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## Knowledge Management in the Pharmaceutical Industry: Between Academic Research and Industry Regulations

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## **Knowledge Management in the Pharmaceutical Industry**

Between Academic Research and Industry Regulations

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## **Knowledge Management in the Pharmaceutical Industry**

### **Between Academic Research and Industry Regulations**

#### **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.

**Keywords** Knowledge Management, Pharmaceutical Industry, Regulatory, Intellectual Capital, Systematic review, ICH Q10, PRISMA.

**Paper type** Literature review

## 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 organizations 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 realized 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 & 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).

*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.

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 at 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).

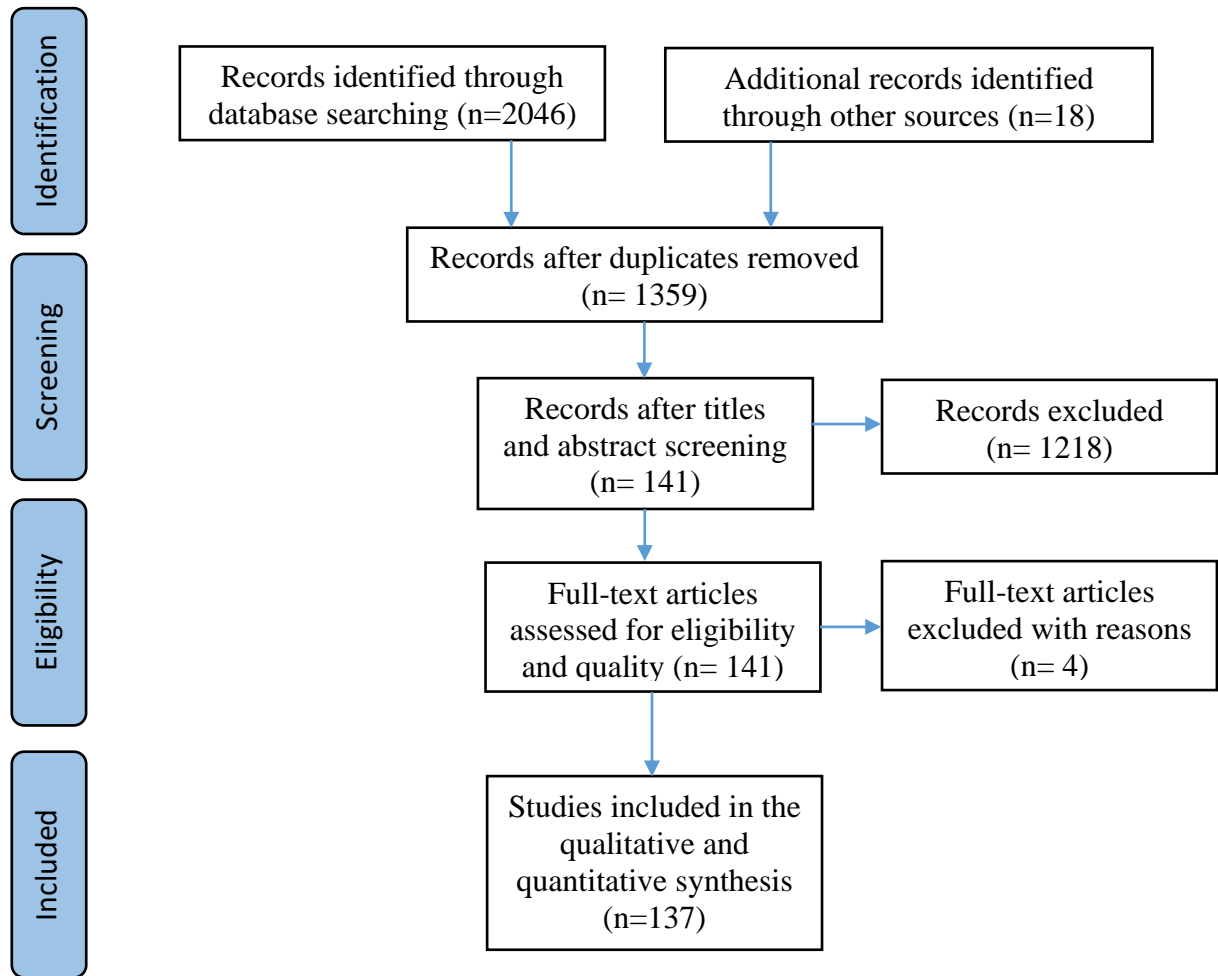


Figure 1 Systematic review process -PRISMA flow diagram (Moher et al., 2015)

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 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 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.





