abbreviated form of the original 41-measures model). Due to the context-specific nature of knowledge (Hoe, 2006; Nikkhah et al., 2018; Nonaka et al., 2000; Vladova et al., 2016), the 2P-K framework addressed the manifestations of personal knowledge in an industry-specific context. The framework depicted five constructs illustrating the key manifestations of the personal knowledge of manufacturing personnel. The 2P-K framework offers researchers and scholars a theoretically grounded model

for measuring personal knowledge. In order to enhance the applicability of the model, the number of measures per construct was reduced to three (15 items in total) by retaining the strongest loading variables and the best fit model. Thus, the model offers an opportunity to be integrated with future research questionnaires to assess personal knowledge in relation to other latent variables using structural equation modelling or similar techniques.



*Figure 7-1 The 2P-K Framework*

Furthermore, measures of the intellectual capital of organisations such as the replacement cost of tangible assets (Tobin, 1969), market share (Edvinsson, 1997) or retention excellence (Wyatt, 2001) are argued to be inaccurate measures of the personal knowledge due to potential synergism of collective knowledge in organisations (Wright & McMahan, 2011). The developed 2P-K framework explored the statistical interrelations of 15 manifestations of personal knowledge in industry-specific context and concluded that a positive correlation between any two of the five constructs should be attributed to the personal knowledge since the underlying constructs have low correlations among them. Unlike classical measures of personal knowledge such as standardised test (Matoskova, 2016) and situational judgment test

(SJT) (Peeters & Lievens, 2005), the study offers an original personal knowledge explanatory model supported by the confirmatory factor analysis statistics.

### *7.8 Practical Implications*

The literature reveals that knowledge measurement aims to offer a tool to identify and allocate knowledge assets, benchmark against other companies, monitor the development of the firm's HC overtime (Matoskova, 2016). The 2P-K framework can be used as a basis for a personal knowledge measurement scale (2P-K-S) in the pharmaceutical manufacturing context. The interviews conducted in the exploratory phase with industry experts concluded that personal knowledge measurement is reliant on informal subjective activities (if existed). In order to develop a quantitative and consistent scale of personal knowledge, the Pharmaceutical Personal Knowledge Scale (2P-K-S) was suggested as a practical application of 2P-K framework.

The use of structural techniques for organising decision making such as Analytic Hierarchy Process (AHP) (Saaty, 2000) can offer relative weights for each of the five factors underlying the personal knowledge latent variable. The AHP allows the use of the experts' assessments to estimate the relative weight of each factor through pair-wise comparisons to achieve a consistent judgement (Li et al., 2019). The assigned weights would be customised to the relative significance of each of the factors within each organisation. Whereas Spearman developed the general intelligence test using the g-Factor, underlying a set of cognitive abilities, as a measure of intelligence (Hally, 2012), the 2P-K scale similarly would measure the personal knowledge of manufacturing employees by explaining the common variance of the 15 observed measures of knowledge. Although this study relied on self-assessment, 360-degree feedback is recommended for the organisational application of this framework. The



360-degree feedback is a form of multi-rater assessment where the feedback is received from supervisor, peers, subordinates in addition to self-evaluation (Atkins & Wood, 2002).

The practitioners' interviews demonstrated a consensus on the value of personal knowledge measurement. It suggested that the personal knowledge measurement tool can help employees' appraisal. As the appraisal process can be multidimensional (Bayo-Moriones et al., 2019), evaluation of new and current employees can include the level of personal knowledge. This might be of particular importance within the learning organisation culture to evaluate the effectiveness of training and learning programs. It was also suggested as a way to compare and monitor the knowledge of teams or departments in a consistent way where the aggregates of personal knowledge echo the collective knowledge of a group (Faucher et al., 2008). The tool can also highlight the opportunities for development and weakness points of employees to be considered for future development. As previously discussed, personal knowledge is a predictor of job performance (Mingers, 2008; Taba et al., 2016). Consequently, awareness of personal knowledge is associated with performance improvement (Tajedini et al., 2018).

Moreover, all manufacturing personnel are required to have the proper training on their job responsibilities (WHO, 2014). The identification of knowledge holders within the organisation can provide evidence that business and quality decisions are made by those who hold the right knowledge. This is deemed to improve the quality and business outcome by raising the level of confidence in the decision-making process. This supports the notion that the organisational ability to exploit existing knowledge is a determinant of a firm's success and competitiveness (Matoskova, 2016).

### *7.9 Limitations*

The research anticipated few limitations of the developed measurement framework. Firstly, the proposed measurement framework/scale relies on 360-degree survey to assess the personal

knowledge of employees. This requires supervisor, peers and subordinates to develop a certain level of awareness of the performance of the assessed employee. In turn, they should encounter shared situations, work jointly and share their reflections about daily work problems. The qualitative study suggests that is not always possible. Some organisations rely on fixed-term contracts to fill certain jobs. In such a case, the limited employment period does not allow proper evaluation or corrections. In some other cases, workers might not be part of a team or in other words, working solely in a particular processor on a niche product. This is deemed to limit the assessor's capacity to evaluate his/her peers too. If the assessed knowledge is associated with a breakthrough product or process, assessors might face difficulties to define what the proper outcome or performance reflecting the acquisition of this new knowledge.

Secondly, the framework validation in this study relied on self-ratings. This might pose a risk of social desirability bias. Social desirability bias describes the tendency of respondents to choose socially desirable answers rather than the answers which describe their true beliefs (Grimm, 2010). Atkins & Wood (2002) criticised the use of self-rating as a reflection of a particular competency either by itself or as in aggregation with other ratings from 360-degree feedback. In order to minimise the impact of social desirability bias, the researcher resorted to the use of a self-administered electronic questionnaire, anonymous survey of practitioners and a careful selection of the wording of survey questions (Grimm, 2010). Finally, Dunning Kruger effect (Kruger & Dunning, 1999; Schlösser et al., 2013) is another source of bias where unskilled generally lack the metacognitive abilities to realise their incompetency. This agrees with the findings of Atkins & Wood (2002) where high performers had less propensity to overestimate their performance compared to low-performers who showed lower self-awareness. For this reason, a 360-degree survey was prescribed for organisational application as shown before.

### *7.10 Recommendations and future directions*

In order to overcome the limitations of this research, a case study employing the 360-degree survey in a pharmaceutical manufacturing organisation is recommended for practical testing of the framework. The use of AHP to determine the relative weights of each of the five factors would personalise the framework to the priorities of each organisation. Also, the framework can be estimated in a bigger sample that includes practitioners from similar manufacturing industries such as chemical, food and beverages.

Finally, as knowledge is context-specific (Nikkhah et al., 2018), the model was developed and tested in an industry-specific context (pharmaceutical manufacturing). However, comparison to similar manufacturing industries (e.g. chemical industries) is recommended to assess the validity of the current model or a modified version of it in other industries.

## **Chapter 8 : Conclusion**

### 8.1 *Introduction*

Knowledge is a dynamic human process to justify our personal belief in pursuit of the truth (Nonaka et al., 2000). Therein, information is processed and stored in people's mind (Thornley et al., 2016). Personal knowledge management and particularly measurement have received little attention, particularly in pharmaceutical manufacturing. This study offers an original framework for measuring personal knowledge of knowledge workers in pharmaceutical manufacturing. The tool has been developed considering the extant literature and guided by experts' insights. The proposed framework has been validated and optimised by surveying 190 practitioners from the pharmaceutical sector. The following section depicts how the study addressed the three research objectives, the contribution to knowledge and finally the author's reflections and conclusion.

### 8.2 *Understanding Personal knowledge Management and Measurement*

In order to develop a framework of personal knowledge in the pharmaceutical industry, it was important to achieve a deep understanding of the current industry practices and predominant theories in the extant literature. Research commenced with a comprehensive literature review of the personal knowledge and knowledge measurement theories as well as the applications of KM and PKM in pharmaceutical manufacturing. The extant literature provided dozens of comprehensive definitions of knowledge at its tacit and explicit dimensions such as “*a dynamic human process of justifying personal belief toward the truth*” (Nonaka et al., 2000). In contrast, practitioners' definitions in the qualitative phase emphasised knowledge acquired by doing and experience. Regulatory and industry guidelines were reviewed to understand the regulatory expectations and requirements. The review of 137 empirical studies revealed a growing interest in KM in the pharmaceutical industry and regulatory endeavours to enforce KM across the product lifecycle. The review also provided a literature map that

identified six popular themes in KM literature in pharmaceutical industry. Regarding knowledge theories, the review identified the dimensions of personal knowledge and key knowledge measurement frameworks (Pirozzi & Ferulano, 2016; Roos et al., 1997; Sveiby, 2010; Tobin, 1969).

However, as the focus of academic and regulatory literature was set on the organisational knowledge management, exploratory interviews with pharmaceutical industry experts were necessary to address this knowledge gap by identifying how personal knowledge is assessed in the pharmaceutical manufacturing organisations. The thematic analysis of interviews provided a thorough analysis of the current KM and PKM practices in pharmaceutical manufacturing. The analysis highlighted the measures of personal knowledge adopted in the organisational context. Measurement strategies were predominately subjective and informal. Participants emphasised the value and growing need for consistent and formal measures of personal knowledge. At the end of the literature review (chapter two and three) and the qualitative study (chapter five), the research developed the required understanding of how personal knowledge was conceptualised in pharmaceutical industry context (RQ1) and how it is currently measured by practitioners (RQ2).

Finally, the level of KM maturity in the pharmaceutical industry was assessed both in the qualitative and quantitative studies. There was an agreement that the levels of implementation and maturity of KM practices are not the same in every pharmaceutical organisation. The quantitative study findings supported this assumption. While most of the surveyed companies had a sort of structured KM system (more than 80%), they were distributed between the four levels of maturity (Oliva, 2014) in similar ratios (18%, 32%, 23% and 27%) -RQ3.

Literature review and the exploratory study paved the road for achieving the first research objective:

**Objective 1** Gain an in-depth understanding of the current practices of the personal knowledge management and measurement focusing on the pharmaceutical manufacturing context.

### *8.3 Development of Personal Knowledge Framework*

Following an abductive reasoning approach, a conceptual framework was developed taking into account the exploratory interviews and literature review findings. The thematic analysis provided the required insights about research phenomenon from the practitioners' perspective. Developing a theoretically grounded model was a prerequisite for the next phase of framework testing and validation. The personal knowledge measurement conceptual framework was hypothesised as a second-order model with 41 observed measures. By the end of chapter five the second research objective was achieved.

**Objective 2** The development of a personal knowledge measurement framework for knowledge workers in the pharmaceutical manufacturing context.

### *8.4 Personal Knowledge Framework Validation and Optimisation*

A survey of 190 manufacturing employees at different job levels was used to achieve the third research objective. Confirmatory factor analysis using IBM AMOS 26 was the chosen technique to estimate the proposed models and to select the most reliable model that best-fit the data with a reasonable number of measures. Model two was the favoured measurement framework (2 P-K) that combined both speed and reliability through 15 observed measures of personal knowledge with five underlying factors that have shown high loading on the latent variable and good model fit. The five underlying factors are: Mastership of product and process, wisdom, organisational awareness, communication and networking as well as performance. Thus, the third objective was addressed.

**Objective 3** Validate and optimise the proposed PK measurement framework in the pharmaceutical manufacturing sector.

### *8.5 Contribution to knowledge*

#### 8.5.1 Development of the Pharmaceutical Personal Knowledge (2P-K) framework

As explained in chapter one, PKM is a relatively new research discipline that has not received proper attention (Cranefield & Prusak, 2016). The research offers a theoretically grounded and validated framework explicating personal knowledge and its manifestations. As knowledge is context-specific (Hoe, 2006; Nikkhah et al., 2018; Nonaka et al., 2000; Vladova et al., 2016), pharmaceutical manufacturing was adopted as the context for the development and testing of 2P-K framework. Due to the limited knowledge on the measurement strategies of personal knowledge particularly in the manufacturing context, the research commenced with an exploratory phase. The exploratory phase merged the knowledge available in literature and industry guidelines with the experiences of industry experts to deductively develop the conceptual framework in the study.

Thematic analysis was the vessel where knowledge from primary and secondary data interacted to hypothesise the measures of personal knowledge and the underlying factors. A theoretically grounded framework was a prerequisite for the following testing phase using structural equation modelling (Kline, 2011). A quantitative survey of 190 practitioners in the pharmaceutical manufacturing was used to test and optimise the proposed models. Finally, the 2P-K framework was developed to explain personal knowledge through its manifestations in a pharmaceutical manufacturing context.

The developed 2P-K framework provides researchers and scholars in the area of PKM with a multifaceted explanation of personal knowledge. The theoretical framework can assist PKM



future researches as an indirect tool to measure PK (which is a latent variable) in relation to other variables.

### 8.5.2 A basis for PK measurement instrument in manufacturing

The study offers a reliable and flexible measurement framework that can be adopted in pharmaceutical manufacturing to assess the level of personal knowledge of employees based on the manifestations and outcome of knowledge itself. Unlike currently applied subjective and informal personal knowledge assessment strategies (as identified in the exploratory study), the framework provides the basis for a systematic objective tool to measure personal knowledge. However, the use of 360-Degree feedback is recommended to avoid bias due to social desirability or Dunning-Kruger effect and consequently achieve accurate results.

In order to enhance the applicability and flexibility of the framework, the final optimised model (2P-K framework) was an abbreviated (15-item) form of the original 41-observed variable framework. In addition, the abbreviated framework showed better model fit than the original model reflecting its accuracy and reliability. The author anticipates that the proposed framework can be applied in organisational context to measure personal knowledge in a way similar to Spearman IQ test where the underlying g-Factor (intelligence) is used to explain the variances in the cognitive abilities (Hally, 2012).

### 8.5.3 Taxonomic analysis of KM literature

KM is a relatively new research discipline with limited applications in the pharmaceutical industry (Ramy et al., 2018). This study contributed by developing a taxonomic map (Figure 3-4) of the predominant themes in the academic journal articles with direct applications in the pharmaceutical industry. Similarly, the review of more than 128 pharmaceutical industry and regulatory guidelines brought forth a literature map of KM related themes addressed in these

guidelines (Figure 3-5). The literature review findings have been published in the Knowledge Management Research and Practice (KMRP) Journal.

### *8.6 Summary and Conclusion*

This thesis presents original research to explore and explain the personal knowledge management and measurement in literature and practice. After a comprehensive review of knowledge measurement theory and application literature, fifteen industry experts were interviewed to obtain a greater understanding of personal knowledge management and measurement practices. The fruit of that stage was the development of an explanatory theoretical framework that describes personal knowledge, knowledge manifestations and the underlying factors of those manifestations. The framework was validated and optimised through a survey of 190 practitioners from pharmaceutical manufacturing where confirmatory factor analysis statistics were applied to test and validate the key measures of the personal knowledge as demonstrated by the 2P-K framework.

(End)

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## **Appendix A “The Questionnaire”**

# The Pharmaceutical Personal Knowledge Scale (<sub>2</sub>P-KS)

A Personal knowledge Measurement Scale for individual employees in the Pharmaceutical Manufacturing sector

**\*Required**



In response to an increasing regulatory and business needs for knowledge management across the commercial life of the drug product, this survey comes as a part of a comprehensive academic study to develop a knowledge assessment scale for pharmaceutical manufacturing employees. It is hoped that the results of this study will enhance the ability to identify knowledge assets and enhance decision-making capabilities within the pharmaceutical industry.

The study is conducted by the College of Business, Technological University Dublin and embracing its research ethics. To ensure confidentiality, we will guarantee the anonymity of both participant and company information. The survey responses are accessible only by the authorised research team members and the academic supervisor Dr. Lorraine Sweeney ([lorraine.sweeney@TUDublin.ie](mailto:lorraine.sweeney@TUDublin.ie)). Mindful of your busy schedule, we are kindly inviting you to participate in this survey which should only take an average of 15 minutes. Your participation in this survey means you consent that your data will be exclusively used for academic research.

As an incentive to complete this survey, we will donate \$1 (one US dollar) per completed survey for the Egyptian National Cancer Institute - Cairo (<http://www.nci.cu.edu.eg/>).

For further enquiries about the survey, kindly contact [Ahmed.Ramy@TUDublin.ie](mailto:Ahmed.Ramy@TUDublin.ie).

Thanks for your kind participation

Ahmed Ramy, MSc

PhD Candidate

3S Group, College of business

TU Dublin

1. Which one of the following best describes your role in the organisation? \*

*Mark only one oval.*

- ☐ Support and administration roles (e.g. accounting, IT, HR, Training, admin, etc.).
- ☐ Manufacturing (e.g. quality, production, warehouse, manufacturing R&D, etc.)

## Demographic data

2. Please indicate the approximate size of your organisation (all the sites and affiliates). \*

*Mark only one oval.*

- ☐ Less than 50 employees
- ☐ From 50 to 249 employees
- ☐ From 250 to 500 employees
- ☐ From 500 to 1000 employees
- ☐ More than 1000

3. Please indicate the category of drug products manufactured at your organisation/site \*
- Choose all that apply

*Tick all that apply.*

- ☐ Conventional
- ☐ Biologics
- ☐ Veterinary
- ☐ Medical devices
- ☐ API

Other: ☐ \_\_\_\_\_

4. Please indicate the age of your organisation (the whole organisation worldwide) \*

*Mark only one oval.*

- ☐ Less than 5 years
- ☐ From 5 to 10 years
- ☐ From 11 to 20 years
- ☐ From 21 to 50
- ☐ More than 50 years

5. Please indicate the ownership of your organisation. \*

*Mark only one oval.*

- ☐ Public (Governmental)
- ☐ Private
- ☐ Other: \_\_\_\_\_

6. Please indicate the type of your organisation. \*

*Mark only one oval.*

- ☐ Domestic
- ☐ Multinational or Global
- ☐ Other: \_\_\_\_\_

7. Please indicate your current department or function. \*

*Mark only one oval.*

- ☐ Quality Assurance
- ☐ Quality Control
- ☐ Production or packaging
- ☐ Warehousing
- ☐ Technical service
- ☐ Other: \_\_\_\_\_

8. Please indicate your current position/title. \*

*Mark only one oval.*

- ☐ Senior manager or director
- ☐ Manager
- ☐ Supervisor
- ☐ Specialist/Representative/Associate
- ☐ Other: \_\_\_\_\_

9. Please indicate the highest level of education you have obtained. \*

*Mark only one oval.*

- ☐ High school
- ☐ Technical certificate/diploma
- ☐ Bachelor degree
- ☐ Postgraduate certificate/diploma
- ☐ Masters Degree
- ☐ PhD
- ☐ Other: \_\_\_\_\_

10. Please indicate your gender.

*Mark only one oval.*

- ☐ Male
- ☐ Female
- ☐ Prefer not to say



11. Please indicate your total experience in the pharmaceutical manufacturing (in years). \*

---

12. Out of your total manufacturing experience (previous question), how many years have you spent in the current department/function? \*

---

13. Out of your total manufacturing experience , how many years have you spent with the current employer? \*

---

14. Please indicate your level of compliance to technical training requirements (including GMP training) \*

**Mark only one oval.**

☐ Less than 40%

☐ 40-50%

☐ 51-60%

☐ 61-70%

☐ 71-80%

☐ 81-90%

☐ More than 90%

15. Please indicate your proficiency with English language (reading, speaking and listening) \*

*Tick all that apply.*

	Beginner	Intermediate	Advanced	Native or bilingual
Reading	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Speaking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Listening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. Which of the following statement best describes the knowledge management practices in your organisation: \*

*Mark only one oval.*

- ☐ There is a general lack of awareness of the need for knowledge management.
- ☐ The management is aware of the importance of knowledge management but there are no or few formal processes for identifying, capturing, sharing, transferring, and applying knowledge.
- ☐ Formal knowledge management initiatives take place at some departments (islands of knowledge) but it is not part of an organisation-wide strategy.
- ☐ Knowledge management is part of a holistic organisation strategy and continuously reviewed by management.

Section  
two

Please indicate the extent to which you are confident that you are able to undertake ( or would be able to , if required) the following:

17. Identify compliance gaps/deviations in your area/process. \*

*Mark only one oval.*

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

18. Associate compliance gaps to a specific clause in a standard, SOP or a Pharmacopeia. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

19. Find relevant standards or regulatory guidelines. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

20. Locate relevant process and product related information. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

21. Identify the appropriate person to obtain information relating to a specific product/process. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

22. Carry out assigned responsibilities without supervision. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

23. Contribute to the design and development of processes/products within your function. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

24. Train others in relation to your current role. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

25. Complete relevant records/forms (including electronic records) associated with products or processes in your department. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

Please indicate the extent to which you are confident that you are able to undertake ( or would be able to , if required) the following:

26. Explain to colleagues the scientific basis and precautions of processes in your area. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

27. Explain to colleagues the technology utilised in machinery and equipment in your area. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

28. Achieve departmental/organisational goals successfully \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

29. Play a key role in successful projects in your area. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

30. Complete assigned tasks "right first time". \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

31. Complete assigned tasks in a consistent manner. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

32. Complete assigned tasks on time. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

33. Meet or exceed the required targets. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

34. Think critically (clearly and rationally) to solve work problems. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

Please indicate the extent to which you are confident that you are able to undertake ( or would be able to , if required) the following:

35. Communicate effectively with co-workers to get the job done. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

36. Communicate effectively with senior management. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

37. Motivate others to achieve organisational goals. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

38. Lead others to achieve organisational goals. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

39. Solve daily work problems efficiently. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

Section three

Please indicate the extent to which you:

40. Understand your role within you organisation. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

41. Understand processes within other departments in your organisation. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent



42. Understand terminology used in your organisation. \*

*Mark only one oval.*

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

43. Understand the values of your organisation. \*

*Mark only one oval.*

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

44. Please provide examples of the values of your organisation (at least three):

---

45. Understand the vision, mission and goals of your organisation. \*

*Mark only one oval.*

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

46. Abide by the values of your organisation. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

47. Explain the historical Out of Specifications (OOS), failures and/or any weaknesses in your area.

\*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

48. Are aware of updates to regulatory standards, specifications and SOPs. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

49. Are involved in the development and improvement of standards and specifications in your organisation. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

50. Are involved in the design, validation, control and continuous improvement of products/processes in your function. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

Section four

Please indicate the extent to which:

51. Other people seek advice or information from you relating to products, processes and systems (including computer systems). \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

52. Other people believe you solve daily work problems efficiently. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

53. Other people believe you make the right decisions in work. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

54. Other people see you as a team player. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

55. Your out of the box suggestions are implemented within your organisation. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

56. You achieve a strong positive evaluation in annual appraisal by management. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

57. You have a wide network of contacts within your organisation. \*

Mark only one oval.

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

58. You have a wide network of contacts outside your organisation (pharmaceutical and non-pharmaceutical). \*

*Mark only one oval.*

	1	2	3	4	5	6	7	
Not at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	To a great extent

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## **Appendix B “Publications”**

## A scientometric analysis of Knowledge Management Research and Practice literature: 2003–2015

Ahmed Ramy, Jenni Floody, Mohamed A. F. Ragab & Amr Arisha

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ORIGINAL ARTICLE



## A scientometric analysis of *Knowledge Management Research and Practice* literature: 2003–2015

Ahmed Ramy<sup>a</sup>, Jenni Floody<sup>a</sup>, Mohamed A.F. Ragab<sup>a</sup> and Amr Arisha<sup>b</sup>

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### ABSTRACT

The purpose of this paper is to explore the current research trends in Knowledge Management (KM) through a scientometric analysis of all literature published in KMRP between 2003 and 2015 (506 articles). The review framework explores three sets of review questions addressing Research Productivity, Research Themes and Methods, and Citation Analysis. The study elucidates wide global interest in KM and an increasing trend towards multi-author collaboration. Although more than 55 different industries have featured in the journal, certain knowledge-intensive sectors remain underrepresented. Country productivity shows few nations taking the lead with an interesting correlation between research activity and economic prosperity. Moreover, a growing tendency towards empirical methods is observed in contrast to a decrease in literature review papers, coupled with a recent rise in articles that integrate KM and Information Technology (IT). In terms of citation and influences, few published articles have stood out in the journal's history. This is the first comprehensive scientometric research of KMRP describes the state-of-the-art value and provides an outlook of the future.

### ARTICLE HISTORY

Received 11 August 2017  
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### KEYWORDS

Scientometric analysis;  
KMRP; knowledge  
management; intellectual  
capital

## 1. Introduction

Knowledge management (KM) has become a predominant field within the business and management landscape for both researchers and practitioners (Moustaghfir & Schiuma, 2013). The recognition of the fundamental role of knowledge in value creation spawned the concept of the *Knowledge Economy*, making it one of the pillars of contemporary management thinking (Roberts, 2009; Weir, Huggins, Schiuma, Lerro, & Prokop, 2010). Economic growth is no longer reliant on physical capital and labour only as established in nineteenth century theories, but also on the human capital comprised of “knowledge workers” whose innovative capabilities lead the advancement of the current “knowledge society” (Drucker, 1994). This was highlighted by a 1999 World Bank report which provided one of the first comprehensive accounts of the emerging role of knowledge in economic development through a focus on acquisition, application, and transfer of knowledge (*World Bank Annual Report*, 1999). By the end of the twentieth century, the notion of managing knowledge had evolved at the corporate level as organisations acknowledged the need to leverage and exploit their knowledge resources (Carmeli & Tishler, 2004). KM is now considered a vital

organisational function and a key source of sustainable competitive advantage (Davenport & Völpe, 2001). On the other hand, progressive academic works have also established KM as an independent and rich scientific discipline. As a research field, KM has witnessed an exponential growth rate in publications amounting to 50% per year, supported by the foundation of a number of dedicated KM journals and conferences (Serenko, Bontis, Booker, Sadeddin, & Hardie, 2010).

One of the key peer-reviewed journals in the KM field is *Knowledge Management Research and Practice* (KMRP). Available online since 2003, KMRP is the first KM journal to gain an impact factor (Thomson Reuters, 2015). Its aim is to provide an outlet for high-quality peer-reviewed publications including both academic and practical dimensions and the relationship between both perspectives. The journal pays particular attention to cross disciplinary research, mixtures of techniques, and differing schools of thought adopting a broad spectrum of publication themes including empirical research and case studies as well as conceptual and theoretical papers (Springer, 2017). Moreover, KMRP was placed third in 2008 then the second in 2013, according to expert survey rankings conducted on a sample of 25 key KM journals (Serenko & Bontis, 2013a).



While the KM field continues to grow, reflections on literature can allow for more efficient future deliberations on subjects within the discipline, minimise repetition, and create starting points for further advancements in KM theory and practice. This paper provides insights into KM research published in the KMRP, which could arguably apply to the whole KM domain considering that KMRP is a representative example of the wider KM literature. To present the work, the paper is divided into five sections. Following the introduction, the second section offers a brief survey of relevant literature and presents the study's research questions. Section 3 details the study's methodology and the development of the review framework. Findings are presented and analysed in the fourth section, while the final section discusses the work's conclusions and implications for future research.

## 2. Background and research questions

A literature review is a "critical analysis of a segment of a published body of knowledge through summary, classification, and comparison of prior research studies" (Jafari & Kaufman, 2006). It helps to interpret what is known about a research field and to identify gaps in the existing knowledge (Jesson, Matheson, & Lacey, 2011). Several reviews covered KM publications and journals using a number of methods over different time periods. These include but are not be limited to: Citation Analysis (Huang, Chen, & Stewart, 2010; Ma & Yu, 2010; Ribière & Walter, 2013; Serenko & Bontis, 2013a; Serenko & Dumay, 2015) Content Analysis (Fteimi & Lehner, 2016), Journal Ranking (Serenko & Bontis, 2009, 2013b), Meta-review (Serenko & Bontis, 2004) and Scientometric Analysis, the approach adopted in this study (Serenko, Bontis, & Grant, 2009; Serenko et al., 2010).

Scientometrics is *science about science* with distinct identity and methodology (Garfield, 2009). The term has grown in popularity and recognition in the last decades, especially after the founding of the dedicated *Journal of Scientometrics* by Tibor Braun in 1978. It is used to describe the study of science including growth, structure, interrelationships and productivity of a certain research discipline (Hood & Wilson, 2001). Scientometrics portrays a comprehensive picture of research activity within the field and is able to present existing trends supported by quantitative data. In this study, the scientometric approach is adopted to investigate three main research issues within KMRP during the review timeframe:

- (1) *Productivity* – Demographic patterns in the production of KMRP research;
- (2) *Themes and methods* – Trends in topics examined and research tools applied; and
- (3) *Citation* – Analysis of referencing frequency of the journal's papers.

Accordingly, three groups of research questions were formulated to guide the research process as follows.

### *Research productivity in KMRP*

RQ1. What are the dominant trends in authorship distribution?

RQ2. What is the prevailing affiliation of KMRP authors (Academics vs Practitioners)?

RQ3. Which countries are leading in KM research?

RQ4. Is there a relationship between a country's economy and its contribution to KM research?

RQ5. What is the institutional productivity in the journal?

### *Research themes and methods in KMRP*

RQ6. Which research methodologies are most used by authors?

RQ7. What are the most popular industrial sectors in KM research?

RQ8. What are the main research themes in the journal?

RQ9. What is the degree of integration of Information Technology in KM research?

### *Citation analysis of KMRP*

RQ10. Which articles are the most influential in the journal's history?

## 3. Methodology

The research methodology adopted in this study can be summarised in a series of steps. First, the boundaries of article selection for analysis were drawn using criteria for inclusion and exclusion. This set initially included 506 articles published in KMRP between the year 2003 – when the first issue was published – and up to 2015. Editorials, position papers, and book reviews were excluded from the article list. Accordingly, a total of 344 peer-reviewed journal articles was retained for analysis, while 162 were excluded. Second, the research framework was synthesised in light of previous similar works (Fteimi & Lehner, 2016; Serenko & Bontis, 2004; Serenko & Dumay, 2015; Serenko et al., 2010). The subsequent design allows exploration into the various attributes of publications within the selected sample (Table 1).

A pilot review of 10 articles was initially conducted by two researchers for validation purposes. The outcomes of this exercise led to minor modifications of the framework, and helped identify what the authors refer to as *grey areas*, which are article attributes within the framework that are subjective in nature and can vary according to the views of the coder. Grey areas are mainly confined to two review parameters: research method and research topic where the same article can be classified under more than one category within the coding scheme. In such cases, the researchers agreed to code the article under the most predominant theme then cross-check their results.

**Table 1.** Research framework.

Theme	Variables
Productivity	<ul style="list-style-type: none"> <li>• Number of authors – <i>Single vs. multiple authors</i></li> <li>• Affiliation of author – <i>Academic vs. Practitioner</i></li> <li>• Country of residence – <i>where the author is based, not where the work was conducted</i></li> </ul>
Research method <i>Includes data collection method, more than one can be selected</i>	<ul style="list-style-type: none"> <li>• Case study</li> <li>• Interviews</li> <li>• Literature review</li> <li>• Modelling tools</li> <li>• Surveys</li> <li>• Other qualitative – e.g., <i>Focus groups, Delphi, site observation, action research, content analysis, ethnography</i></li> </ul>
Research Topic <i>Most prominent topic in the paper, more than one can be selected</i>	<ul style="list-style-type: none"> <li>• Intellectual capital</li> <li>• Innovation</li> <li>• Organisational learning</li> <li>• Culture and Social issues (social capital)</li> <li>• Performance management</li> <li>• Information system</li> <li>• Communities of practice</li> <li>• Knowledge measurement</li> <li>• Knowledge philosophy/ontology</li> <li>• Other knowledge management</li> <li>• Knowledge sharing</li> <li>• Knowledge transfer</li> <li>• Knowledge creation</li> <li>• Knowledge process</li> <li>• Knowledge acquisition</li> <li>• Knowledge exchange</li> <li>• Use of knowledge</li> <li>• Knowledge audit</li> <li>• Other</li> </ul>
Technology adoption	<ul style="list-style-type: none"> <li>• Use of Technology (<i>yes/no</i>)</li> </ul> <p>Type of KM Technology:</p> <ul style="list-style-type: none"> <li>• Knowledge management system</li> <li>• Internet</li> <li>• Communication technology</li> <li>• Wiki</li> <li>• Social Media</li> <li>• Prototype</li> <li>• Database</li> <li>• Blogs</li> <li>• Decision support systems</li> <li>• Other</li> </ul>
Referencing	<ul style="list-style-type: none"> <li>• Number of citations from Google Scholar database</li> <li>• Keywords</li> </ul>

In the subsequent stage, the articles were mutually coded by both researchers. Finally, full analysis of the resultant data-set was undertaken to identify patterns. When addressing Research Questions 2–5 pertaining to Research Productivity, methods utilising credit analysis were enacted and the researcher had to select the most appropriate method. Authorial credit is generally provided using one of four methods depicted in Table 2.

The Equal Credit Method was selected because it avoids the shortcomings of the three other methods and provides mostly unbiased authorial credit. In addition to Equal Credit, the Direct Count Method was employed in Research Questions 2 and 3 as well and results of both methods were compared. It is worth noting that studies have suggested that the Direct Count, Author Position, and Equal Credit methods can produce similar results, particularly when utilising aggregate data (Serenko, Cocosila & Turel, 2008).

In addressing Research Question 10 regarding citation impact of influential KMRP publications, each

paper's citation impact index was computed to determine the single most highly cited article. The most commonly used measure is the calculation of the total number of citations of each paper since its publication. However, according to Holsapple, Johnson, Manakyan, and Tanner (1994), the weakness of this method is that it does not consider the publication date of the article. It will provide the same score to two publications that are cited the same number of times even if they are published in different years, although the most recent of them would have a higher average number of citations per year. This suggests that the latter publication has had a higher contribution to the field having achieved the same number of citations in a shorter time period, an aspect which the traditional citation index overlooks. To overcome this drawback, Holsapple et al. (1994) propose the use of *Normalised Citation Impact Index (NCII)* which accounts for the paper's longevity thus reflecting the relative contribution of each article. It is calculated by dividing the number of times the article has been

**Table 2.** Methods for assigning author credit.

Method	Description	Example	Criticism
Normalised page size	Number of pages is divided by the number of authors	For 15 pages and 3 authors: Author 1 = 5 Author 2 = 5 Author 3 = 5	<ul style="list-style-type: none"> <li>Assumes longer papers make higher contribution</li> <li>Affected by journal pages' limits</li> </ul>
Author position	Values are assigned according to the author's order in the citation	For 4 authors: Author 1 = 0.415 Author 2 = 0.277 Author 3 = 0.185 Author 4 = 0.123	<ul style="list-style-type: none"> <li>Co-authors are sometimes listed in alphabetical order; so those whose names are earlier in the alphabet are unjustly favoured</li> <li>Does not consider cases where authors have equal contributions</li> </ul>
Direct count	A value of 1.0 is assigned to each author	For 3 authors: Author 1 = 1 Author 2 = 1 Author 3 = 1	<ul style="list-style-type: none"> <li>Gives advantage to researchers who co-author numerous papers regardless of their contribution</li> </ul>
Equal credit	Each author receives an equal credit equivalent to the inverse of the number of authors, regardless of author position	For 3 authors: Author 1 = 0.333 Author 2 = 0.333 Author 3 = 0.333	<ul style="list-style-type: none"> <li>Avoids the drawbacks of previous methods</li> </ul>

Source: Table adapted from Chua and Cousins (2002), Lowry, Karuga, and Richardson (2007).

referenced by the number of years the article has been available [NCII = Total Citations (count)/Longevity in years]. The NCII method is hence adopted in this study in order to provide more reliable results. Individual article citations obtained from the *Google Scholar* database are used to compute the NCII for each article and publications are ranked in descending order according to their indices.

Finally, author keywords were extracted from the review pool using the open-source bibliography reference software *JabRef*. Keywords were then electronically sorted and counted as a part of trend analysis.

## 4. Findings

In an attempt to identify the trends within the current sample, the analysis results are presented over two time periods (2003–2008) and (2009–2015). This format helps to highlight the major changes in the nature of research work published in the journal over its lifetime.

### 4.1. Authorship trends

The average number of authors within the sample is 2.28 authors per paper, however, a growing trend towards multi-authored papers is evident. While the average paper authorship in the first time period (2003–2008) is 1.96 authors per paper, it increased to 2.46 authors per paper in the second time period (2009–2015). The median number of authors has also increased from two to three after 2013 (Table 3). The percentage of single authored papers dropped from 40% in 2003–2008 to less than 20% in 2009–2015, whereas papers with two, three, and four authors witnessed significant increases of 1.5, 8.5, and 9.8%, respectively, (Figure 1). This confirms the findings of Akhavan, Ebrahim, Fetрати, and Pezeshkan (2016) who observe a decline in single-authored works over time and the emergence of collaboration patterns among KM scholars.

### 4.2. Author affiliations

From an affiliation perspective, more than 90% of authors have an academic background and are in direct affiliation with educational and/or research institutions (Figure 2). The remaining 10% of authors are practitioners from service or industrial sectors. Both the Direct Count and Equal Credit methods are used to compute

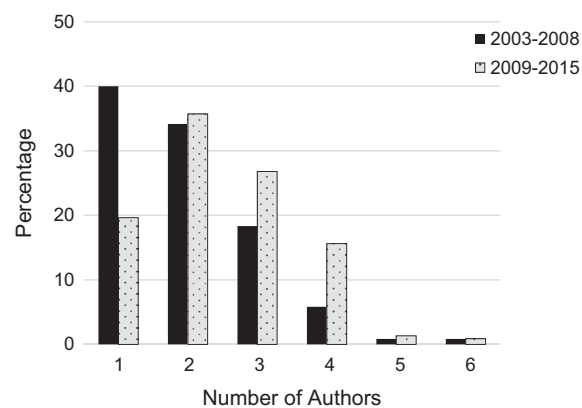


Figure 1. Number of authors.

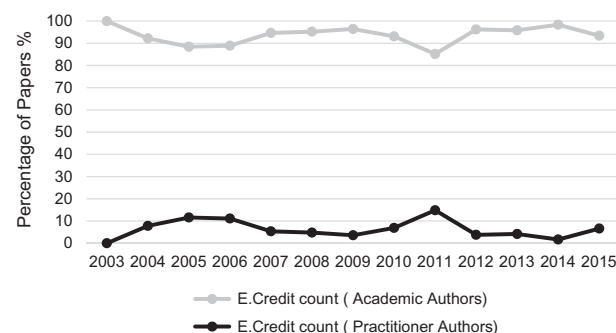


Figure 2. Author affiliation.

the contribution of practitioners and academic authors and no statistically significant difference is found between the results of both methods ( $p$ -value = 0.592).

### 4.3. Country productivity and GDP

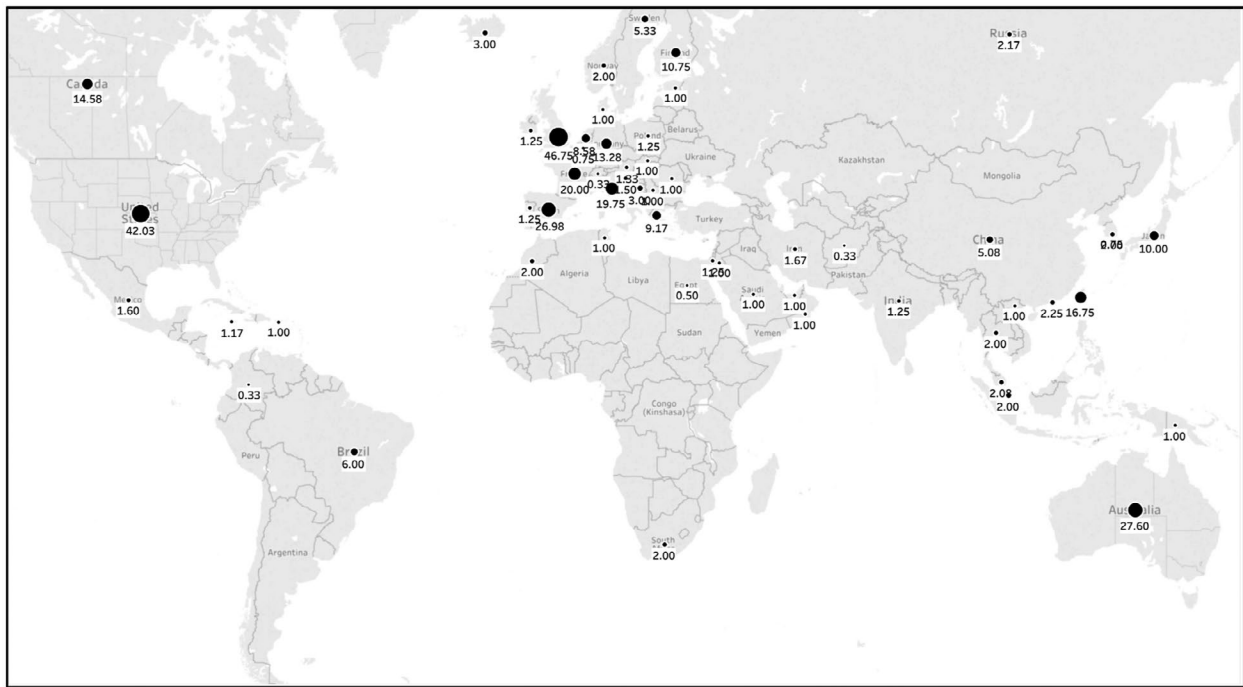
In order to identify the leading countries in the KM field, the relative contributions of 57 countries whose papers are published in the KMRP are traced and ranked using both the Equal Credit and Direct Count methods. Similar results from both methods are obtained and the Pareto Principle or “The Law of Vital Few” is heavily observed (Pareto, 1971). The majority of publications originate from roughly 20% of participating countries as shown in Figure 3 and Table 4. To confirm the findings, the number of citations from each country is counted using the NCII method for all the countries. The same countries of the highest contribution to the journal are found to be on the top of the articles citation list. Statistical analysis also revealed a moderate positive correlation (0.559) between the country Gross Domestic Product (GDP) and contribution to KM research.

### 4.4. Institutional productivity

When examining institutional productivity, Equal Credit is the method of choice for organisations as well. Analysis revealed that, to-date, more than 400 unique

Table 3. Co-authorship Distribution – Number of Authors.

Year	2003	2004	2005	2006	2007	2008	2009
Mean	1.78	1.93	1.61	2.07	2.32	1.86	2.18
Median	2	2	1	2	2	2	2
Year	2010	2011	2012	2013	2014	2015	
Mean	2.34	2.48	2.34	2.48	2.83	2.58	
Median	2	2	2	2	3	3	



**Figure 3.** Country productivity (equal credit score).  
Source: Authors.

**Table 4.** Country productivity ranking.

Rank	Equal credit method		Direct count method		NCII	
	Country	Percentage	Country	Percentage	Country	Percentage
1	UK	13.76	UK	12.74	UK	12.92
2	USA	12.37	USA	12.02	USA	12.52
3	Australia	8.13	Spain	7.69	Japan	8.95
4	Spain	7.94	Australia	7.69	Spain	7.67
5	France	5.89	Italy	5.53	Canada	7.49
6	Italy	5.81	France	5.05	Italy	6.74
7	Taiwan	4.93	Canada	4.81	Finland	4.25
8	Canada	4.29	Taiwan	4.09	Germany	4.14
9	Germany	3.91	Germany	3.85	France	4.10
10	Rest of the world	32.95	Rest of the world	36.54	Rest of the world	31.22

institutions have published articles in the KMRP. The noticeable finding is the minimal variation among individual contributions of each institution where no single institution dominates publications in the journal as shown in Table 5 (*range* = 3.8, *standard deviation* = 0.65). By the same token, the top fifth of contributions comes from more than 27 different institutions. It is also noted that two-thirds of papers are the product of a single institution and 38.6% of the papers are the outcome of multi-institutional collaboration. Furthermore, the top 20% contributors are all academic organisations, which coincide with the prevalence of academic authorship as previously mentioned.

#### 4.5. Research methods

Research methods can be described as all the data collection and analysis techniques that are used for conduction of research activities to solve research problems (Kothari, 2004). Nearly half of the articles (47%) utilised a single method, while the rest of articles used two or more. A

mild to moderate increase in published empirical studies, both quantitative and qualitative, is observed in the second review time period (2009–2015) in comparison to conceptual models and literature reviews which are prevalent in the first review period (Figure 4). Nevertheless, modelling tools and frameworks are still the most used methodology by KMRP researchers, followed by case studies.

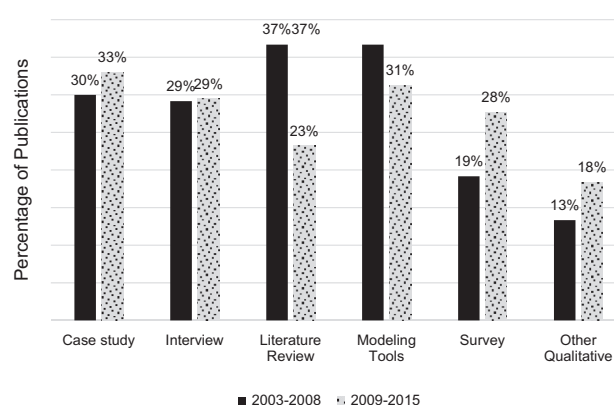
#### 4.6. Industrial sectors

Expanding on the findings from the previous section, articles were thoroughly surveyed for industries which are selected as research fields. While 33% of studies are classified as conceptual studies and thus have no industries, the other two-thirds are conducted in more than 57 different industries and service sectors. Moreover, 15% of papers do not specify a single sector used in data collection. Instead, a mixture of different businesses is used as a non-industry specific convenience sample. This is expected since researchers often tend to gather data



**Table 5.** Institutional productivity.

Rank	Institution	Equal credit	Percentage	Cumulative sum (%)
1	National Technical University of Athens	3.999	1.16	1.16
2	University of Sydney	3.999	1.16	2.33
3	Tampere University of Technology	3.998	1.16	3.49
4	Queens University	3.916	1.14	4.63
5	University of Southampton	3.5	1.02	5.64
6	University of Hull	3.166	0.92	6.56
7	National Taiwan Ocean University	3	0.87	7.44
8	Universidad Computense de Madrid	3	0.87	8.31
9	University of Sao Paulo	3	0.87	9.18
10	Politecnico di Milano	2.75	0.80	9.98
11	Hitotsubashi University	2.5	0.73	10.71
12	University of South Australia	2.5	0.73	11.43
13	University of Southern Queensland	2.499	0.73	12.16
14	Kingston University	2.333	0.68	12.84
15	University of Salento	2.333	0.68	13.52
16	University of Sheffield	2.333	0.68	14.19
17	Loughborough University	2.166	0.63	14.82
18	Bangkok University	2	0.58	15.40
19	Edith Cowan University	2	0.58	15.99
20	Politecnico di Bari	2	0.58	16.57
21	Robert Gordon University	2	0.58	17.15
22	Soochow University	2	0.58	17.73
23	University of Akureyi	2	0.58	18.31
24	University of Alicante	2	0.58	18.89
25	University of Castilla La Mancha	2	0.58	19.47
26	University of Melbourne	2	0.58	20.06
27	University of New South Wales	2	0.58	20.64
28	Other 375 unique institutions	N/A	79.36	100

**Figure 4.** Research methods.

from companies in their network and the ones that they have access to.

Moreover, research and education institutions are on the top of the popularity list. Approximately 12% of the studies are conducted either within universities, research labs and/or rely on the classroom as a case study. Once again, this could be simply attributed to convenience. Information and Communication Technologies (ICT), Healthcare, and High-Tech firms come in the second, third, and fourth places, respectively. Nonetheless, some knowledge-intensive industries such as Pharmaceuticals, Aerospace, and Energy have not received adequate attention in industry-specific publications. Table 6 illustrates the main industry/service sectors in the articles and their relative percentage.

#### 4.7. Research themes

Two approaches are adopted to identify the common research themes within the KMRP body of literature. First, two researchers qualitatively categorised the papers according to their research topic as explained in the review framework. A counter review of the same papers by the other researcher was used to confirm the categorisation of each paper under a single theme. In cases where researchers coded a paper differently, the article was jointly reviewed by both researchers until a classification is agreed, or third opinion was sought. Secondly, a quantitative keywords analysis is used in parallel in order to compare the findings of the thematic analysis.

Results show that 61% of research papers falls within five topics; (1) Knowledge Sharing, (2) Intellectual

**Table 6.** Industrial sectors.

Rank	Industry	%
1	Multi Sectoral	14.8
2	Research & Education	11.6
3	ICT	8.7
4	Healthcare	5.2
5	Technology	4.1
6	Civic Society	2.3
7	Consulting and Training	2.0
8	Automotive	1.7
9	Unspecified	1.7
10	Construction	1.2
11	Engineering	1.2
12	Entertainment	1.2
13	Insurance	1.2
14	Metal industry	1.2
15	Oil and Gas	1.2
16	Aerospace	0.9
17	Banking	0.9
18	Pharmaceuticals	0.9
19	Other industries	13.1
20	Conceptual (none)	32.8

Capital, (3) Knowledge Creation, (4) Knowledge Transfer, and (5) Culture. Some research themes indicate significant growth in the second review time period (2009–2015) in comparison to the first period (2003–2008). For example, there is a growing interest in Intellectual Capital, Knowledge Transfer, Innovation and Culture, while issues such as Knowledge Creation, Knowledge Measurement, Organisational Learning, Information Systems, Communities of Practice have received less interest (Figure 5).

#### 4.8. Keyword analysis

A comprehensive keyword analysis of KMRP articles between 2003 and 2012 undertaken by Ribière and Walter (2013) demonstrate that *Knowledge Sharing* is the most used keyword in the journal. A similar exercise extending until 2015 conducted in this research unsurprisingly yielded the same outcome (Figure 6). The predominance of *Knowledge Sharing* as a keyword, as well as a research theme, confirms the validity of the

thematic analysis outcomes of the previous section. It also elucidates the emphasis researchers have placed on the knowledge sharing process as a precursor of effective KM. Whether the objective is spreading best practice, disseminating innovative ideas, or creating digital repositories, sharing knowledge is often at the core of KM initiatives.

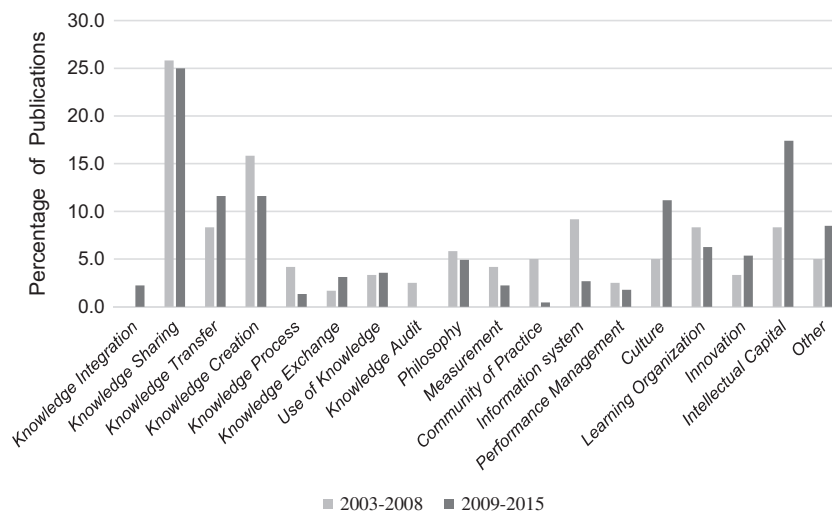
#### 4.9. KM technology

The role of Information Technology (IT) in KM is widely discussed in the literature (Ragab & Arisha, 2013). A common view is that KM should not be reduced to a solely IT-based project as there is a tacit dimension of knowledge which cannot be managed using technological tools (Chatzkel, 2007; Schiuma, 1998). IT is rather envisaged as an essential KM catalyst and an enabler of knowledge sharing processes within and between organisations (Tsui, 2005). This view seems to be reinforced by scientometric figures as, overall, 91% of papers did not include reference to IT.

However, by contrasting the first review period (2003–2008) to the second (2009–2015) in regards to discussing technology, an increase from 4.2 to 11.6% is observed (Figure 7). This demonstrates a movement towards further integration of IT in KM. In this area, the Internet, Databases, and Social Media are the most popular IT solutions within the published papers, a trend in tandem with the digital revolution and the explosive growth of social networking (Figure 8).

#### 4.10. Citation analysis

By examining citation frequency, three articles stand out as the most influential articles in the journal's history based on their NCII (Table 7). It is noted that the top three articles gained 11.8% of the NCII score for all the articles and approximately 80% of citations came from the top 144 articles ( $\approx 40\%$ ). Interestingly, the most



**Figure 5.** Research themes.

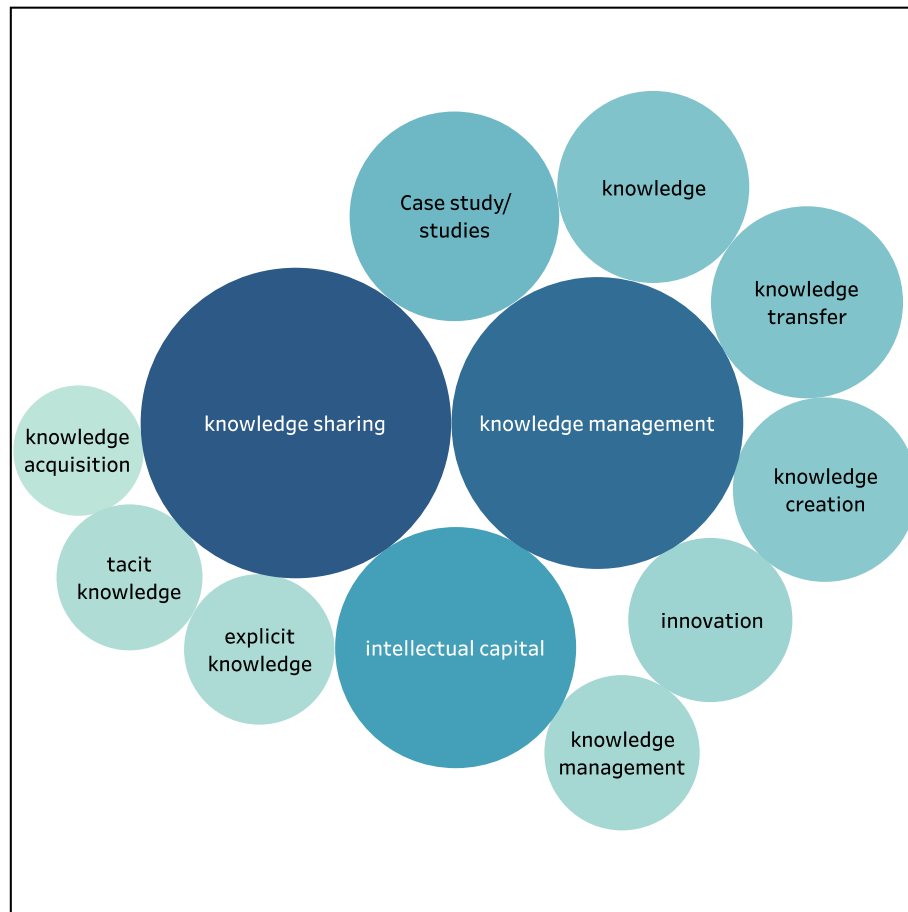


Figure 6. Keyword analysis.

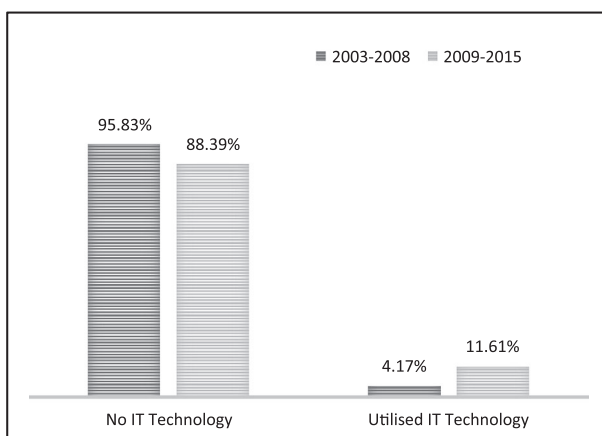


Figure 7. Integration of IT in KM research.

cited article is authored by renowned KM thinker Ikujiro Nonaka and extends on his SECI model (Nonaka, 1994) of knowledge creation, which is regarded as one of the most seminal and highly-cited theories in the history of KM at large, cited 21,360 times.

## 5. Implications and conclusion

In a global economy of knowledge-intensive nature, KM efforts have become a necessity for any organisation to survive and prosper (Davenport & Prusak, 1998). The

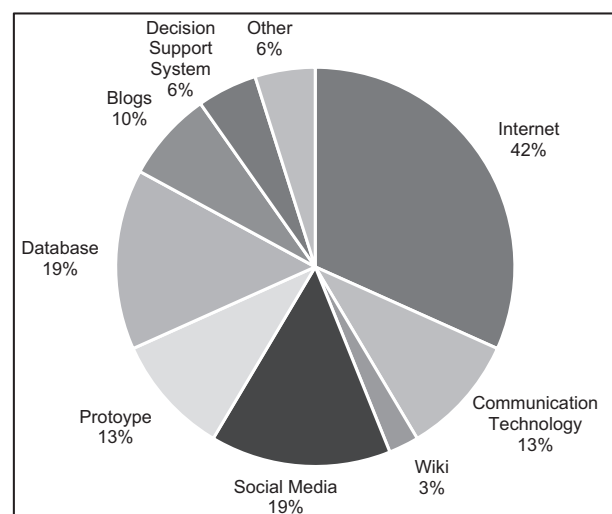


Figure 8. IT technologies.

capacity of an organisation to create value is tied to its ability to identify, manage, and renew its key knowledge assets (Stewart & Ruckdeschel, 1998). The journal of *Knowledge Management Research and Practice* (KMRP) depicts one of the key scientific outlets that has significantly contributed to the development of main research streams in the field of KM. KMRP publications have paid considerable attention to models, tools,



**Table 7.** Highest cited KMRP articles.

Author	Title	Year	NCII
Nonaka, Ikujiro, and Toyama, Ryoko	The Knowledge-Creating Theory Revisited: Knowledge Creation as a Synthesising Process	2003	77.1
Baskerville, Richard, and Dulipovici, Alina	The Theoretical Foundations of Knowledge Management	2006	26.8
Usoro, Abel; Sharratt, Mark W; Tsui, Eric, and Shekhar, Sandhya	Trust as an Antecedent to Knowledge Sharing in Virtual Communities of Practice	2007	18.8

factors, and mechanisms that can support managers in translating knowledge into business performance. After almost 15 years since the foundation of KMRP by the Operations Research Society, the scientometric analysis in this study portrays a comprehensive picture of the growth, structure, interrelationships, and productivity of the published research activities within the journal.

Initially, the study elucidates an increasing trend towards multi-author collaboration especially in recent years. This posits an indication of the maturity of the KM domain where authors develop relationship networks and collaborate to overcome the current increasingly challenging journal acceptance rates. The findings are also in line with the broader bibliometric studies of Metz (1989) and Terry (1996) which report a general phenomenon of progressive trends in co-authorship in other research disciplines. An additional indicator of maturity is represented in the findings of unbiased distribution of papers among a wide range of research and professional organisations. Over 400 institutions are involved in KM research, either in individual or cooperative studies, emphasising the growing interests in knowledge-based research.

Looking at research methods, there is an increasing propensity towards empirical methods in contrast to a decrease in literature review studies. This is further suggestive of maturity and an ongoing shift from theory to practice where field studies are increasingly undertaken to explore KM issues in real-life contexts and collect first hand data. This tendency seems to be a general trend in the KM field, as indicated by results of similar studies. For example, a recent content analysis of the proceedings of the European Conference of Knowledge Management (ECKM) between 2006 and 2013 revealed that model and framework development were the most favoured research method followed by case studies and questionnaires (Fteimi & Lehner, 2016). With respect to the contribution of practitioners, the study reveals it is academic authors and institutions who dominate publications with the percentage of practitioners averaging around 10% over the years. Despite the apparent stability in the percentages of practitioners to academic authors in KMRP over the years (Figure 2), other studies have shown otherwise. A study by Serenko et al. (2009) revealed that the number of practitioners declined from approximately one third of all contributors in the late 1990s to 10% by 2008. These findings suggest an impetus to deeper engagement of practitioners in KM research

to support the movement towards the development of applied KM solutions.

While this study encompasses a multitude of research topics, knowledge sharing emerges as the leading choice of researchers. Along the same line, knowledge sharing technologies (e.g., internet and social media) are the leading IT solutions employed to support the KM process. The prevalence of the knowledge sharing theme elucidates the emphasis researchers have placed on the knowledge sharing process as a precursor of effective KM. Whether the objective is spreading best practice, cultivating and disseminating innovative ideas, or creating digital repositories, sharing knowledge is often at the core of KM initiatives. KM work often focuses on the role of *knowledge flows* among individuals and between individuals and the organisation to drive value creation (Bolisani & Oltramari, 2012; Schiuma, 2006). It is hence not surprising that the most influential article published by the journal extends Nonaka's work on the *SECI Model*, a fundamental theory of knowledge creation and sharing antecedents within organisations.

Furthermore, statistical analysis has revealed a correlation between KM research activity and economic prosperity as the leading contributing countries are in North America, Western Europe, and Australia. The link between the focus on knowledge and national wealth reinforces the theory established by Drucker (1994) in his discussion of the post-Second World War (WWII) economic transformations from goods to intangibles in what is dubbed today as the *Knowledge Economy*. Nevertheless, from an industry perspective, key knowledge-intensive industries remain underrepresented in KM research. This could be considered as an opportunity for future researches to direct their efforts towards such relatively under-published sectors. The fact that most KM research is conducted in education and research institutions could be simply attributed to convenience. Researchers often find access within their own organisations, or in similar academic ones, more feasible than the challenge of penetrating new industries to obtain data. Unless sectorial comparison is sought, limited access could also explain why 15% of authors opted to gather data from multiple sectors within the same study.

In conclusion, this study provides evidence that the field of KM is reaching maturity which poses at least two challenges. Firstly, the need to identify key future trends of research development in the field, and second, the

need to conduct research of more applied nature. KMRP publishes both quantitative and qualitative papers, however, the discriminating factor to bear in mind is the relevance of the contribution to KM practice. Emphasis must be placed upon the consideration that while managers are interested in knowledge and its management, it is often not for the sake of mere KM theories. Rather, their interest is rooted in the need to understand how organisational knowledge assets can be translated into drivers that positively impact and enhance business value creation mechanisms.

Limitation of this study lies in the fact that it encompasses only one single journal (i.e., KMRP). While KMRP is one of the most established periodic in the KM field, exclusion of others does not ensure the generalisability of findings across wider KM landscape. It is, therefore, recommended that a similar review framework would be applied to other KM journals in future studies to enable comparison and validation of results garnered from this project.

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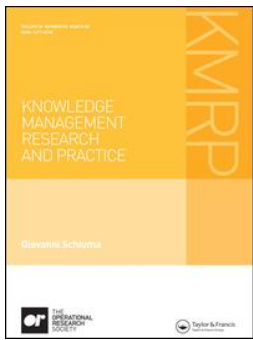
## Disclosure statement

No potential conflict of interest was reported by the authors.

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## Knowledge management in the pharmaceutical industry between academic research and industry regulations

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ORIGINAL ARTICLE



# Knowledge management in the pharmaceutical industry between academic research and industry regulations

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## ABSTRACT

The pharmaceutical sector is one of the pillars of the world's economy. A significant proportion of its value lies in intellectual assets generated through continuous innovation and lengthy development cycles within a strictly regulated environment. The purpose of this paper is to address the gap between knowledge management (KM) as an expanding academic discipline in the pharmaceutical industry and at the same time a growing regulatory expectation. A systematic review of 137 refereed KM articles revealed six empirical research themes in the pharmaceutical industry. In a subsequent step, the discovered themes and subthemes were compared with the extant regulatory expectations as explained in 128 regulatory guidelines. Findings shed the light on the gap between academic KM research and the current thinking of regulatory bodies. Some regulated knowledge processes were underrepresented in academic literature. The paper offers also novel insights and recommendations for future developments in academic research, regulations, and/or industry.

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regulatory; intellectual  
Capital; systematic review;  
ICH Q10; prisma

## 1. Introduction

The acknowledgement of knowledge as a pivotal strategic resource in the current smart economy has impelled considerable organisational change. This progressive movement by individuals and organisations to manage their intellectual assets developed into KM (Davenport & Völpe, 2001). The Pharmaceutical industry is not an exception to this trend, not only as a knowledge-intensive industry but also as a leading economic partner with transcendent investments in innovation and research. According to European Federation of Pharmaceutical Industries and Associations (EFPIA), The Pharmaceutical industry employs more than 750,000 employees in Europe, 16% of them working in Pharmaceutical Research and Development (R&D) (EFPIA, 2018).

It is not strange that the significance of KM is also realised by major pharmaceutical regulatory authorities. International Council for Harmonisation (ICH) recommends management of drug and process knowledge from development and up to product discontinuation as an enabler of effective quality management systems. From this perspective, KM creates the basis for the manufacturing process, control strategy, and ongoing continual improvement (ICH, 2009). On the other hand, there are some signs of regulatory immaturity of KM. The term “knowledge” is relatively new in regulatory publications and is routinely replaced by indirect words such as “science” or “product/process understanding” (Calnan et al., 2018). Moreover, KM

is seen by ICH only as an enabler of The Pharmaceutical quality system (ICH, 2009).

Thus, as knowledge is another core product of the pharmaceutical industry (Riddell & Goodman, 2014), managing stocks and flows of knowledge in this sector emerges as a key economic and regulatory objective as well as a growing area of academic research. Nonetheless, some knowledge-intensive industries such as pharmaceuticals have not received adequate attention in industry-specific publications (Ramy et al., 2017). This paper comes as a comprehensive industry-specific systematic review of KM literature between the academic research and regulatory expectations.

## 2. Review methodology

The high expectations of improving the quality of reviews through well-defined methodologies led to the development of systematic review protocols (Jesson et al., 2011). Systematic review protocol encompasses specific research questions, the population that is the focus of the study, the search strategy, and terms for identification of the relevant studies. Studies that meet all inclusion criteria and manifest none of the exclusion criteria need to be integrated into the review (Davies & Crombie, 1998; Tranfield et al., 2003). The authors commenced his review by identifying three research questions:



Q.1 How is the KM literature in pharmaceutical/biopharmaceutical industry developing?

Q 2. What are the expectations of regulatory agencies with regard to the identified research themes?

Q 3. What is the future of KM research within the pharmaceutical industry?

After refining the review questions, the timeframe of review is set to be the last twenty years (1996–2016). This time period represents the prosperous period of KM research (Ragab and Arisha, 2013a). Furthermore, the timeframe took into account the relative novelty of online KM journals. According to Serenko and Bontis (2013) ranking of the KM journals, the top-ranked four KM journals (JKM, KMRP, IJKM, and JIC) have been published online only since 1997, 2003, 2005, and 2000, respectively.

The criteria for inclusion comprise peer-reviewed electronic business journals in the English language retrieved from *Emerald Insight* and *Science Direct* database (Table 1). Pharmaceuticals related search strings in the titles, keywords, or abstracts were used to identify the relevant articles. Search strings were synthesised by combining terms like “pharmaceutical” or “pharmaceutical industry” with the most popular KM keywords (such as knowledge sharing, intellectual capital, knowledge transfer, or innovation) extracted from two comprehensive keyword analysis studies in the KM discipline: Fteimi and Lehner (2016) along with Ribière and Walter (2013). After a brainstorming session by the authors, potential search strings were approved. The list was updated during the search process. It was meant not to tightly plan the review process as this may inhibit researchers’ capacity to explore, discover, and develop ideas (Tranfield et al., 2003).

After the exclusion of duplicates, Articles that have been retrieved from the search results were screened against the inclusion and exclusion criteria by reviewing the titles and abstracts (Pati & Lorusso, 2018). A full-text assessment followed where the full-text articles were scrutinised to assess relevance to the review questions. The retained articles addressed a KM related topic exclusively in the field of pharmaceutical industry or in conjunction with other industries. To mitigate the risk of bias of the reviewed studies (Moher et al., 2015), 141 eligible articles were quality-assessed for the

clarity of research objectives, adequacy of description of the data collection methods and finally the link between data, results, and conclusion as advised by Kitchenham and Charters (2007). Four articles were excluded at this stage due to ambiguous methodology and irrelevance to pharmaceutical industry. Ultimately, only 137 articles were retained for analysis after application of inclusion/exclusion criteria and quality assessment. A limited number of non-business journal papers (e.g., medical journals) and papers identified through cross-referencing and hand searching were included (Figure 1).

After acknowledgement of main themes and processes in KM literature; the identified themes were scrutinised in the regulatory guidelines of five major regulatory bodies. The reviewer collected all the published guidelines for pharmaceutical industry on the official websites of World Health Organisation (WHO), FDA, ICH, The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (jointly referred to as PIC/S) and EudraLex- European Union (EU) Legislation. At the end, 128 guidelines were searched for KM related topics in light of the identified themes from academic literature review. The analysis was meant to recognise the significance of research themes from regulatory perspective as well as the possible research gaps in this field.

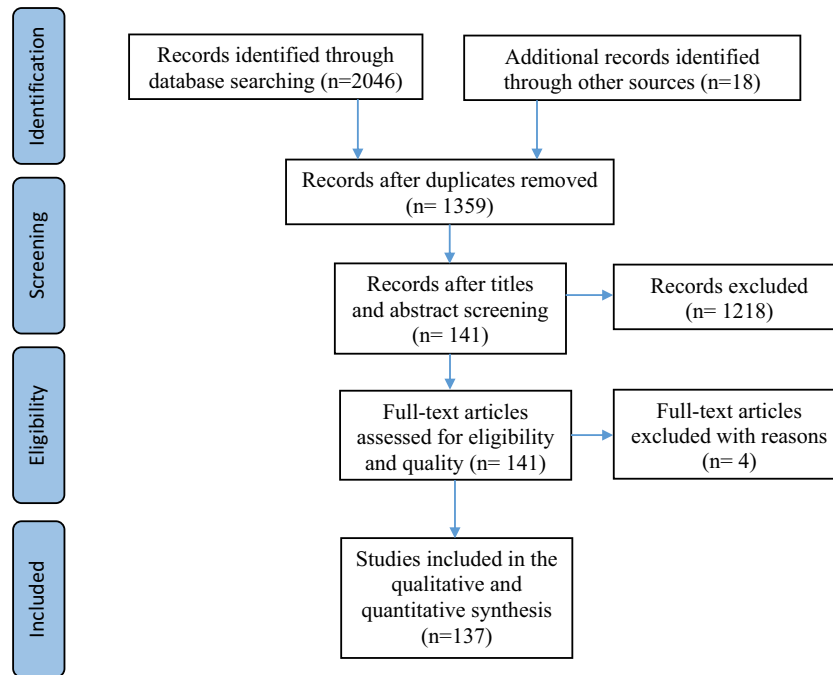
### 3. Findings

#### 3.1. Scientometric trends

Initially, findings indicate that KM in the Pharmaceutical industry has become a well-established academic research area. Authorship trends show that approximately 93% of articles are published by academic researchers, while the remaining 7% is the product of practitioner work. Over the past ten years, a significant increase in collaborative research from 62% to 85% is also evident. Among the articles which do specify the function under study (approx. 40%), 83% fall within pharmaceutical development and innovation functions in contrast to only 8% in production, 4% in sales and 4% in supply chain. In order to identify the leading countries in the KM field, the relative contributions of 36 countries whose papers were included in this review are traced and ranked using the Equal Credit counting method (Chua & Cousins, 2002; Lowry et al.,

**Table 1.** Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
KM theories and processes	Not related to KM
With applications in pharmaceutical industry	Applied exclusively in other industries
Peer reviewed journal articles	Editorials and position papers
In English language	Articles that use languages other than English
Published online between 1996 and 2016	From journals that don't have online domains and unpublished work.



**Figure 1.** Systematic review process – PRISMA flow diagram (Moher et al., 2015).

2007). The USA and UK were ranked highest with regards to productivity (18% and 11%, respectively, of all reviewed articles); followed by Iran (7%), Australia (7%) and India (6%). It is worth noting that country contribution in this research addresses the country of residence of the author not necessarily where the research was held (Figure 2).

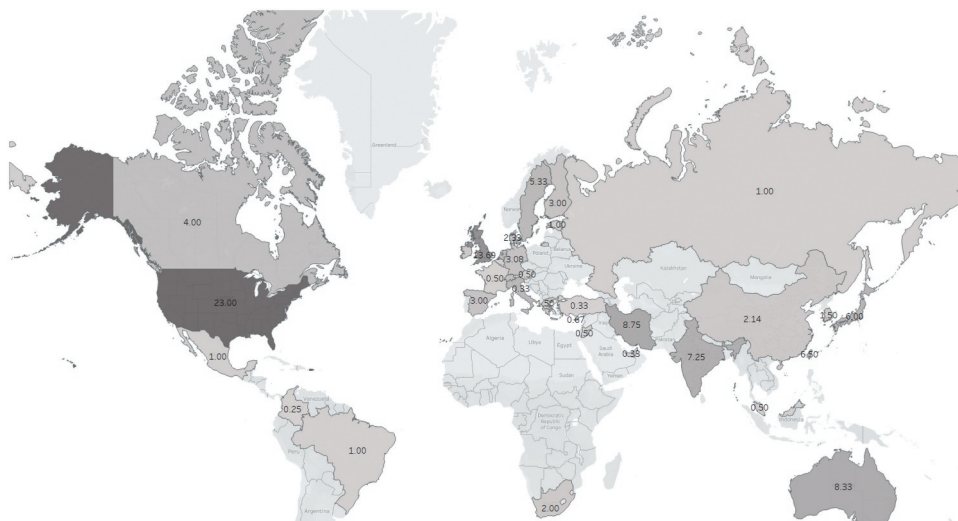
In terms of methodology, only 29% of the articles adopt literature review as the research strategy; while over 70% are empirical studies employing one or more data collection methods, e.g., surveys (29%), case studies (10%) and interviews (17%).

### 3.2. Research themes

A hybrid method of quantitative keyword analysis and qualitative thematic analysis is proposed to

identify the common research topics or themes. The most frequent themes and keywords (after exclusion of generic keywords, e.g., knowledge management, pharmaceutical ..., etc..) are presented in (Table 2).

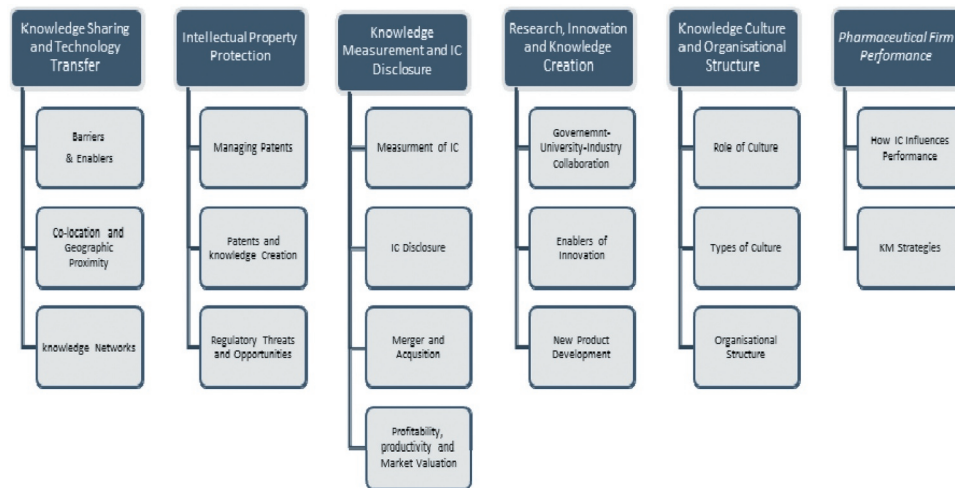
The identified themes and keywords offer a birds-eye view of the KM landscape. The paper presents a classification of KM publications into six areas: knowledge sharing and technology transfer, Intellectual Property Protection (IPP), knowledge measurement and Intellectual capital (IC) reporting, innovation and knowledge creation (KC), organisational knowledge culture and structure as well as Pharmaceutical firm performance (Figure 3). The rest of articles falls in miscellaneous category that includes other themes such as: organisational learning, knowledge management maturity, data mining, etc. Table 3 presents the key articles under each of the featured themes.



**Figure 2.** Country productivity.

**Table 2.** Themes and keyword analysis.

Rank	Themes & K. processes	Frequency	Keywords	Frequency
1	Intellectual Capital	29	Intellectual Capital	27
2	Innovation	25	Innovation	18
3	Knowledge Transfer	14	Knowledge Sharing	10
4	Knowledge Sharing	13	Knowledge Transfer	10
5	Organisational Performance	12	New Product Development	9
6	Organisational Culture	12	Research and Development	9
7	Intellectual Property	10	Intangible Assets	8
8	Knowledge Creation	9	Organisational Learning	7
9	New Product Development	6	Organisational Culture	5
10	Organisational Learning	6	Project Management	5

**Figure 3.** Literature map.**Table 3.** Key articles under the featured themes.

Category	
Knowledge Sharing and Technology Transfer	(Wakefield, 2005); (Styhre et al., 2008); (Qureshi & Evans, 2015); (Akhavan et al., 2015); (Pedroso & Nakano, 2009); (Mets, 2006); (Lilleore & Hansen, 2011); (Lawson & Potter, 2012); (Hemmert, 2004); (Gray et al., 2011); (Dooley & Kirk, 2007); (Delaney, 1999); (Crisuolo, 2005); (Coradi et al., 2015); (Chávez & Viquez, 2015); (Brachos et al. 2007); (Bourouni et al., 2015); (Azan and Huber Sutter 2010); (Allen et al., 2016); (Santos, 2003); (Mohan, Jain, and Ramesh 2007); (Malik, 2012); (Iwasa and Odagiri 2004); (Filieri et al. 2014); (Chang, Yeh, and Yeh 2007); (Buchel et al. 2013); (Bourouni et al., 2015)
Pharmaceutical Firm Performance	(Mehralian et al. 2012); (Malik, 2012); (Kim et al., 2014); (Vishnu & Gupta, 2014); (SubbaNarasimha et al., 2003); (Sharabati et al., 2010); (Pal & Soriya, 2012); (Kamath, 2008); (Garcia Morales et al., 2008); (Bollen et al., 2005)
Research, Innovation and Knowledge Creation	(Terziovski and Morgan 2006); (Styhre et al., 2002); (Sternitzke, 2010); (Standing and Kiniti 2011); (Sharma and Goswami 2009); (Roth, 2003); (Parisi and Hockerts 2008); (Palacios-Marqués, Popa, and Mari 2016); (O'Dwyer et al. 2015); (Nightingale, 2000); (Mehralian et al. 2014); (Lowman et al., 2012); (Lauto and Valentin 2016); (Kneller, 2003); (Khemka & Gautam, 2010); (Kazadi, Lievens, and Mahr 2015); (Kale & Little, 2005; Huang, 2011; Hohberger, 2016; (Herrmann and Peine 2011); (van Geenhuizen and Reyes-Gonzalez 2007); (Gassmann & Reepmeyer, 2005); (Garcia Morales et al., 2008); (Filieri et al. 2014); (Chen, Jiao, and Zhao 2008); (Chang et al. 2007); (Cardinal & Hatfield, 2000); (Styhre et al., 2008); (Mets, 2006); (Lowman et al., 2012); (Lauto and Valentin 2016); (Kazadi et al. 2015); (Gassmann & Reepmeyer, 2005); (Cardinal & Hatfield, 2000); (Boasson and Boasson 2015); (Mohan et al. 2007)
Intellectual Property Protection	(Yang et al. 2014); (Iwasa and Odagiri 2004); (Boasson and Boasson 2015); (Allarakhia & Walsh, 2011); (Sternitzke, 2010); (Kale and Little 2005); (Hohberger, 2016); (Chávez & Viquez, 2015); (Russell 2016); (Bollen et al., 2005)
Knowledge Culture and Organisational Structure	(Wang, Ashleigh, and Meyer 2006); (Mehralian et al., 2016); (Magnier-Watanabe & Senoo, 2008); (Magnier-Watanabe & Senoo, 2010); (Magnier-Watanabe et al., 2011); (Magnier-Watanabe & Senoo, 2009); (Lindner & Wald, 2011); (Guzman, 2008); (Evans & Brooks, 2005); (Ebrahimi et al., 2008); (Bigliardi et al., 2012); (Filieri et al. 2014)
Knowledge Measurement and IC Disclosure	(Vishnu & Gupta, 2014); (Tahvanainen and Hermans 2005); (SubbaNarasimha et al., 2003); (Singh & Kansal, 2011); (Sharabati et al., 2010); (Palacios-Marques & Garrigos-Simon, 2003); (Pal & Soriya, 2012); (Narula, 2016; Naidenova & Parshakov, 2013; (Mehralian et al. 2013); (Mehralian et al. 2013); (Kamath, 2008); (Huang and Wu 2010); (Hine, Helmersson, and Mattsson 2008); (Ghosh & Mondal, 2009); (Erickson & Rothberg, 2009); (Hosein Chizari et al., 2016); (Bollen et al., 2005); (Boekestein, 2006); (Boekestein, 2009); (Abhayawansa & Azim, 2014); (Sydler et al., 2014); (Russell, 2016); (Rossi et al., 2015); (Nito, 2005); (Mehralian et al. 2012); (Mehralian et al. 2014); (Huang et al., 2011)



### 3.3. Publication years

The review shows that the majority of included articles have been published between 2004 and 2016 as shown in (Table 4).

### 3.4. Knowledge Sharing (KS) and technology transfer

More than 19% of reviewed articles addressed knowledge sharing and transfer signifying that Knowledge transfer (KT) holds a special significance in the Pharmaceutical industry. Therefore, the WHO dedicates Annex 7 of Technical Report Series no.961 to discuss dynamics and controls of technology transfer occurring at some stage in the lifecycle of most products in the pharma industry. However, the real significance of KS comes from the fact that it is the component that facilitates continuous knowledge creation (Akhavan et al., 2012) and is a key driver of long-term success in a knowledge-intensive organisation (Coradi et al., 2015). Accordingly, Qureshi and Evans (2015) identify nine categories of deterrents of KS in the pharmaceutical organisation. They can be broadly classified as either structural barriers, cultural barriers, or managerial barriers.

Other studies focused on the attitudes necessary to enhance knowledge sharing (Akhavan et al., 2015). Also, Knowledge Networks (KN) are increasingly considered vital channels to achieve strategic objectives in project-based organisations particularly Pharma R&D (Bourouni et al., 2015). By the same token, structural indexing and knowledge dictionaries can identify knowledge agents and evaluate intra-organisational knowledge sharing. Enhancing knowledge flow among R&D stages can be crucial to shorten the product to market timing (Wakefield, 2005).

As physical proximity is one of the suggested barriers for *Knowledge Sharing and Technology Transfer* (Lilleoere & Hansen, 2011), several studies handle this topic in pharma explicitly. For instance, studies conducted in the R&D department of multinational drug manufacturer *Novartis* reveal that co-location of dispersed project teams leads to faster and more precise flow of knowledge (Coradi et al., 2015).

On a macro scale, an equally significant aspect of inter-organisational KS is geographic distribution. Higher quality risk can accompany offshore manufacturing due to challenges of KT from headquarters (Gray et al., 2011). Pharmaceutical firm location is found to influence the intensity of communication between different firms but not the innovation. Relocation (e.g., into industry clusters) and expensive real estate investments can be replaced by enhancing the social connections through technology (Allen et al., 2016). In spite of that, having an R&D laboratory near corporate headquarter enhances new drug productivity as proximity is necessary for the integration of R&D with other functions (Cardinal & Hatfield, 2000).

### 3.5. Intellectual Propriety Protection (IPP)

There is no industry where firms build their competitive advantage more closely to IPP than the pharmaceutical industry. However, in response to dramatic transitions in bioscience and computational chemistry, biopharmaceutical companies commence newer approaches for managing their IP and innovation including open access, exclusive and non-exclusive licencing (Allarakhia & Walsh, 2011). Although the exclusive licencing is more preferred in the pharmaceutical industry (2:1), non-exclusive licencing provides a strategic advantage to the company and

**Table 4.** Publications per year.

Year	Intellectual property protection	Knowledge culture and organisational structure	Knowledge measurement and IC disclosure	Knowledge sharing and technology transfer	Pharmaceutical firm performance	Research, innovation and knowledge creation	Miscellaneous	Total
1996							1	1
1997							1	1
1998							1	1
1999				1				1
2000						3	1	4
2001								
2002						1	1	2
2003			2	1	1	2	1	7
2004	1			2			5	8
2005	2	1	3	2	1	3	5	17
2006		1	1	1		2	2	7
2007				4		3	4	11
2008		3	2	1	2	4	9	21
2009		1	4	1		1	3	10
2010	1	1	2	1	1	2	2	10
2011	1	2	2	2		3	3	13
2012		1	2	2	3	2	1	11
2013			3	1			3	7
2014	1	1	4	1	2	2	4	15
2015	2		1	6		4	3	16
2016	2	1	3	1		4	3	14

reduces market uncertainty by decreasing competition (Malik, 2012).

The real significance of IP for the pharmaceutical industry comes from the belief that patents are used as a proxy indicator of knowledge creation (Nerkar, 2003). Also, patent citations studies in pharma exploit patent-related data to estimate the quality of innovation, diffusion of knowledge and geographic localisation of knowledge (Chávez & Viquez, 2015). For this reason, patents can affirm firm's value and market performance. Association between company value, reported intangible assets and R&D capitals is proven (Russell, 2016).

In a highly dynamic global economy, enforcing IP protection laws implies significant costs particularly on developing economies (Mazzoleni & Nelson, 1998). Nevertheless, IPP is an important incentive for innovation in advanced countries enjoying both a superior technological infrastructure as well as a rich market for new drug (WHO, 2006a).

### 3.6. Knowledge measurement and IC disclosure

Empirical evidence supports the notion that the nature and value of knowledge assets differ from industry to another with a direct impact on investment decisions. By using Tobin's Q model for knowledge measurement, it is noticed that not only the level of intellectual capital (IC) and competitive intelligence are both higher in consumer industries (such as pharmaceuticals) in comparison to business to business industries, but also investments in knowledge assets are more promising (Erickson & Rothberg, 2009). Measurement of pharmaceutical IC at organisational level relies on the identification of most relevant constructs or indicators in each industry (Palacios-Marques & Garrigos-Simon, 2003). For example, management experience and technical knowledge are on the top of HC indicators in pharma. Regarding structural capital, organisational culture, the ratio of investment in R&D and the number of R&D projects are the highest priority indicators. Additionally, mutual trust with customers and their satisfaction are the highest priority RC indicators (Mehralian et al., 2013).

However, the disclosure of IC in balance sheet (BS) is still a measurement barrier and an opportunity for improvement in the pharmaceutical industry, particularly in developing countries. The lack of standardised accounting guidelines on this vital asset results in unreporting of resources of billions in firm's annual reports with an impact on their performance in the stock market (Abhayawansa & Azim, 2014).

Intellectual capital is widely adopted as a predictor for firm's profitability in pharmaceutical sector (Sydler et al., 2014). Healthcare patents reflect firm's innovative capabilities and enhance the capacity to raise necessary start-up capital (WHO, 2006a). However,

no significant relationship was observed either between IC and productivity or market valuation (Ghosh & Mondal, 2009; Pal & Soriya, 2012). This argument is subject to controversy as companies which generate more profits are able to invest more in IC (Naidenova & Parshakov, 2013).

In the pharmaceutical industry, Merger and Acquisition (M&A) is used as a cost-effective way to gain access to new product platforms, technologies and patents; traditional pharmaceutical companies with dried-out research pipelines but sufficient cash acquire innovative biotech firm as a source of new products (Rossi et al., 2015). M&A can be seen as an opportunity to overcome the underestimation of intangible assets under current accounting systems in pharma companies (Boekestein, 2009).

### 3.7. Research, innovation, and Knowledge Creation (KC)

The emergence of new discoveries in the twenty-first century will urge Pharmaceutical manufacturing to employ innovation and cutting-edge technology as ways of doing business (FDA, 2004b). Nowadays, pharmaceutical industries do not typically fit to the classic economy of scales theories as they transformed into R&D intensive rather than production intensive (Gassmann & Reepmeyer, 2005). Pharmaceutical industry becomes more than other industries dependent on scientific advances, particularly in basic sciences, developed in public sector (Sternitzke, 2010). Historically, public sector role in drug discovery was limited to basic research to elucidate the basic pathological mechanisms. However, this role has significantly expanded in the biotechnology era (Stevens et al., 2011). In contrast with publically funded drug research model in EU and US universities, it is noticed that drug discovery in Japanese companies occurs predominately in-house which may be no longer compatible with global competitiveness (Kneller, 2003).

In such a complex R&D environment, information sharing and intrinsic motivation are recognised as important drivers for organisational creativity (Sundgren et al., 2005). There is a significant influence of knowledge transfer on firm innovative capability ( $r = 0.893$ ) too (Palacios-Marqués et al., 2016). As the bulk costs of R&D come from the clinical phases, sharing knowledge and experiences coming from terminated projects would be of high significance (Styhre et al., 2008).

Surveyed literature highlights some of the dynamics of innovation within pharma organisation. Management support and effective management of knowledge are found indispensable if the organisation wants to adopt an innovative environment. Additionally, Job satisfaction explains up to 25% of the variance in innovation regression models (Khemka & Gautam, 2010).

Transformational leadership shows a positive relationship with innovation (Garcia Morales et al., 2008). Also, a significant positive relationship is established between organisation capital and innovation confirming the remarkable role of intangible assets in generation and enhancement of innovative capabilities (Huang et al., 2011).

Conversely, outsourcing of R&D and clinical studies for new product development (NPD) and the associated knowledge losses as well as regulatory delays create innovation risks (Lowman et al., 2012). Likewise, FDA warned from the threats of broad interpretations of 21 CFR part 11 (electronic records and electronic signatures) on innovation and technological advances without any benefit for patient health (FDA, 2003).

### 3.8. Knowledge culture and organisational structure

FDA encourages management to implement quality systems and procedures that support a communicative culture. Under such work culture, employee suggestions are appreciated and used for continual improvement (FDA, 2006). Along the same line, beliefs and knowledge-related values (love, care and trust) can be potential sources of competitive advantages in pharma (Magnier-Watanabe & Senoo, 2009).

Knowledge culture is a way of organisational life that empowers people to create, share, and use knowledge for the good of the organisation (Oliver & Kandadi, 2006). In the pharmaceutical industry, knowledge culture is believed to compensate for the lack of organisation memory in temporary project teams where information Communication Technology (ICT) systems are not enough alone for ensuring the exchange of knowledge (Evans & Brooks, 2005; Lindner & Wald, 2011). Organisation memory held by ageing workers can be transferred to the younger workers through bridges of socialisation and adequate organisational climate (Ebrahimi et al., 2008).

Organisational characteristics of pharmaceutical firm such as structure and strategy affect knowledge acquisition activities including knowledge storage, diffusion, and application (Magnier-Watanabe & Senoo, 2008). In fact, organisational characteristics can have even more influence over KM than national culture (Magnier-Watanabe & Senoo, 2010). For example, open culture where employees can raise questions and feel at ease explains 31% of the variance in four modes of SECI process compared to only 16% for bureaucratic culture (Magnier-Watanabe et al., 2011). In pharmaceutical R&D, bureaucratic culture has a negative impact on knowledge workers' job satisfaction while innovative or supportive culture positively influences them (Bigliardi et al., 2012).

### 3.9. Pharmaceutical firm performance

Human and Relational Capital is deemed to positively impact business performance of the pharmaceutical firm (Sharabati et al., 2010). Several empirical studies have underlined this paradigm utilising either return on asset (ROA) as performance measures (Vishnu & Gupta, 2014); whereas, Value Added Intellectual Coefficient (VAIC) (Chizari et al., 2016) or generation of new patents were used as proxies for technical knowledge of firms (SubbaNarasimha et al., 2003). Even more striking is the fact that each of the three components of IC is not only individually related to firm performance, but also they collaborate together in the way they influence firm performance (Bollen et al., 2005). KM performance is considered as a predictor of superior financial performance in terms of higher profit ratios (ROA, ROS) and lower cost ratios (OPEX) (Holsapple & Wu, 2011).

KM strategies can influence organisational performance in pharma. Information system maturity in the pharmaceutical firm as well as knowledge intensity would be the determinants for the most effective KM strategy (Kim et al., 2014). Internal organisational tensions between tacit-oriented and explicit-oriented strategies, which are difficult to reconcile, would negatively impact the performance (Choi et al., 2008).

### 3.10. Regulatory insights

A thorough exploration of KM in 128 Good Practice (GxP) quality guidelines (Table 5) has revealed a slightly different pattern of interests and expectations in comparison with the academic business journals (Figure 4).

An overview of the current thinking and expectations of key regulatory bodies regarding KM is presented as follow:

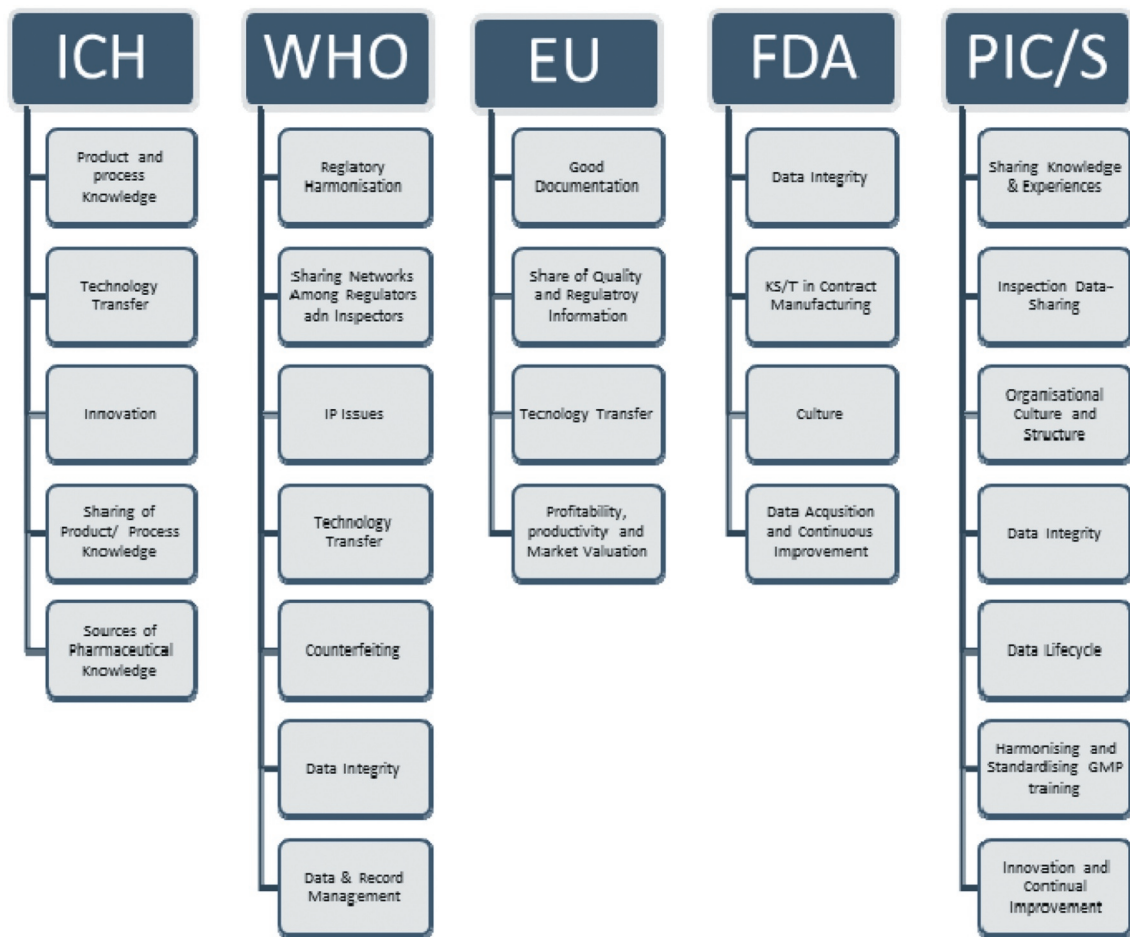
### 3.11. ICH

From the previous review sections, KM expresses a considerable level of maturity as an academic research field in the pharmaceutical industry. Despite that, KM shows less mature roles at industry level which might hinder the achievement of ICH Q10 desired state (Calnan et al., 2018). KM received meagre attention by regulatory agencies (Rathore et al., 2017). For instance, ICH Q10 considers KM together with QRM as the enablers of its effective implementation throughout the product lifecycle. Proper implementation of ICH Q10 guidelines is deemed necessary for innovation and continual improvement and strengthening the link between pharmaceutical development and manufacturing activities. Last but not least, ICH Q10 suggests monitoring of all innovations

**Table 5.** Regulatory insights into knowledge management.

KM theme	EU GMP	ICH	FDA	WHO
Knowledge Sharing and Technology Transfer:	N/A	ICH Q9 on quality risk management (4.5.); ICH Q9 on quality risk management. (II.3.); ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7 (17.60); ICH Q11 – Development and Manufacture of Drug Substances (9); ICH Quality Risk Management Q9 (II.3.); ICH pharmaceutical quality system Q10 (1.6.1); ICH pharmaceutical quality system Q10 (3.1.2)	FDA Guidance for Industry: Contract Manufacturing Arrangements for Drugs: Quality Agreements (1.e.); FDA Guidance for Industry: Contract Manufacturing Arrangements for Drugs: Quality Agreements (1.d.); FDA Guidance for Industry: Contract Manufacturing Arrangements for Drugs: Quality Agreements (1.e.); Approach to Pharmaceutical CGMP Regulations (3); CFR Title 21 Part 820 Quality System Regulations	WHO TRS 1003 Annex 4 (4.1.1.2.); WHO TRS 996 Annex 4 (1.1.); WHO TRS 996 Annex 1 (4.); WHO TRS 1003 Annex 4 (1.5.); WHO TRS 953 (2.1.3.); WHO TRS 953 (2.1.9.); WHO TRS 953 (2.1.13.); WHO TRS 953 (8.1.); WHO TRS 953 (17.); WHO TRS 1003 Annex 4 (4.2.4.3.); WHO TRS 1003 Annex 4 (4.4.); WHO TRS 981 Annex 2 (1.1.); WHO TRS 981 Annex 2 (glossary); WHO TRS 961 Annex 7; WHO TRS 957 Annex 2 (17.60); WHO TRS 996 Annex 5 (7.6.); WHO TRS 996 Annex 5 (Appendix 1); WHO TRS 973 Annex 4 (1.4.); WHO TRS 973 Annex 4 (3.3.); WHO TRS 986 Annex 2 (1.4.); WHO TRS 986 Annex 2 (7.17.); WHO TRS 981 Annex 2 (1.2.); WHO TRS 957 Annex 5 (14.11); WHO TRS 953 (8.2.)
IPP	N/A	N/A	N/A	WHO TRS 1003 Annex 4 (1.6.); WHO TRS 953 (2.1.7., 2.1.11)
Knowledge Measurement and IC Disclosure	EudraLex Annex 15: Qualification and Validation	ICH pharmaceutical quality system Q10 (2.8.)	FDA Guidance for Industry: PAT: A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance (1.d.)	WHO TRS 961 Annex 7 (1.4)
Research, Innovation and Knowledge Creation	N/A	ICH Q11 – (3.1.3.); ICH Q10 (Glossary); ICH Q10 (1.1.); ICH Q10 (1.5.3.); ICH Q10 (1.6.); ICH Q10 (1.6.1.); ICH Q10 (3.2.3.); ICH Q10 (4.2.b);	FDA Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (III. B.); FDA Guidance for Industry: Process Validation: General Principles and Practices (1); FDA Guidance for Industry: Data Integrity and Compliance With CGMP (Draft) (III.1.c)	WHO TRS 981 Annex 2 (1.1)
Knowledge Culture	N/A	N/A	FDA Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations (B.2.)	WHO TRS 996 Annex 5 (1.4.)
Pharmaceutical Firm Performance	N/A	N/A	N/A	Knowledge strategies: WHO TRS 996 Annex 5 (1.4., 5.4., 5.5., 7.5.)





**Figure 4.** Key themes in regulatory guidelines.

that might enhance QMS (ICH, 2008). Other ICH guidelines refer sporadically to KM with a focus on KS/KT. ICH Q9 suggested the need for further studies related to technology transfer should be assessed through QRM (ICH, 2005). ICH Q11 endorses the management and sharing of product/process-related knowledge throughout product lifecycle including knowledge related to drug substance and its manufacturing process. This is supposed to enhance the manufacturing process and establish a control strategy especially in cases of product ownership changes.

### 3.12. WHO

For the purpose of earlier detection of potential problems, WHO guidelines pay close attention to regulatory harmonisation and participation in information (e.g., from inspections and clinical studies) sharing networks among regulatory agencies with special considerations to confidentiality and intellectual property issues (e.g., WHO, 1999, 2003, 2017). Parallel efforts are exerted to contain escalating costs of drug prices by minimising duplication of inspection activities through: better networking, enhanced collaboration, and increased mutual trust (WHO, 1999). Information sharing efforts with the European Directorate for the

Quality of Medicines & Healthcare (EDQM) extends to certification programmes (WHO, 1999). Risk communication and sharing risk-related knowledge are also addressed in WHO guidelines (WHO, 2013). Finally yet importantly, sharing public alerts and warning alerts for imported drugs or medical devices can prevent similar faulty products from being exported to other markets (WHO, 2017).

WHO identifies the technology transfer as the middle stage in the drug lifecycle where GMP regulations must apply (WHO, 2013, 2014). The organisation requires validation of the process of data transfer (WHO, 2016). Whenever the transfer involves analytical methods, it is required to conduct this validation by the development before transfer to manufacturing quality control. Periodic checks are necessary to ensure the accuracy and reliability of the process (WHO, 2006b). As a general requirement, mechanisms should be addressed to facilitate the transfer of information not only between manufacturers and customers but also to the relevant regulatory bodies (WHO, 2010a).

With regard to IPP, The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) is led by WHO, where the focal point is public health protection from the implications of counterfeiting

(WHO, 1999). The ever-changing business strategies and their accompanying intra- and intercompany transfers of technology obliged the WHO Expert Committee on Specifications for Pharmaceutical Preparations in its 42<sup>nd</sup> report to assign a special guideline to address this issue (TRS 961 Annexe 7). However, this guideline is meant to be a flexible framework rather than rigid technology transfer guidance. Although a multifunctional team is proposed to manage the transfer process, it is affirmed to be under the umbrella of a quality system (WHO, 2011).

WHO requires pharmaceutical manufacturers to build their quality decisions and regulatory commitments on science-based understanding of the process and QRM which can offer a greater freedom of how to comply, hence enhances innovation (WHO, 2013). Development of quality culture in the pharmaceutical organisation is believed to improve transparency about failures and ensure good data management strategies are in place. Besides, data integrity and protection occupied a featured position in WHO regulations. Pharmaceutical firms are expected to develop appropriate tools and strategies for the management of data integrity risks based upon their own GxP activities, technologies, and processes (WHO, 2016).

### 3.13. EU GMP

Furthermore, EU Guidelines for Good Manufacturing Practices (EudraLex) have adopted Good Documentation Practices as an enabling tool for knowledge management throughout different stages of product lifecycle (EudraLex, 2015). Similar to WHO, PIC/S and ICH recommendations, the guidelines encourage agents, brokers, distributors, repackers, or relabellers to share regulatory and quality information with the manufacturers and customers (EudraLex, 2014; ICH, 2000; PIC/S, 2017; WHO, 2010b). EudraLex requires analytical method transfer protocol (EudraLex, 2006) with no explicit transfer framework as in WHO TRS961 Annexe 7. However, it confirmed the coverage of technology transfer by cGMP regulations as a part of product lifecycle (EudraLex, 2011).

### 3.14. FDA

FDA pays special attention to process understanding and knowledge management as effective strategies for preventing and detecting data integrity issues (FDA, 2016c). On the other hand, FDA accentuates on knowledge sharing and transfer in contract manufacturing as explained in the quality agreement (FDA, 2016a). The agency highlights the role of senior management in the creation of communicative organisational culture as a tool for improving knowledge sharing and communication in addition

to cross-functional groups to share ideas for improvement purposes (FDA, 2006). In addition, FDA encourages data acquisition and accumulation over the lifecycle as an important way for continuous improvement which in turn can facilitate the scientific communication with the agency (FDA, 2004a). Similarly, following process validation FDA guidelines would support process improvement and innovation (FDA, 2011).

### 3.15. PIC/S

In response to the increasingly complex global supply chains in the pharma industry, PIC/S facilitates voluntary inspection data-sharing between member authorities. This is deemed to enable risk-based assessment of the need for inspections based on shared confidence in inspected firms (PIC/S, 2011b). It has not escaped our notice that data sharing and transfer in PIC/S guides is focused on inspection data rather than knowledge created in pharmaceutical firms. The statute of the International Medicinal Inspectorates Database (IMID), which aims at establishing a database of GMP inspections carried out by IMID participating Regulatory Authorities, was adopted by PIC/S to reduce the number of duplicative inspections (PIC/S, 2012). Besides, the PIC/S committee is cooperating with other global agencies such as WHO, EMA, the ICMRA (International Coalition of Medicines Regulatory Authorities) and United Nations Children's Fund (UNICEF) with regard to training and sharing of inspections' information (PIC/S, 2011a, 2015, 2016b; WHO, 2003).

Because data integrity is essential for successful implementation of GMP, the requirements for good data management are embedded in the current PIC/S guidelines to GMP/GDP for Medicinal products. Good data management practices (GDMP) are envisaged as fundamental enabler for the integrity of the generated data. The manufacturer or distributor undergoing inspection is required to enforce GDMP that ensure the accuracy, completeness, and reliability of data (PIC/S, 2016a).

The data lifecycle (from generation till discard at the end of retention period) is also featured in GMP guidelines including data transfer throughout the product lifecycle. In case of computerised systems, interfaces should be assessed and addressed during computer system validation to guarantee the correct, accurate, and complete transfer of data (PIC/S, 2016a, 2017). Risk review should be considered specially for supply chains and outsourced activities to assess the extent of data integrity controls required (PIC/S, 2016a). It is noteworthy that PIC/S has repeatedly warned of inappropriate interpretation of guidelines making them barriers to technical innovation or the pursuit of excellence (e.g. PIC/S, 2011c).

Organisational culture and behaviour are a complementary part of the effective data governance system when combined with an understanding of data criticality, data risk, and data lifecycle. The value behind this appears in the empowerment of employees to report failures and opportunities for improvement. This reduces the incentive to falsify, alter, or delete data (PIC/S, 2016a). GMP inspectors have to be sensitive to the effects of organisational culture and structure on the organisation behaviour where data reporting differs between open and close cultures. In order to ensure data integrity within the pharmaceutical organisation, appropriate values, beliefs, thinking and behaviours need to be demonstrated consistently by management, team leaders, and quality personnel (PIC/S, 2016a).

#### 4. Discussion and implications

The pharmaceutical industry is not only one of the knowledge-intensive sectors, but also an industry with a direct effect on health promotion (Mehralian et al., 2016). It comprises distinct characters making pharmaceutical knowledge management a unique process. Being research-intensive, highly innovative and a great source of IC (Kamath, 2008), building networks of R&D personnel with research institutions, providing ultimate protection of IP rights, having high influence of political, legal, and administrative factors on technology acquisition (Hemmert, 2004), achieving high level of maturity in project management (Wakefield, 2005), involving suppliers in product development activities (Lawson & Potter, 2012), involving collaborative research with universities and governments (Dooley & Kirk, 2007), presenting sophisticated drug discovery and development systems (Criscuolo, 2005), facing challenges of regulated prescription drugs (Pedroso & Nakano, 2009), being one of the fast growing economic sector (Singh & Kansal, 2011), together with huge economic productivity and high number of employees (Bigliardi et al., 2012) are some of reasons for choice of pharmaceutical industry as empirical research field in KM literature.

Based on an in-depth review of the literature, few trends emerge. Domination of academic authorship (93% of authors) and empirical research (>70%) in 36 countries along with 20% increase in co-authorship reflects the academic maturity of the research area. Participation of practitioners is relatively limited (7%) in spite of the colossal investments in KM by pharma companies (Riddell & Goodman, 2014). This also validates the notion that the role which “knowledge” plays in the pharmaceutical industry is still immature and disabling the ICH Q 10 desired pharmaceutical quality system (Calnan et al., 2018). This can also accentuate what has been described by M. A. F. Ragab and Arisha (2013) as a theory-practice gap in KM literature in general.

Since R&D is considered the key space for knowledge creation (Ingelgård et al., 2002; Parisi et al., 2006), most of the studies ignored other functions (e.g., manufacturing, sales or quality) or other sources of knowledge in pharmaceutical organisation (e.g., process validation studies; manufacturing experience, continual improvement, and change management activities). From a regulatory perspective, managing the knowledge throughout commercialisation and manufacturing phases until product discontinuation is supposed to be as important as managing drug development knowledge (ICH, 2009).

Taxonomical analysis of literature affirms six main knowledge processes/themes extensively covered by researchers (Figure 3). In spite of that, the research in some other potential areas is relatively scarce (e.g., knowledge acquisition). In addition, the current thinking of the pharmaceutical regulatory bodies does not match the trending themes in business literature. For example, technology transfer and method/process transfer are regulated practices under pharmaceutical quality systems (ICH, 2009; WHO, 2011); case studies or empirical research is quite limited in this area.

IC is the most frequently used keyword and research theme in pharmaceutical KM literature. The influence of pharmaceutical IC on profitability, productivity, and market value is addressed in several papers (e.g., Pal & Soriya, 2012). Pharmaceutical IC reporting in BS suffers from inconsistency and lack of standardised guidelines. Yet, Intellectual Capital, knowledge measurement or disclosure are not recognised by cGMP guidelines. While M&A implications were a subject of academic research in pharma companies, regulatory publications focus on knowledge transfer after product/process acquisition or data acquisition during product lifecycle (FDA, 2004a).

Although KM at product and process level is explicitly required in ICH Q10 1.6.1. (ICH, 2008), regulatory authorities did not suggest any framework for either measurement or disclosure of IC. With poor reporting and disclosure of IC in pharma (Abhayawansa & Azim, 2014), further research is needed to induce industry-specific measurement frameworks not only at organisational IC level but also at the individual knowledge level. As a part of company intangible capital, patent-related keywords are mentioned 10 times in the review pool (e.g., patent citation, analysis, research, count, etc.) reflecting the importance of IP rights as a research subject.

Governmental role in innovation, either through the outputs of basic science or public funding of growing industry R&D, is emphasised in the literature. Dynamics of innovation as managed by the Triple Helix model can be a meticulous explication of this phenomenon (Etzkowitz & Leydesdorff, 2000; Leydesdorff & Meyer, 2006). When the FDA announced the Pharmaceutical cGMPs for the Twenty-first Century in 2006; corrective



actions, innovation, and continuous improvement were considered as three complementary improvement approaches in Pharmaceutical Manufacturing (FDA, 2004b). However, only innovation has received enough attention in the surveyed literature. It is worth noting that the term “creation” was mainly used by the regulators to signify creation of data and/or electronic records (FDA, 2016b).

The review explored the role of pharmaceutical organisational culture and structure in knowledge management. The review confirmed the notion that some values are found to be associated with the prosperity of knowledge within workspace (Remy Magnier-Watanabe & Senoo, 2009) and a new technology is not able alone to bring about a successful KM system (Chatzkel, 2007). The KM performance of the company was found in general related to its market performance. Unlike pharmaceutical quality system (ICH, 2008), organisational performance as a function of its KM practices was not considered by any of the four regulatory bodies.

## 5. Conclusion and limitations of research

According to the pharmaceutical regulatory guidelines, personnel must be qualified and knowledgeable with functions related to their work activities (FDA, 2006; WHO, 2014). It is a requirement to manage product and process knowledge throughout the product lifecycle (ICH, 2008). However, the academic research interests in pharmaceutical knowledge as presented in the extant KM literature partially overlap with the regulatory concerns. This incomplete overlap offers an opportunity for business researchers to design their future work to help industry meet regulatory expectations. Regulatory bodies recommended knowledge management but did not provide comprehensive frameworks to manage knowledge of pharmaceutical firms at the time industry practitioners refrain from serious contribution to academic research. This supports the notion that knowledge management in pharmaceuticals is still a growing research area, particularly in non-research and development functions.

The review has the limitation of being restricted to articles extracted from the *Emerald Insight* and *Science Direct* databases. Knowledge management conference proceeding and other academic portals can be explored in future studies. Despite the limitations, this paper offers an integrative and comprehensive taxonomy of KM literature in an industry-specific context that offers valuable insights for future research.

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## Scientometric Analysis of Knowledge Management Research and Practice (KMRP): 2003 -2015

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### Structured Abstract

**Purpose** - The purpose of this paper is to explore the current research trends in Knowledge Management (KM). To achieve this objective, a scientometric analysis of all literature published in *Knowledge Management Research and Practice (KMRP)*, a leading journal, is conducted ranging from the year 2003 to 2015.

**Design/Methodology/Approach** - A comprehensive literature review framework is synthesised from previous studies in KM. The analysis is designed based on three sets of review questions addressing Research Productivity, Research Themes and Methods, in addition to Citation Analysis. A total of 344 articles are reviewed and coded according to the adopted framework. To examine research output, Equal Credit and Direct Count methods are applied to assign authorial credit, while Normalized Citation Impact Index (NCII) is used for research impact analysis. A qualitative approach is introduced for thematic and methodological analysis.

**Practical Implications** – The study elucidates an increasing trend towards multi-author collaboration especially in recent years. The KMRP’s publication list includes more than 400 academic and research institutions showing the wide global interest in KM research. It also points at no particular dominant institution in the field. More than 50 different industries are represented in the ranking of sector application. Nevertheless, certain knowledge-intensive business fields have featured less such as pharmaceuticals and aerospace. Country productivity shows few nations taking the lead with research initiatives. Interestingly, statistics reveal a correlation between research activity and economic prosperity. There is a growing tendency towards empirical methods in contrast to a drop in literature review papers which is a sign of the field’s maturity. Results have also demonstrated that there is an increased contribution from practitioners. It is noticed that there is a recent rise in number of articles that present the integration between KM and Information Technology (IT). This is a natural trend given the current inconceivable advances in technology. This study also looked at the most influential publications in the journal’s history, taking into consideration their issuing date. Finally, insights on the current status of the KM research landscape is discussed in line with future trends.

**Originality/Value** - It is the first comprehensive scientometric research of KMRP. The paper describes the state-of-the-art value and provides an outlook of the future.

**Keywords** – Scientometric Analysis, KMRP, Knowledge, Knowledge Management, Intellectual Capital.

## 1 Introduction

Knowledge management (KM) has become a predominant field within the business and management landscape for both researchers and practitioners. The recognition of the fundamental role of knowledge in value creation spawned the concept of the *Knowledge Economy*, making it one of the pillars of contemporary management thinking (Roberts, 2009). Economic growth is no longer reliant on physical capital and labour only as established in nineteenth century theories, but also on the human capital comprised of “knowledge workers” whose innovative capabilities lead the advancement of the current “knowledge society” (Drucker, 1994). This was highlighted by a 1999 World Bank report which provided one of the first comprehensive accounts of the emerging role of knowledge in economic development through a focus on acquisition, application, and transfer of knowledge (World Bank Annual Report, 1999). By the end of the twentieth century, the notion of managing knowledge had evolved at the corporate level as organisations acknowledged the need to leverage and exploit their knowledge resources (Carmeli and Tishler, 2004). KM is now considered a vital organisational function and a key source of sustainable competitive advantage (Davenport and Vo, 2006). On the other

hand, progressive academic works have also established KM as an independent and rich scientific discipline. As a research field, KM has witnessed an exponential growth rate in publications amounting to 50% per year, supported by the founding of a number of dedicated KM journals and conferences (Serenko et al., 2010).

One of the key peer-reviewed journals in the KM field is *Knowledge Management Research and Practice (KMRP)*. Available online since 2003, KMRP is the first KM journal to gain an impact factor (Thomson Reuters, 2015). Its aim is to provide an outlet for high quality peer reviewed publications, which include articles on all aspects of KM whether this is academic or in practice. The journal pays particular attention to cross disciplinary research, mixtures of techniques, and differing schools of thought adopting a broad spectrum of publication themes including empirical research and case studies as well as conceptual and theoretical papers (Springer, 2017). Moreover, KMRP was placed third in 2008 then the second in 2013, according to expert survey rankings conducted on a sample of 25 key KM journals (Serenko and Bontis, 2013a).

While the KM field continues to grow, reflections on literature can allow for more efficient future deliberations on subjects within the discipline, minimise repetition, and create starting points for further advancements in KM theory and practice. This paper provides insights into KM research published in the KMRP, which could arguably apply to the whole KM domain considering that KMRP is a representative example of the wider KM literature. To present the work, the paper is divided into five sections. Following the introduction, the second section offers a brief survey of relevant literature and presents the study's research questions. Section 3 details the study's methodology and the development of the review framework. Findings are presented and analysed in the fourth section, while the final section discusses the work's conclusions and implications for future research.

## **2 Background and Research Questions**

A literature review is a "*critical analysis of a segment of a published body of knowledge through summary, classification, and comparison of prior research studies*" (Jafari and Kaufman, 2006). It helps to interpret what is known about a research field and to identify gaps in the existing knowledge (Jesson et al., 2011). Several reviews covered KM publications and journals using a number of methods over different time periods. These include but are not be limited to: Citation Analysis (Huang et al., 2010; Ma and Yu,



2010; Ribière and Walter, 2013; Serenko and Dumay, 2015) Content Analysis (Fteimi and Lehner, 2016), Journal Ranking (Serenko and Bontis, 2009, 2013b), Meta-review (Serenko and Bontis, 2004) and Scientometric Analysis, the approach adopted in this study (Serenko et al., 2009, 2010).

Scientometrics is *science about science* with distinct identity and methodology (Garfield, 2009). The term has grown in popularity and recognition in the last decades, especially after the founding of the dedicated *Journal of Scientometrics* by Tibor Braun in 1978. It is used to describe the study of science including growth, structure, interrelationships, and productivity of a certain research discipline (Hood and Wilson, 2001). Scientometrics portrays a comprehensive picture of research activity within the field and is able to present existing trends supported by quantitative data. In this study, the scientometric approach is adopted to investigate three main research issues within KMRP during the review timeframe:

- (1) Productivity - Demographic patterns in the production of KMRP research;
- (2) Themes and Methods - Trends in topics examined and research tools applied; and
- (3) Citation - Analysis of referencing frequency of the journal's papers.

Accordingly, three groups of research questions were formulated to guide the research process as follows:

*Research Productivity in KMRP*

*RQ1.* What are the dominant trends in authorship distribution?

*RQ2.* What is the prevailing affiliation of KMRP authors (Academics vs Practitioners)?

*RQ3.* Which countries are leading in KM research?

*RQ4.* Is there a relationship between a country's economy and its contribution to KM research?

*RQ5.* What is the institutional productivity in the journal?

*Research Themes and Methods in KMRP*

*RQ6.* Which research methodologies are most used by authors?

*RQ7.* What are the most popular industrial sectors in KM research?

*RQ8.* What are the main research themes in the journal?

*RQ9.* What is the degree of integration of Information Technology in KM research?

*Citation Analysis of KMRP*

*RQ10.* Which articles are the most influential in the journal's history?

### 3 Methodology

The research methodology adopted in this study has a number of steps. First, the boundaries of article selection for analysis are drawn using criteria for inclusion and exclusion. This set initially included 506 articles published in KMRP between the year 2003 - when the first issue was published – and up to 2015. Editorials, position papers, and book reviews are excluded from the article list. Accordingly, a total of 344 articles are retained for analysis, while 162 are excluded. Second, the research framework is synthesised in light of previous similar works (Fteimi and Lehner, 2016; Serenko et al., 2010; Serenko and Bontis, 2004; Serenko and Dumay, 2015) and subsequent design allows exploration into the various attributes of publications within the selected sample (Table 1).

Table 1: Research Framework

Theme	Variables
<b>Productivity</b>	<ul style="list-style-type: none"> <li>• Number of authors</li> <li>• Affiliation of author -<i>Academic vs. Practitioner</i></li> <li>• Country of Residence - <i>where the author is based, not where the work was conducted.</i></li> </ul>
<b>Research Method</b>  <i>Includes data collection method, more than one can be selected</i>	<ul style="list-style-type: none"> <li>• Case study - <i>single or multiple</i></li> <li>• Interviews</li> <li>• Literature review</li> <li>• Modelling tools</li> <li>• Surveys</li> <li>• Other qualitative - <i>Focus groups, Delphi, site observation, action research, content analysis, ethnography.</i></li> </ul>
<b>Research Topic</b>  <i>Most prominent topic in the paper, more than one can be selected</i>	<ul style="list-style-type: none"> <li>• Intellectual Capital</li> <li>• Innovation</li> <li>• Organizational Learning</li> <li>• Culture &amp; Social Issues (Social Capital)</li> <li>• Performance Management</li> <li>• Information System</li> <li>• Communities of Practice</li> <li>• Knowledge Measurement</li> <li>• Knowledge Philosophy/Ontology</li> <li>• Other Knowledge Management</li> <li>• Knowledge Sharing</li> <li>• Knowledge Transfer</li> <li>• Knowledge Creation</li> <li>• Knowledge Process</li> <li>• Knowledge Acquisition</li> <li>• Knowledge Exchange</li> <li>• Use of Knowledge</li> <li>• Knowledge Audit</li> </ul>

<b>Technology Adoption</b>	<ul style="list-style-type: none"> <li>• Use of Technology (<i>yes/no</i>)</li> </ul>
	Type of KM Technology: <ul style="list-style-type: none"> <li>• Knowledge management system</li> <li>• Internet</li> <li>• Communication technology</li> <li>• Wiki</li> <li>• Social Media</li> <li>• Prototype</li> <li>• Database</li> <li>• Blogs</li> <li>• Decision support systems</li> </ul>
<b>Referencing</b>	<ul style="list-style-type: none"> <li>• Number of citations from Google Scholar database</li> <li>• Keywords</li> </ul>

For cross-validation, coding process has been structured so that each researcher conducts a round of ten articles before they compare the codes for agreement. The outcomes of this exercise led to minor modifications of the framework, and helped identify what the authors refer to as *grey areas* - article attributes within the framework that were subjective in nature and could vary according to the views of the coder. For example, the same article could be classified under more than one category within the coding scheme. In this case, the authors have agreed to code the article under the most predominant theme and then cross-check their results. In the third stage, the articles are mutually coded by both researchers, and results are cross-checked to minimise *grey* coded articles. Finally, the full analysis of the resultant dataset is conducted to identify patterns. When addressing Research Questions 2-5 pertaining to Research Productivity, methods utilising credit analysis are enacted. Authorial credit is generally provided using one of four methods depicted in Table 2 below.

Table 2: Methods for Assigning Author Credit

<i>Method</i>	<i>Description</i>	<i>Example</i>	<i>Criticism</i>
<b>Normalised Page Size</b>	Number of pages is divided by the number of authors.	For 15 pages and 3 authors: Author 1= 5 Author 2= 5 Author 3= 5	<ul style="list-style-type: none"> <li>- Assumes longer papers make higher contribution.</li> <li>- Affected by journal pages' limits</li> </ul>

<b>Author Position</b>	Values are assigned according to the author's order in the citation.	For 4 authors: Author 1= 0.415 Author 2= 0.277 Author 3= 0.185 Author 4= 0.123	<ul style="list-style-type: none"> <li>- Co-authors are sometimes listed in alphabetical order; thus those whose names are earlier in the alphabet are unjustly favoured.</li> <li>- Does not consider cases where authors have equal contributions.</li> </ul>
<b>Direct Count</b>	A value of 1.0 is assigned to each author.	For 3 authors: Author 1= 1 Author 2= 1 Author 3= 1	<ul style="list-style-type: none"> <li>- Gives advantage to researchers who co-author numerous papers regardless of their contribution.</li> </ul>
<b>Equal Credit</b>	Each author receives an equal credit equivalent to the inverse of the number of authors, regardless of author position.	For 3 authors: Author 1= 0.333 Author 2= 0.333 Author 3= 0.333	<ul style="list-style-type: none"> <li>- Avoids the drawbacks of previous methods.</li> </ul>

Adapted from Chua and Cousins (2002) and Lowry et al. (2007)

The Equal Credit Method is selected because it avoids the shortcomings of the three other methods and provides mostly unbiased authorial credit. In addition to Equal Credit, the Direct Count Method is employed in Research Questions 2 and 3 as well and results of both methods were compared. It is worth noting that studies have suggested that the Direct Count, Author Position, and Equal Credit methods can produce similar results, particularly when utilising aggregate data (Serenko et al., 2008).

In addressing Research Question 10 regarding citation impact of influential KMRP publications, each paper's citation impact index is computed to determine the single most highly cited article. The most commonly used measure is the calculation of the total number of citations of each paper since its publication. However, according to Holsapple et al. (1994), the weakness of this method is that it does not consider the publication date of the article. It will provide the same score to two publications that are cited the same number of times even if they are published in different years, although the most recent of them can have a higher average number of citations per year. This suggests that the latter publication has had a higher contribution to the field having achieved the same number of citations in a shorter time period, an aspect which the traditional citation index overlooks. To overcome this drawback, Holsapple et al. (1994) proposed the use of *Normalized Citation Impact Index (NCII)* which accounts for the paper's longevity thus reflecting the

relative contribution of each paper. It is calculated by dividing the number of times the article has been referenced by the number of years the article has been available [NCII = Total Citations (count) / Longevity in years]. The NCII method is hence adopted in this study in order to provide more reliable results. Individual article citations obtained from the *Google Scholar* database are used to compute the NCII for each article and publications are ranked in descending order according to their indices.

## 4 Findings

In an attempt to identify the trends within the current sample, the analysis is presented over two time periods (2003 – 2008) and (2009 – 2015). This format facilitates in highlighting the major changes in the nature of research work published in the journal over its lifetime.

### 4.1 Authorship Trends

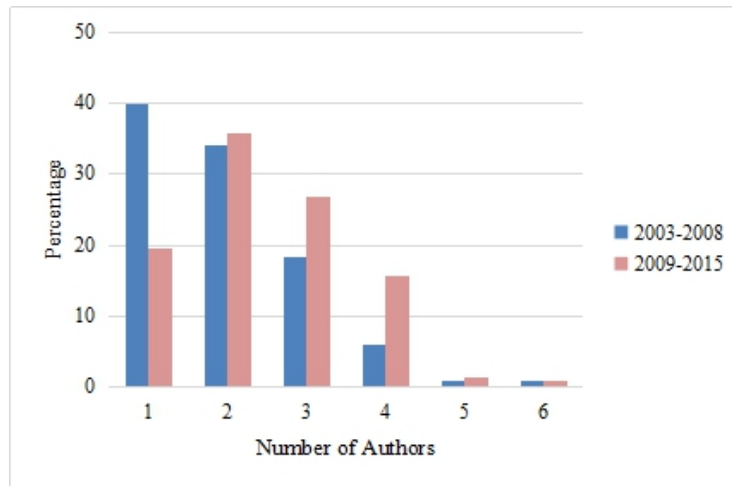


Figure 1: Number of Authors

The average number of authors within the sample was 2.28 authors per paper, however, a growing trend towards multi-authored papers is evident. While the average paper authorship in the first time period (2003 – 2008) was 1.96 authors per paper, it increased to 2.46 authors per paper in the second time period (2008 – 2015). The median number of authors has also increased from two to three after 2013 (Table 3). The percentage of single authored papers dropped from 40% in 2003-2008 to less than 20% in 2009-2015,

whereas papers with two, three, and four authors witnessed significant increases of 1.5%, 8.5%, and 9.8% respectively (Figure 1). This confirms the findings of Akhavan et al. (2016) who observe a decline in single-authored works over time and the emergence of collaboration patterns among KM scholars. This is justified by the maturity of the KM domain where authors develop relationship networks and collaborate to overcome the current increasingly challenging journal acceptance rates. The findings are also in line with the broader bibliometric studies of Cline et al. (1979), Metz (1989), Terry (1996) which report a general phenomenon of progressive trends in co-authorship in other research disciplines.

Table 3: Co-authorship Distribution - Number of Authors

Year	2003	2004	2005	2006	2007	2008	2009
Mean	1.78	1.93	1.61	2.07	2.32	1.86	2.18
Median	2	2	1	2	2	2	2
Year	2010	2011	2012	2013	2014	2015	
Mean	2.34	2.48	2.34	2.48	2.83	2.58	
Median	2	2	2	2	3	3	

#### 4.2 Author Affiliations

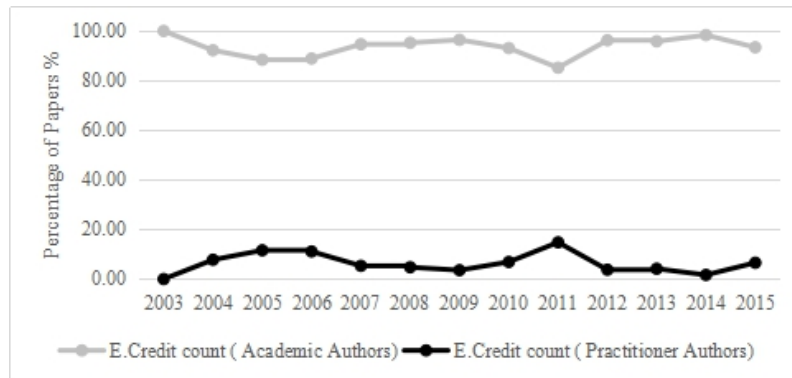


Figure 2: Author Affiliation

From an affiliation perspective, more than 90% of authors have an academic background and are in direct affiliation with educational and/or research institutions. The rest of authors are practitioners from service or industry sectors. Both the Direct Count

and Equal Credit methods are used to compute the contribution of practitioners and academic authors and no statistically significant difference is found between the results of both methods ( $p\text{-value}=0.592$ ). Despite the apparent stability in the percentages of practitioners and academic authors in KMRP over the years (Figure 2), other studies have shown otherwise. A study by Serenko et al. (2009) revealed that the number of practitioners decline from approximately one third of all contributors in the late 1990s to 10% by 2008. Their findings suggest that there is room for further engagement of practitioners in KM research and publication.

### 4.3 Country Productivity and GDP



Figure 3: Country Productivity

In order to identify the leading countries in the KM field, the relative contributions of 57 countries whose papers were published in the KMRP are traced and ranked using both the Equal Credit and Direct Count methods. Similar results from both methods are obtained and the Pareto Principle or “The Law of Vital Few” is heavily observed. The majority of publications originate from roughly 20% of participating countries as in Table 4 (Pareto, 1971). To confirm the findings, the number of citations from each country is counted using the NCII method for all the countries. The same countries of the highest contribution to the journal are found to be on the top of the articles citation list. Moderate positive correlation (0.559) is discovered between the country Gross Domestic Product (GDP) and contribution to KM research. This explains the finding that the majority of leading contributors are in North America, Western Europe, and Australia. The link

between knowledge and wealth reinforces the theory established by Drucker when he discussed the post-WWII transformation of the American economy from goods to what we call today the Knowledge Economy (Drucker, 2011).

Table 4: Country Productivity Ranking

Rank	Equal Credit Method		Direct Count Method		NCII	
	<u>Country</u>	<u>Percentage</u>	<u>Country</u>	<u>Percentage</u>	<u>Country</u>	<u>Percentage</u>
1.	UK	13.76%	UK	12.74%	UK	12.92%
2.	USA	12.37%	USA	12.02%	USA	12.52%
3.	Australia	8.13%	Spain	7.69%	Japan	8.95%
4.	Spain	7.94%	Australia	7.69%	Spain	7.67%
5.	France	5.89%	Italy	5.53%	Canada	7.49%
6.	Italy	5.81%	France	5.05%	Italy	6.74%
7.	Taiwan	4.93%	Canada	4.81%	Finland	4.25%
8.	Canada	4.29%	Taiwan	4.09%	Germany	4.14%
9.	Germany	3.91%	Germany	3.85%	France	4.10%
10	Rest of the world	32.95%	Rest of the world	36.54%	Rest of the world	31.22%

#### 4.4 Institutional Productivity

When examining institutional productivity, Equal Credit is the method of choice for organisations as well. Analysis revealed that, to-date, more than 400 unique institutions have published articles in the KMRP. The noticeable finding is the minimal variation among individual contributions of each institution where no single institution dominated publications in the journal as shown in Table 5 (*range* = 3.8, *standard deviation* = 0.65). Approximately 20% of contributions come from 27 different institutions which indicates unbiased distribution of papers between a wide range of research and professional organisations. It is also noted that two thirds of papers are the product of a single institution and 38.6% of the papers are the outcome of multi-institutional collaboration. Furthermore, the top 20% contributors are all academic organisations, which coincides with the prevalence of academic authorship as previously mentioned.



Table 5: Institutional Productivity

Rank	Institution	Equal Credit	Percentage	Cumulative Sum
1.	National Technical University of Athens	3.999	1.16%	1.16%
2.	University of Sydney	3.999	1.16%	2.33%
3.	Tampere University of Technology	3.998	1.16%	3.49%
4.	Queens University	3.916	1.14%	4.63%
5.	University of Southampton	3.5	1.02%	5.64%
6.	University of Hull	3.166	0.92%	6.56%
7.	National Taiwan Ocean University	3	0.87%	7.44%
8.	Universidad Computense de Madrid	3	0.87%	8.31%
9.	University of Sao Paulo	3	0.87%	9.18%
10.	Politecnico di Milano	2.75	0.80%	9.98%
11.	Hitotsubashi University	2.5	0.73%	10.71%
12.	University of South Australia	2.5	0.73%	11.43%
13.	University of Southern Queensland	2.499	0.73%	12.16%
14.	Kingston University	2.333	0.68%	12.84%
15.	University of Salento	2.333	0.68%	13.52%
16.	University of Sheffield	2.333	0.68%	14.19%
17.	Loughborough University	2.166	0.63%	14.82%
18.	Bangkok University	2	0.58%	15.40%
19.	Edith Cowan University	2	0.58%	15.99%
20.	Politecnico di Bari	2	0.58%	16.57%
21.	Robert Gordon University	2	0.58%	17.15%
22.	Soochow University	2	0.58%	17.73%
23.	University of Akureyri	2	0.58%	18.31%
24.	University of Alicante	2	0.58%	18.89%
25.	University of Castilla La Mancha	2	0.58%	19.47%
26.	University of Melbourne	2	0.58%	20.06%
27.	University of New South Wales	2	0.58%	20.64%
28.	Other 375 unique institutions	N/A	79.36%	100

#### 4.5 Research Methods

Research methods can be described as all the data collection and analysis techniques that are used for conduction of research activities to solve research problems (Kothari, 2004). Nearly half of the articles (47%) utilised a single method, while the rest of articles used two or more. A mild to moderate increase in published empirical studies, both quantitative and qualitative, is observed in the second review time period (2009-2015) in comparison to conceptual models and literature reviews which are prevalent in the first review period (Figure 4). Nevertheless, modelling tools and frameworks are still the most used methodology by KMRP researchers, followed by case studies. This rise in case study and survey work along with the decline in literature reviews suggests an ongoing shift of KM research from theory to practice where first hand studies are increasingly held with knowledge workers to explore knowledge related phenomena in real-life organisational contexts. This tendency seems to be a general trend in the KM field, as indicated by the results of other similar studies. For example, a recent content analysis of the proceedings of the European Conference of Knowledge Management (EKCM) between 2006 and 2013 revealed that model and framework development were the most preferred research method followed by case studies and questionnaires (Fteimi and Lehner, 2016).

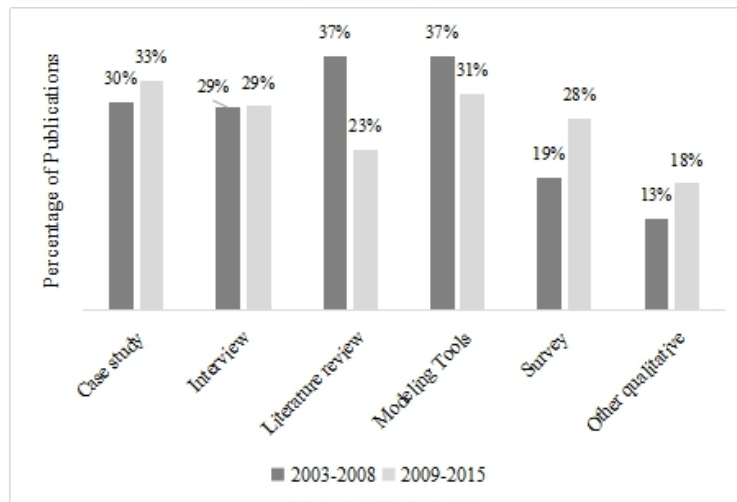


Figure 4: Research Methods

#### 4.6 Industrial Sectors

Expanding on the findings from the previous section, articles are thoroughly surveyed for industries which are selected as research fields. While 33% of studies are classified as conceptual studies and thus have no industries, the other two thirds are conducted in more than 57 different industries and service sectors. Moreover, 15% of papers do not specify a single sector used in data collection. Instead, a mixture of different businesses is used as a convenience sample that is non-industry specific. This is expected since researchers often tend to gather data from companies in their network and the ones that they have access to.

Moreover, research and education institutions are on the top of the popularity list. Approximately 12% of the studies are conducted either within universities, research labs and/or rely on the classroom as a case study. Once again, this could be simply attributed to convenience. Researchers often find access within their own organisations, or in similar academic ones, more feasible than the challenge of penetrating new industries to obtain data. Information and Communication Technologies (ICT), Healthcare, and High-Tech firms come in the second, third, and fourth level places respectively. Nonetheless, some knowledge intensive industries such as Pharmaceuticals, Aerospace, and Energy have not received adequate attention in industry-specific publications. This could be considered as an opportunity for future researches to direct their efforts towards such relatively under-published sectors. Table 6 illustrates the main industry/service sectors in the articles and their relative percentage.

Table 6: Industrial Sectors

Rank	Industry	%	Rank	Industry	%
1	Multi Sectoral	14.8%	11	Engineering	1.2%
2	Research & Education	11.6%	12	Entertainment	1.2%
3	ICT	8.7%	13	Insurance	1.2%
4	Healthcare	5.2%	14	Metal industry	1.2%
5	Technology	4.1%	15	Oil and Gas	1.2%
6	Civic Society	2.3%	16	Aerospace	0.9%
7	Consulting & Training	2.0%	17	Banking	0.9%
8	Automotive	1.7%	18	Pharmaceuticals	0.9%
9	Unspecified	1.7%	19	Other industries	13.1%
10	Construction	1.2%	20	Conceptual (none)	32.8%

#### 4.7 Research Themes

Two approaches are adopted to identify the common research themes within the KMRP body of literature. First, two researchers qualitatively categorised the papers according to their research topic as explained in the review framework. A counter review of the same papers by the other researcher is used to confirm the categorisation of each paper under a single theme. In cases where researchers coded a paper differently, the article is jointly reviewed by both researchers until a classification is agreed, or third opinion is sought. Secondly, a quantitative keywords analysis is used in parallel in order to compare the findings of the thematic analysis.

Results show that 61% of research papers fell under only five topics; (1) Knowledge Sharing, (2) Intellectual Capital, (3) Knowledge Creation, (4) Knowledge Transfer, and (5) Culture. Some research themes indicate significant growth in the second review time period (2009-2015) in comparison to the first period (2003 – 2008). For example, there is a growing interest in Intellectual Capital, Knowledge Transfer, Innovation and Culture (Figure 5). Nevertheless, themes such as Knowledge Creation, Organisational Learning, Information Systems, Communities of Practice (CoP) have received less interest.

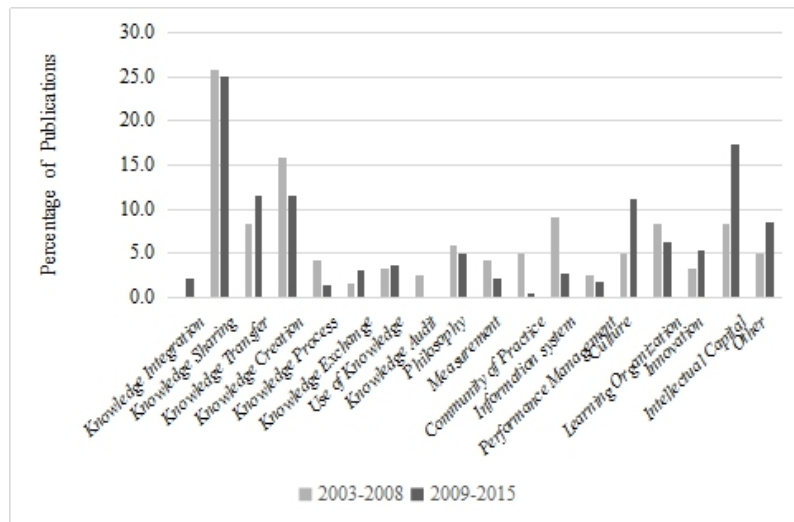


Figure 5: Research Themes

#### 4.8 Keyword Analysis

A comprehensive keyword analysis of KMRP articles between 2003 and 2012 undertaken by Ribi  re and Walter (2013) demonstrate that *Knowledge Sharing* is the most used keyword in the journal. A similar exercise extending until 2015 conducted in this research unsurprisingly yielded the same outcome. The predominance of *Knowledge Sharing* as a keyword, as well as a research theme, confirms the validity of the thematic analysis outcomes of the previous section. It also elucidates the emphasis researchers have placed on the knowledge sharing process as a precursor of effective KM. Whether the objective is spreading best practice, disseminating innovative ideas, or creating digital repositories, sharing knowledge is often at the core of KM initiatives.

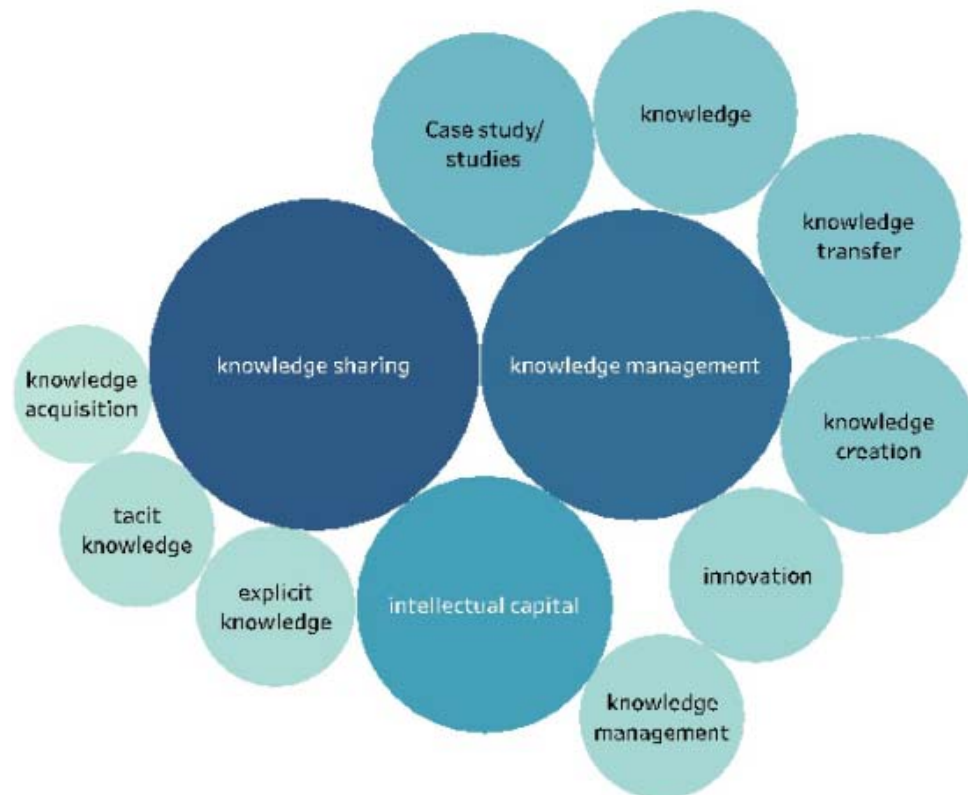


Figure 6: Keyword Analysis

#### 4.9 KM Technology

The role of Information Technology (IT) in KM is widely discussed in the literature. A common view is that KM should not be reduced to a solely IT-based project as there is a tacit dimension of knowledge which cannot be managed using technological tools (Chatzkel, 2007). IT is rather envisaged as an essential KM catalyst and an enabler of knowledge sharing processes within and between organisations (Tsui, 2005). This view seems to be reinforced by scientometric figures as, overall, 91% of papers did not include reference to IT. However, by contrasting the first review period (2003-2008) to the second (2009-2015) with regards to discussing technology, an increase from 4.2% to 11.6% is observed indicating a movement towards further integration of IT in KM. In this area, the Internet, Databases and Social Media were the most popular IT solutions in the published papers (Figure 8), a trend in tandem with the digital revolution and the explosive growth of social networking.

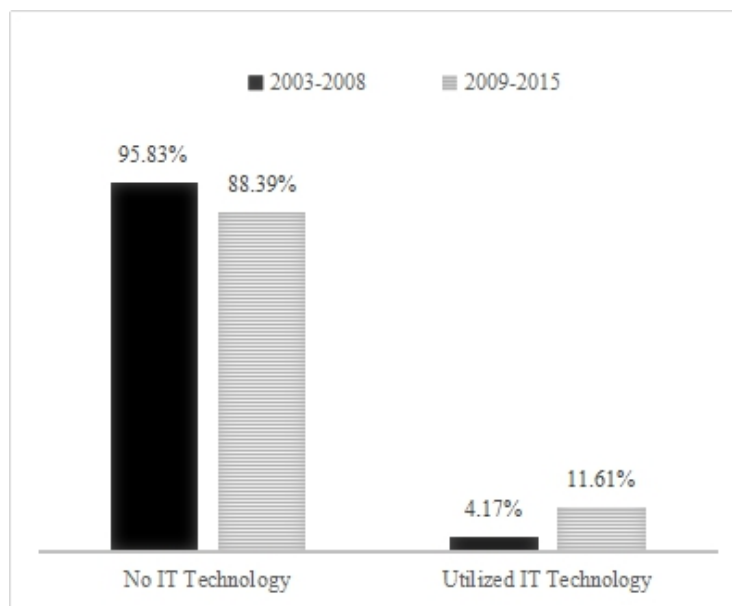


Figure 7: Integration of IT in KM Research

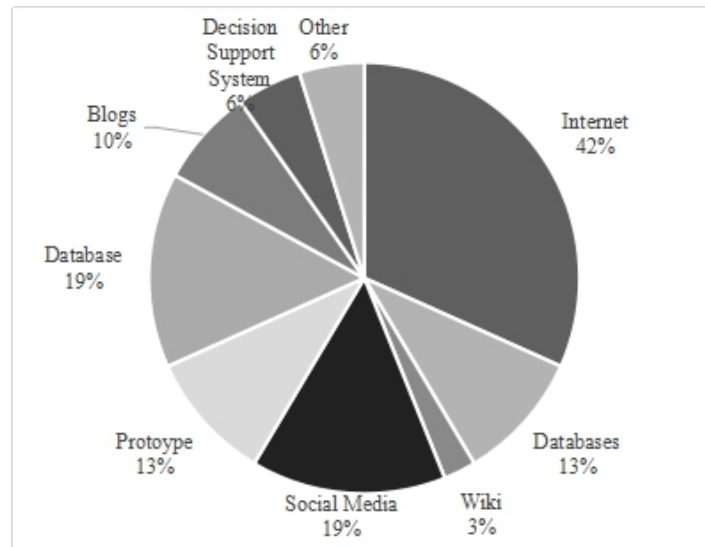


Figure 8: IT Technologies

#### 4.9 Citation Analysis

By examining citation frequency, three articles stood out as the most influential articles in the journal's history based on their NCII (Table 7). It is noted that the top three articles gained 11.8% of the NCII score for all the articles and approximately 80% of citations came from the top 144 articles ( $\approx 40\%$ ). Interestingly, the most cited article is authored by renowned KM thinker Ikujiro Nonaka and extends on his SECI model of knowledge creation, which is regarded as one of the most seminal and high-cited theories in the history of KM at large.

Table 7: Highest Cited KMRP Articles

Author	Title	Year	NCII
Nonaka, Ikujiro & Toyama, Ryoko	The Knowledge-Creating Theory Revisited: Knowledge Creation as a Synthesizing Process	2003	77.1
Baskerville, Richard & Dulipovici, Alina	The Theoretical Foundations of Knowledge Management	2006	26.8
Usono, Abel; Sharratt, Mark W; Tsui, Eric & Shekhar, Sandhya	Trust as an Antecedent to Knowledge Sharing in Virtual Communities of Practice	2007	18.8

## 5 Discussion and Implications

The journal of *Knowledge Management Research and Practice* (KMRP) stands for one of the key scientific outlet in the field of knowledge management and has significantly contributed to the development of the research streams related to strategic knowledge management, learning organisation, intellectual capital measurement and management, and knowledge-based information technologies, just to name few fundamental domains of investigation.

With the economy and organisations showing increasingly a knowledge-intensive nature, in today's business landscape managing knowledge is acknowledged as a necessary condition to survive and prosper. The ability of an organisation to create value is tied to its ability to identify, manage and renew the key knowledge assets at the basis of organisational competences and, in turn, processes affecting company value creation dynamics. KMRP has contributed to shed light and disclose the functions, factors and mechanisms characterising knowledge as a resource and source of organisational competitiveness as well as the processes, models, approaches and tools that can support managers in translating knowledge into business performance.

After almost 15 years since the foundation of KMRP from Operation Society, this study proposes a scientometric analysis of the studies published by the journal. This helps to provide a comprehensive picture and to understand the growth, structure, interrelationships, and productivity of the published research activities within the field of managing knowledge.

The study elucidates an increasing trend towards multi-author collaboration especially in recent years. The KMRP's publication list includes more than 400 academic and research institutions showing the wide global interest in KM research. More than 50 different industries are represented in the ranking of sector application, although it is surprising that certain knowledge-intensive business fields have featured less such as pharmaceuticals and aerospace. The majority of leading contributors are in North America, Western Europe and Australia. Interestingly, statistics reveal a correlation between research activity and economic prosperity. There is a growing tendency towards empirical methods in contrast to a drop in literature review papers which is a sign of the field's maturity. Results have also demonstrated that there is an increased contribution from practitioners, although there is a dominant position of academia's contribution. This denotes the efforts of scholars to set up the foundation of the theory of managing



knowledge integrating evidences from practice, but at the same time as the field is progressively becoming more mature it indicates a potential shortcoming related to the lack of a stronger involvement of practitioners in order to make sure that the research outputs are relevant to advance the practice as well as for theory building. The study shows that 61% of research papers fell under only five topics; (1) Knowledge Sharing, (2) Intellectual Capital, (3) Knowledge Creation, (4) Knowledge Transfer, and (5) Culture. In particular, the topic of Knowledge Sharing emerges a predominant indicating that it is considered as one of the key process at the core of managing knowledge, in terms of spreading best practice, disseminating innovative ideas, or creating digital repositories, and sharing knowledge. This points out that one of the fundamental reasons for implementing knowledge management initiatives is related to the need of moving knowledge from individual to individual, from individual to team and organization, from organisation to organisation, and from organisation to artefacts. In other words, knowledge sharing is the key strategic knowledge process to support learning organisation and the translation of knowledge into organisational and business performance. In this light it is not surprising that the most influential article published by the journal are those focusing on the SECI model of Nonaka and on the antecedents and factors affecting the knowledge sharing characteristics of an organisation.

Concluding this study provides evidences that the field of knowledge management is reaching a maturity which poses at least twofold challenges. On the one hand to identify what are the future key trends of research development in the field, and on the other hand the need to adopt more empirical based investigation. KMRP publishes both quantitative and qualitative papers, however the discriminating factor to bear in mind is the relevance of the contribution. From this point of view we need to remind that managers are interested to knowledge and its management not for the sake of knowledge and knowledge management, but because they need to understand how they can translate organisational knowledge assets into drivers that positively impact and enhance the business value creation mechanisms.

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## **A HYBRID PROCESS-MINING APPROACH FOR SIMULATION MODELING OF HOSPITALS**

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### **ABSTRACT**

Simulation modeling is extensively applied to address hospital challenges. To build the right model, unbiased accurate conceptual model has first to be produced. Conventional modeling process requires all data and information to be collected by interviews and/or focus groups then collated manually to produce a conceptual model before validation. This paper embraces modeling hybridization by introducing process mining for conceptual modeling stage in order to enhance the time factor of developing the model and equally increase accuracy of the conceptual model. Patient's pathways will be generated using data-driven approach (i.e. data from an Emergency Department - ED). The hybrid framework demonstrates the high variance in patient pathways and then identify the system bottlenecks. A Discrete-Event Simulation (DES) model is complementing the solution by adding the stochastic layer of the system dynamics. Results show that the unblocking of ED outflows by in-patient bed management rather than increasing capacity of the ED.

### **1 INTRODUCTION**

Health-care management are currently under constant pressure to control rapidly escalating expenses, while still responding to growing demands for better patient service levels and safe medical treatment. Addressing these challenges requires a thorough understanding of health-care system constraints, which can be an overwhelming task, given the high levels of uncertainty and interdependence. Simulation modeling has contributed strongly to the understanding of different level of complexity within healthcare processes (Arisha and Rashwan 2016). Discrete event simulation (DES), agent-based simulation (ABS), Monte Carlo simulation (MCS), and system dynamics (SD) are widely used in healthcare applications (Brailsford et al. 2009; Katsaliaki and Mustafee 2011). Each of these simulation techniques addresses a particular level of complexity within the system. Modelers are often challenged to accurately model the system complexity in order to provide managers with effective results resembling reality (Lynch et al. 2014). Research indicated that the use of hybrid simulation will improve the capabilities of simulation solutions (Brailsford 2008; Djanatljev and German, 2013; Viana 2014; Zulkepli and Eldabi 2015; Gao et al. (2015). Despite the growing number of hybrid simulation studies, there are still a number of challenges that has not been addressed adequately. For instance, most reported hybrid simulation cases have attained their findings mainly on model implementation phase rather than considering other phases such as conceptual modeling. In addition, the human behavior in healthcare processes and activities has always been a challenge for most of the simulation approaches (Daellenbach 2001). Therefore, hybrid approach has to extend to reach the conceptual modelling (Robinson 2008), data collection, model optimization, analysis and implementation. This approach of a hybrid Modeling and Simulation (M&S) study applies various interdisciplinary methods in the wider simulation study has been discussed in (Powell and Mustafee 2016). A hybrid M&S study is characterized by the use of methods from fields such as Operations Research (OR), Computer Science,

Systems Engineering, Information Systems and Distributed Computing; these methods are applied to specific stages of a simulation study.

Most of the simulation studies develop the process model using documentation, direct system observations and interviews with stakeholders and experts (e.g. consultants, nurses...etc.). This manual process is time-consuming, and arguably the longest stage of any M&S project. This lengthy process significantly affects the validity and effectiveness of the M&S study recommendations. In addition, the perception of the actual process is influenced by the experience of the individual studying the system and this often results in biased models. Therefore, it is essential for any successful M&S healthcare study to develop conceptual models that are unbiased, reusable, and close reflection of reality in a timely manner. To do so, a data-driven process mining approach can be adopted using event logs (van der Aalst 2011). Through the application of process mining techniques, healthcare organizations can: discover the actual patient pathways that are conducted in reality (Saunders, Makens, and Leblanc 1989); understand the high variance in clinical pathways taken by diverse groups of patients; and gain insights into bottlenecks and resource utilization (McGregor, Catley, and James 2011; Abo-Hamad 2017).

The aim of this research is to introduce a hybrid framework that integrates process mining techniques in the conceptual modeling phase. This will minimize the latency between the occurrence of events and decision-making. The main objective is to automatically identify patients' pathway patterns that are consistent with the observed dynamic behavior. Hence, a more accurate and unbiased process model for patients' journey is obtained in a timely manner. Using this model then as an input for simulation model and for what-if scenario analysis. The proposed framework is tested on a real-world case study of an emergency department of one of the leading hospitals in Ireland.

## **2 PROPOSED FRAMEWORK**

### **2.1 Literature Review**

Conceptual modeling has been identified as potentially the most significant stage of any simulation study, however, it is the most underestimated aspect (Law 1991). Building a valid and credible model is a sophisticated process (Law et al. 2001). Data collection for conceptual model construction can be complicated due to confidentiality, security or subjectivity concerns. Although organizations utilize procedures to manage its processes, usually procedures are either informal, not documented or entirely different from reality (van der Aalst 2012). Process Mining (PM) techniques have emerged to handle the discrepancy between what should be done and how processes operate in the real world (Turner et al. 2012). The input data of PM is an event log (i.e. dataset of traces). Each trace has a sequence of ordered process activities (i.e. events). By utilizing evolutionary computational intelligence techniques (e.g. Artificial Neural Networks, Fuzzy logic, and Support Vector Machines), PM can provide an unbiased view of the underlying processes based on what is actually happening, and not on subjective views of the system (Maita et al. 2015). On the one hand, PM techniques can bridge the gap between data capabilities and process modeling analytics. Event logs can be exploited in three main approaches: discovery, conformance, and enhancement. In discovery approach, process models are discovered automatically by analyzing event logs without using any further information. Conformance process mining can be used to compare an existing process model with real life data expressed in event log (van der Aalst 2011). Whereas conformance and enhancement techniques can improve current process models through checking conformance, analyzing deviations and enriching existing models with conformance-related diagnostics (Centobelli, Converso, and Gallo 2015; Rovani et al. 2015).

The proposed framework in this paper focuses only on the Process Discovery step that studies the event log activities and results in the creation of a conceptual model. The Alpha-Algorithm (van der Aalst, Weijters, and Maruster 2004), the Fuzzy Miner (Günther and Aalst 2007), and the Heuristic Miner (Weijters, van der Aalst, and Medeiros 2006) are the most reported techniques for process discovery. Process mining can be considered as a relatively new research discipline with a successful record in

Healthcare applications. A recent extensive literature review (more than 74 articles) conducted by Rojas et al. (2016) on the application of process mining in healthcare has identified the research opportunities with this area. Interestingly, only one paper in their review has attempted to combine process mining with simulation models for an outpatient clinic model (Zhou, Wang, and Li 2014).

## 2.2 Proposed Framework

The proposed hybrid framework consists of three phases; Formulation and Data Analysis, Conceptual Modeling, and Model Development (Figure 1). Typically, each hospital department has its own database that supported its functions. The database usually contains information on patients and records detailed information regarding the journey or movements of patients within the hospital. Process mining techniques usually use a transactional event log data set. Therefore, the “extraction” step in the framework is used to construct the event log data set from the raw database. Each row in the transactional event log corresponds to an event that was executed in the process. Multiple events are linked together in a process instance or case where each case forms a sequence of events—ordered by their timestamp. In contrast, data mining techniques uses the raw database directly where each row represents a complete process instance (i.e. patient episode). In the conceptual modelling phase, process mining algorithms are used to analyze the event log.

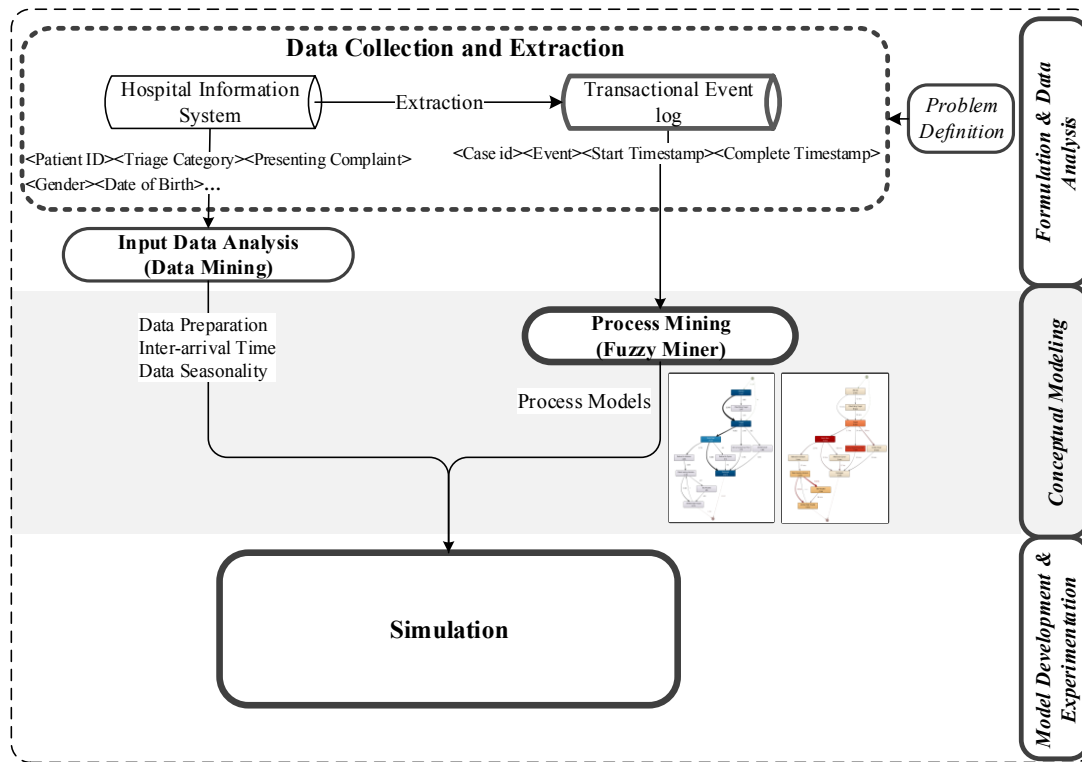


Figure 1 An overview of the proposed process-mining-based M&S Framework

Due to the unstructured nature of healthcare process, the selection of the process mining discovery algorithm is crucial. The Fuzzy miner (Günther and Aalst 2007) is more suitable for unstructured processes and for the purposes of simulation and managerial analysis. Other algorithms such as Alpha-algorithm produces a very complicated process models which shows all process details without distinguishing what is crucial and what is unnecessary. On the other hand, fuzzy miner algorithm observe complex processes at different levels of granularity and provides meaningful abstraction and different views. This is achieved by

applying two fundamental metrics: significance and correlation. The significance metric assesses the relative importance of a precedence relation between two event classes, i.e. the more often two event classes are observed after one another, the more significant their precedence relation. The correlation metrics indicates how closely two events (i.e. activities) are following each other. Therefore, fuzzy mining could reduce and focus the displayed event classes by applying the two metrics on the discovered process map to achieve different levels of aggregation and abstraction. Therefore, various process models of different abstraction levels (number of activities and pathways) can be produced. The discovered process models combined with the analysis of patients' records are used in the model development and experimentation phase. Depending on the model scope and objective, the model can be implemented using a single simulation technique such as Monte Carlo simulation (MCS), discrete event simulation (DES), system dynamics (SD) and agent-based simulation (ABS) or a hybrid between these simulation techniques.

### **3 CASESTUDY**

#### **3.1 Project Background**

The hospital studied in this paper is an acute public teaching hospital located in North Dublin, Ireland. This 570-bed hospital includes a 24-hour Emergency Department (ED) which services over 50,000 patients annually. The ED is operating at approximately 99% occupancy, according to the task force report in 2007, which is an indication of inadequate physical space and infrastructure. This is often aggravated by delays in patients transfer to critical care (ICU/HDC) beds. Consequently, the ED is not compliant with volume and waiting time targets (6-hour Length of Stay target). A detailed simulation model for the ED was developed in (Abo-Hamad and Arisha, 2013), and some improvement strategies were proposed to achieve the national target. Although these strategies were effective, the model was not flexible to accommodate the constant changes in patient care pathways and to sustain improvement efforts. To overcome these issues, the process model of the ED (that was developed manually) should be updated to capture the changes in patient flow. Following the manual process of developing and updating the ED process model would take 6 – 8 weeks. Given the fast changes in healthcare process, by the time the model is completed the process model will not be reflective. Therefore, process mining techniques were applied to discover patients' pathways from historical data automatically.

#### **3.2 Dataset**

A real-time patient tracking information system was used to track the patient's journey within the ED. The hospital managers have provided a one-year historical data with anonymous patients' records. The dataset was provided in an event log structure with a total of 229,971 event logs representing 40,777 patients. Each log in the table represents an event (i.e. one process stage of the patient journey in the ED) with the following attributes (patient ID, Triage Category, Presenting Complaint, Date of Birth, Gender, Event ID, Tracking Step Name, Tracking Step Date Time, Location, Staff). Events with the same name, patient ID and timestamp were removed which resulted in a total of 210,180 records in the ED event log.

#### **3.3 Patient pathway discovery and analysis**

The event log for patients was analyzed to discover patient's pathways and to extract statistics on their characteristics and types. Upon their arrival, patients are assigned a clinical priority (triage category) according to the Manchester Triage System (Cronin 2003). The MTS uses a five-level scale for classifying patients according to their care requirements; immediate, very urgent, urgent, standard, and non-urgent. Immediate and very urgent patients represent 15%, urgent patients (triage category 3) represent the largest group of attendees to the ED annually (59% average), while standard and non-urgent patient 26% of all patients. As advised by ED consultants, the analysis of these patients' groups is critical as each group of patients can have a different journey within the ED and hence a different pathway.

### 3.3.1 Patient Pathway Discovery

The main building block of patient pathways are the activities that patients go through during their journey in the ED. Twenty-two different activities within the ED are identified from the event log data. The fuzzy miner has then applied on the whole event log to construct the first top-level process map of the overall ED (Figure 2a).

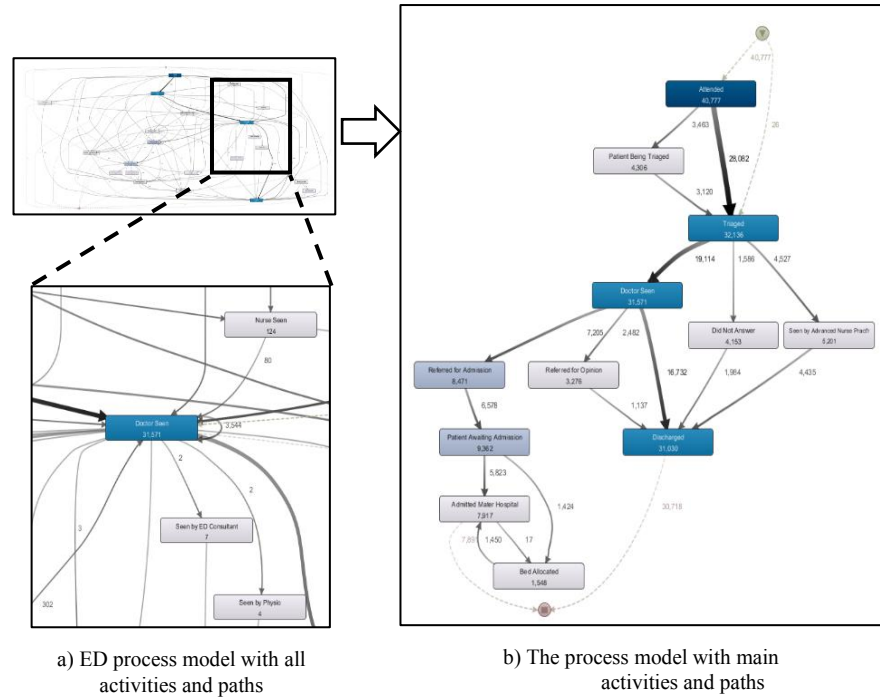


Figure 2 The discovered patient flow model of the emergency department

The resulted complete map is complex and hard to interpret due to the high variances in patients' pathways. This confirms the perception of the complex nature of patient journeys within the ED; there will always be patients presenting to the ED with non-standard characteristic that would require the patient to follow a different or new care pathway. This complexity is what doctors and nurses deal with daily, and make them not believe that system engineering techniques can contribute to help with patient flow complexity. But the fact is that the fuzzy miner allows observing complex processes at different levels of granularity by applying two fundamental metrics: significance and correlation. The significance metric assesses the relative importance of a precedence relation between two event classes, i.e. the more often two event classes are observed after one another, the more significant their precedence relation. On the other hand, the correlation metrics indicates how closely two events (i.e. activities) are following each other. Therefore, fuzzy mining can reduce and focus the displayed event classes by applying the two metrics on the discovered process map to achieve different levels of aggregation and abstraction. Fuzzy process miner has therefore applied to the data to show the main highway paths for patients and to hide less frequent paths (Figure 2b). The count inside each rectangle (Figure 2) shows how many times an activity has been executed (e.g. activity 'Doctor Seen' occurred 31,571 times). While, the count on the arc represents the co-occurrence frequency between any two activities. For example, the co-occurrence frequency between 'Doctor Seen' and 'Referred for Admission' is 7,205. Due to excluding low frequent paths there are differences between the numbers of activities shown on incoming arrows and activity boxes on the process maps. Further analysis of this model revealed that there are 1,984 different patient pathway patterns (Table 1).



Table 1 Discovered patient pathway patterns

Pathway	Cases	Relative frequency	Events	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	...	Step 13
1	9374	23%	4	Attended	Triaged	Doctor Seen	Discharged				
2	3406	8%	4	Attended	Triaged	Seen by Advanced Nurse Practitioner	Discharged				
3	3264	8%	3	Attended	Doctor Seen	Discharged					
4	3005	7%	3	Attended	Triaged	Discharged					
5	1949	5%	6	Attended	Triaged	Doctor Seen	Referred for Admission	Patient Awaiting Admission	Admitted to Hospital		
.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	.	.	.	.
1984	1	0.002%	6	Attended	Did Not Answer	Triaged	Referred for Opinion	Doctor Seen	Admitted to Hospital		

Over 60% of these patterns are one-off path and only 31 patterns account for 80% of ED patients. Therefore, the remaining 1,951 patterns, which accounts to 20% of patients, were filtered out in order to reflect the common behavior of the ED. However, the filtering process output will depend on the project objectives. For example, the one-off paths can be the focus if the project is to investigate the reasons of the variations in patients' flow. The fuzzy miner was applied again on the resulted 31,447 patients to drive final top-level process map of the ED (Figure 3). The most followed paths are shown with thick arcs between activities. However, the analysis of exceptional pathways (paths with very low frequency) can give deep insights for medical professionals regarding the main factors behind these patterns.

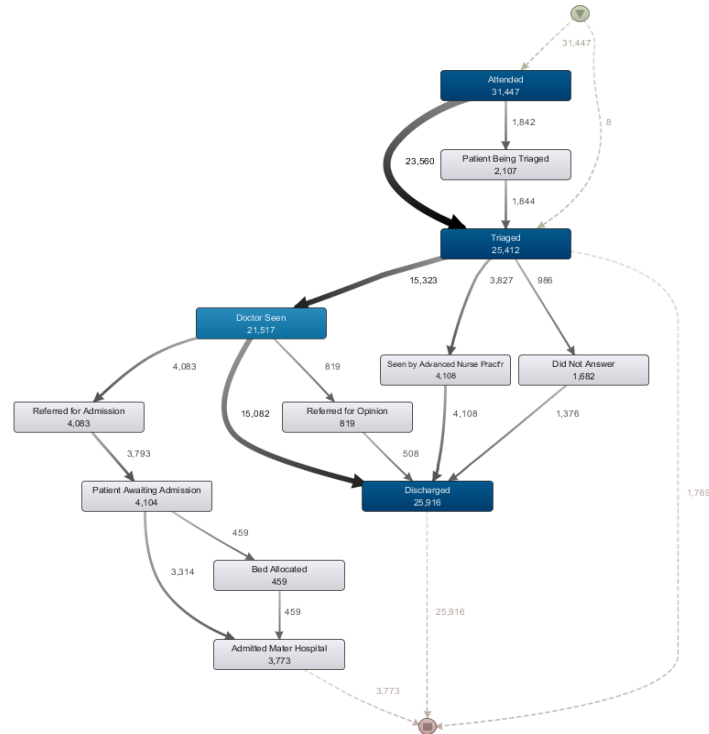


Figure 3 The top-level process map of patient pathways

### 3.3.2 Performance and Bottleneck Analysis

By considering the timestamp of events in the dataset, the ED performance and bottlenecks can be identified and analyzed (Figure 4). The number inside the rectangle represents the average activity time while the numbers on the arcs represents the waiting time between any two activities. The average length of stay (LOS) for all patients from arrival to departure (whether discharged or admitted to the hospital) is 9.1 hours which is 3 hours above the national target of 6-h average LOS in Ireland. However, the waiting time for admitted patients is 14 hours on average (with an average LOS of 18 hrs). Patients have to wait 3.3 hours on average to be seen by a doctor and 5.1 hours afterwards to be discharged from the department. The main bottlenecks in the ED are the “Seen by Doctor” and “Patients waiting admission” activities.

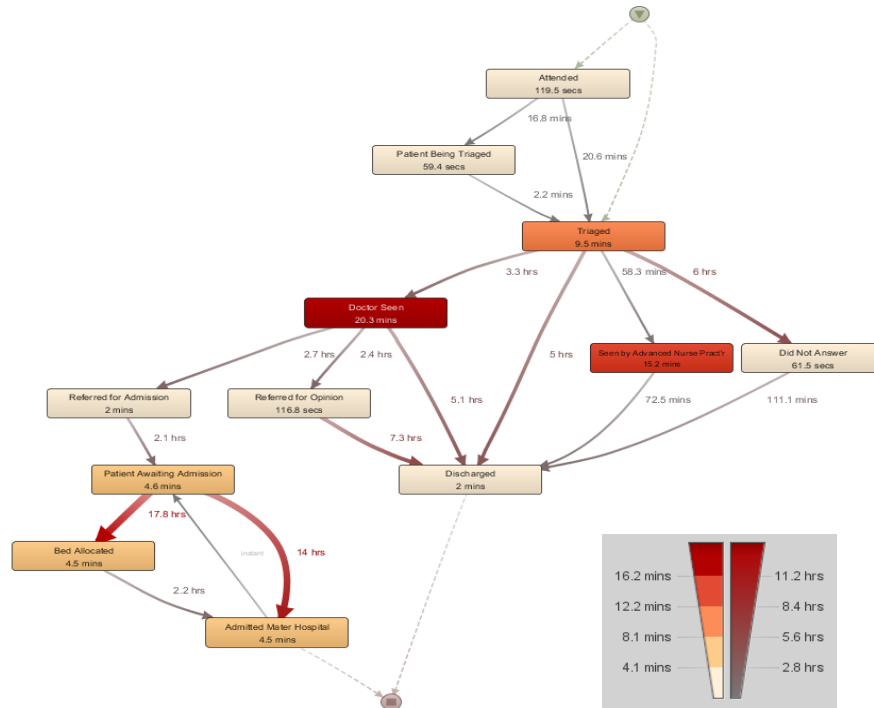


Figure 4 Performance analysis of the top-level process map

To gain a deeper understanding of the process flow of patients and the causes of these bottlenecks, the process model was analyzed at a more fine-grained level. The “Triage Category” attribute was used to divide patients into three groups; Immediate and very urgent, non-urgent and standard, and urgent patients. The process map of each patient group was constructed using the fuzzy miner and pathway patterns that reflect the common behavior for each group was analyzed (Figure 5). There are obvious variances in the associated pathways for patients with different urgency categorization (i.e. triage). The first patient groups (Immediate and Very Urgent) represents 15% of all patients with the majority of them have been admitted to the hospital with an average waiting time of 13.7 hrs. for the admission process to be completed (Figure 5a). While 26% of all patients are Standard and Non Urgent patients whom have a shorter pathway with a discharge outcome and 5.1hrs average LOS. The “Did not Answer” activity represents patients who left the ED after being triaged without waiting to be investigated by a physician (whether a doctor or advanced nurse practitioner) (Figure 5b). Patients leave the ED after being triaged (9.6% of all patients) due to the overcrowding of the ED and the prolonged waiting times.

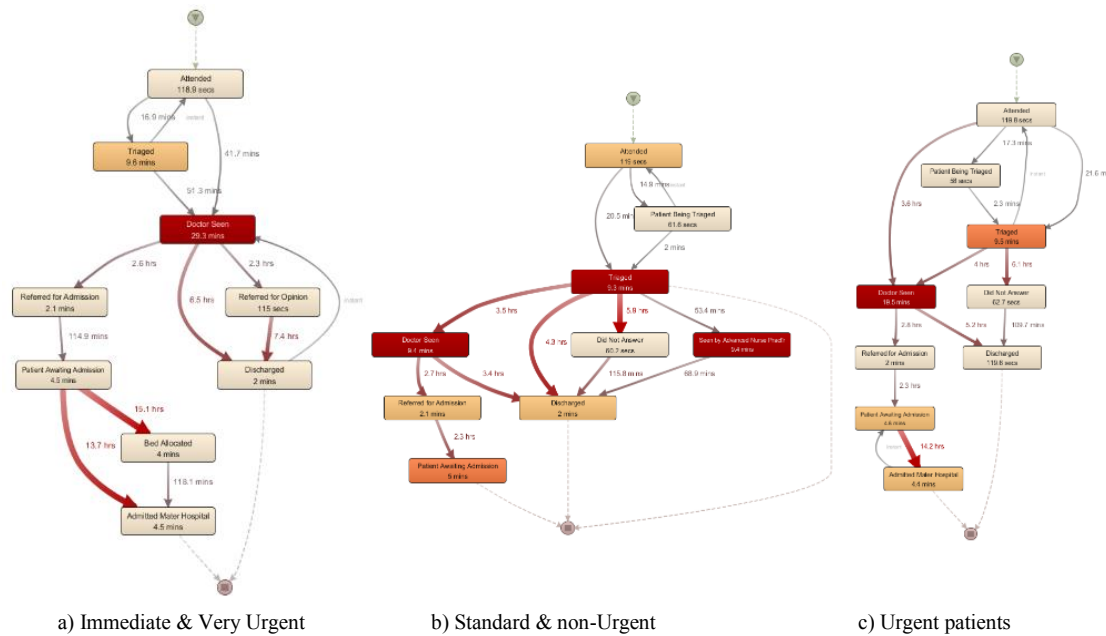


Figure 5 Performance Analysis for patients with different Triage Categories

Urgent patients represent almost 60% of all patients with 10.1 hrs average LOS. This group are presented to the ED with a wide range of complaints with 27% are referred for admission and the remaining are discharged with an average waiting time of 5.2 hrs (Figure 5c). The insights from this analysis enabled the ED decision makers to identify the bottlenecks for each group of patients and the challenges that they need to address.

### 3.3.3 Staff and Resources Analysis

The department has officially, 12 monitored trolley spaces; 3 of these trolley spaces (resuscitation area) are reserved for major trauma and critical care patients. Besides, the ED has an ambulatory car area with a capacity of six trolley spaces. Two rapid assessment triage bays and two triage rooms are also provided by the ED. As a 24hr department, the ED has eleven nurses during the day and nine nurses at night which collectively are divided into six types of nurses; Advanced Nurse Practitioner (ANP), triage nurse, resuscitation nurse, respiratory nurse, majors/minors nurse, and healthcare assistant. Physicians (excluding the 3 Consultants who provide shop floor cover between 9-5 or 8-8 with 24/7 on-call provision) are divided into two types: registrar/specialist registrar and Senior House Officer (SHO). Two types of resources were recorded in the eventlog for each record; location and staff type. Therefor resource requirement was analyzed for different activities in patients' pathways (Table 2). The resource analysis gives deep insights regarding the gap between the guidelines that should be followed and what is actually happening. For example, the triage activity should take place in the triage room by a registered nurse (RGN). However, the analysis reveals that 68% this activity takes place in the triage room and 77% of the times is performed by the RGN. This is a clear evidence of the overcrowding of the ED and quantify how fare this activity from the guidelines. Similarly, the "Doctor seen" activity is performed by SHOs (58%) and registrars (20%) in the Majors area in the ED (55%) and in the Resuscitation room (18%). This highlights the actual time spent by doctors in this activity and the actual locations where this is happening. These insights helped the ED managers to understand the actual allocation of staff and resources within the ED and to identify the gaps between best practices and the actual performance.

Table 2 Resource analysis for the main activities in patient pathways

		Triaged	Doctor Seen	Seen by ANP	Referred for Admission	Referred for Opinion	Discharged	Admitted to Hospital
Medical Staff	ED Consultant				46%		21%	95%
	ANP			24%		4%	3%	3%
	SPR		15%		11%	10%	10%	1%
	RGN	77%	0%					1%
	ADN			76%		13%	11%	
	SHO		58%		36%	51%	30%	
	Registrar		20%		7%	10%	12%	
	CNM	13%				5%	9%	
	Intern		7%			7%	4%	
Physical	Majors Area (9)	6%	55%		65%	57%	71%	72%
	Resuscitation Room (3)	6%	18%		31%	29%	4%	24%
	Ambulatory Care Unit (6)	3%	11%	57%	3%	14%	23%	2%
	Rapid Assessment Triage (2)	17%	9%					
	Triage Room (2)	68%						

ANP: Advanced Nurse Practitioner  
RGN: Registered General Nurse  
CNM: Clinical Nurse Manager

SPR: Specialist Registrar  
SHO: Senior Hospital Officer  
ADN: Associate Degree in Nursing

### 3.4 Model Development and Experimentation

A discrete event simulation model is developed using the discovered process models along with analysis of the staff, and resources, and performance (Figure 6).

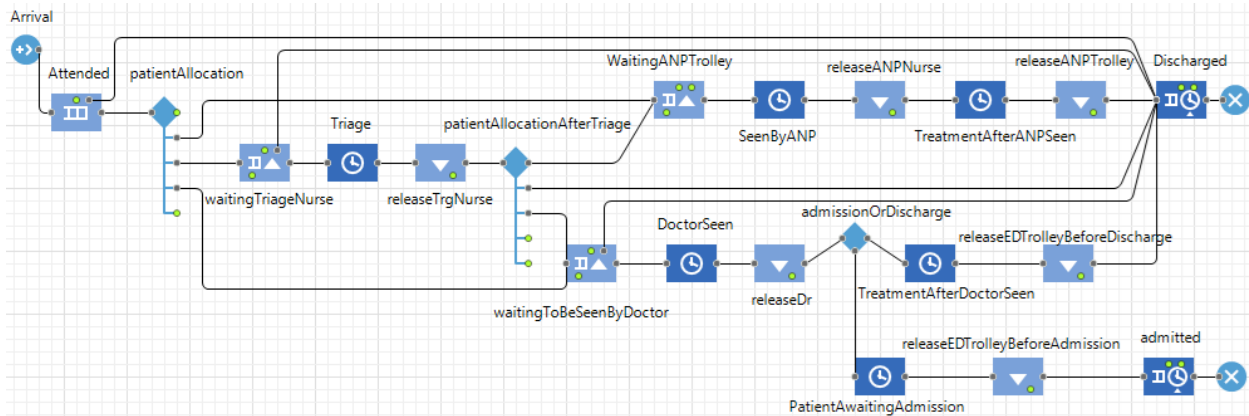


Figure 6 The ED Simulation Model

The simulation results of the baseline represent runs for one year (Table 3). The results are very close to the information extracted from the event log as following: average length of stay (LOS) is 9 hour vs 9.1 hour, average waiting time for triage is 19.9 min vs 20.6 min, average waiting for first clinical contact either by a doctor or ANP is 190.8 mins and 57.5 min vs 198 min and 58.3 min respectively, and percentage of patients left without being seen (L.W.B.S) by clinician (due to extended waiting time) is 10% vs 9.6%. Accordingly, simulation results have a satisfactory level of inaccuracy and that allows the model to be deemed as a valid model for experimentation. Based on the simulation results and process mining outcomes,

the main bottlenecks in the workflow are the “Seen by Doctor” and “Patients waiting admission” activities. Therefore, the simulation scenarios tested were the impact of variation in medical staffing (an increase of 25%), increasing clinical assessment space (an increase of 50%), and finally assessing the impact of incorporating a ‘zero-tolerance’ policy regarding exceeding the national 6-hour boarding time. According to the ED managers, the goal of the ‘zero-tolerance’ policy is to assess the performance of the ED if the average LOS of patients complies with the HSE 6 hour target and to identify the real factors that contribute the unacceptable overcrowding status of the ED; inappropriate physical space, insufficient staffing levels, or operational difficulties beyond the direct control of the ED. This scenario is implemented in the simulation model by dismissing patients from the ED model who are waiting to be admitted to the hospital and their LOS exceeds 6 hour. The rationale beyond this is that hospitals can provide a short stay unit, with an appropriate capacity, for patients who are waiting to be admitted but there are no available beds in the hospital. The simulation results of these scenarios are shown in Table 3.

Table 3 Simulation results of Baseline and Scenarios

	<b>Baseline</b>	<b>Scenario 1</b>	<b>+/- (%)</b>	<b>Scenario 2</b>	<b>+/- (%)</b>	<b>Scenario 3</b>	<b>+/- (%)</b>
Avg. W. T. Triage (mins)	19.9	19.6	-1%	19.8	0%	20.4	3%
Avg. W. T. Doctor (mins)	<b>190.8</b>	186.9	-2%	2.5	<b>-99%</b>	12.2	<b>-94%</b>
Avg. W. T. ANP (mins)	57.5	60.7	6%	65.6	14%	62.5	9%
Avg. # of Pts in W.R.	13.4	13.1	-2%	1.2	<b>-91%</b>	1.7	<b>-87%</b>
% of Pts L.W.B.S	10%	9%	<b>-3%</b>	0.01%	<b>-100%</b>	0.01%	<b>-100%</b>
Avg. LOS Discharged Pts (hrs)	7.5	7.5	-1%	5.2	-30%	4.1	<b>-45%</b>
Avg. LOS Admitted Pts (hrs)	<b>17.8</b>	17.7	0%	15.9	-11%	2.8	<b>-84%</b>
Avg. LOS All Pts (hrs)	9.0	9.0	0%	7.0	-23%	3.9	-56%

The simulation model shows that adoption of the cost-neutral scenario 3 has the highest impact on patients LOS at every stage, especially among patients who are discharged directly after ED care (45% improvement LOS). Furthermore, while scenario 3 improves the LOS of boarders, the more expensive Scenarios 1 and 2 have negligible impact on ED boarding times.

#### 4 CONCLUSION

Hybrid modeling approach is used in this paper to demonstrate the impact of using process mining techniques to support the development of simulation models for healthcare applications. Using the healthcare information systems, event log data can be generated for patient-care activities and this can feed into the analysis process. Process mining approach aims to utilize these event logs in order to find out the patients’ pathway patterns that are consistent with the observed dynamic behavior. This process secures a more accurate process model for patient treatment paths and provides a better foundation to develop an effective simulation model. The proposed framework was tested using a case study of an Emergency Department with event logs of 210,000 records. The discovered process model revealed that there are 1,984 different patient pathway patterns with only 31 patterns account for 80% of ED patients. However, infrequent behaviors show variants in clinical pathways, and thus require to be investigated. A more fine-grained level analysis was also performed for different patient groups to gain better insights on the treatment of patients within ED. The average length of stay (LOS) for all patients from arrival to departure (whether discharged or admitted to the hospital) is 9.1 hours – 3 hours above the national target of 6 hours average LOS in Ireland. However, the waiting time for admitted patients is 14 hours on average (with an average LOS of 18 hours). Patients had to wait 3.3 hours on average to be seen by a doctor and 5.1 hours afterwards to be discharged from the department. A discrete-event simulation model is used to implement the discovered process models and to examine the impact of potential what-if scenarios. The simulation scenarios tested were the impact of variation in medical staffing (an increase of 25%), increasing clinical assessment space (an increase of 50%), and finally assessing the impact of incorporating a ‘zero-tolerance’

policy regarding exceeding the national 6-hour boarding time. The results show that the unblocking of ED outflows by in-patient bed management had the highest impact on patients LOS at every stage, especially among patients who are discharged directly after ED care (45% improvement LOS) with 87% improvement for patients waiting times. Furthermore, the embedded process mining capabilities within the hybrid framework resulted in a 85% reduction in the time required to develop conceptual model and equally increased its accuracy.

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