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%).

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).

*Table 2 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. 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 fall 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.

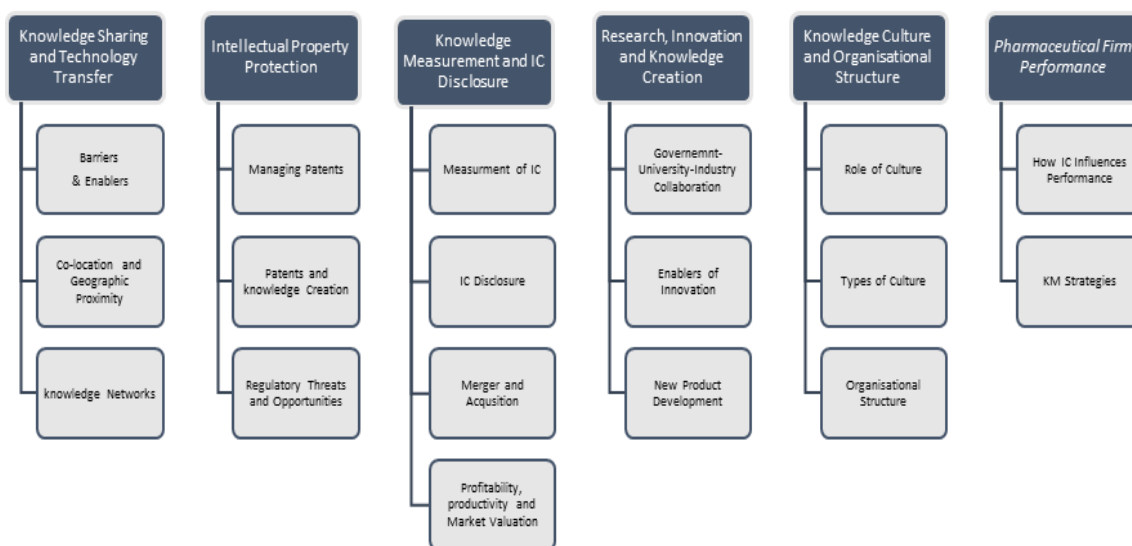


Figure 3 Literature Map

Table 3 Key articles under the featured themes

Category	
<b>Knowledge Sharing and Technology Transfer</b>	(Wakefield 2005); (Styhre et al. 2008); (Qureshi and Evans 2015); (Akhavan et al. 2015); (Pedroso and Nakano 2009); (Mets 2006); (Lilleoere and Hansen 2011); (Lawson and Potter 2012); (Hemmert 2004); (Gray, Roth, and Leiblein 2011); (Dooley and Kirk 2007); (Delaney 1999); (Criscuolo 2005); (Coradi, Heinzen, and Boutellier 2015); (Chávez and Viquez 2015); (Brachos et al. 2007); (Bourouni, Noori, and Jafari 2015); (Azan and Huber Sutter 2010); (Allen et al. 2016); (Santos 2003); (Mohan, Jain, and Ramesh 2007); (Malik 2012); (Iwasa and Odagiri 2004); (Fileri et al. 2014); (Chang, Yeh, and Yeh 2007); (Buchel et al. 2013); (Bourouni et al. 2015)
<b>Pharmaceutical Firm Performance</b>	(Mehralian et al. 2012); (Malik 2012); (Kim et al. 2014); (Vishnu and Gupta 2014); (SubbaNarasimha et al. 2003); (Sharabati et al. 2010); (Pal and Soriya 2012); (Kamath 2008); (Garcia Morales, Matias Reche, and HurtadoTorres 2008); (Bollen et al. 2005)
<b>Research, Innovation and Knowledge Creation</b>	(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 and Gautam 2010); (Kazadi, Lievens, and Mahr 2015); (Kale2005; Huang2011; Hohberger2016; (Herrmann and Peine 2011); (van Geenhuizen and Reyes-Gonzalez 2007); (Gassmann and Reepmeyer 2005); (Garcia Morales et al. 2008); (Fileri et al. 2014); (Chen, Jiao, and Zhao 2008); (Chang et al. 2007); (Cardinal and Hatfield 2000); (Styhre et al. 2008); (Mets 2006); (Lowman et al. 2012); (Lauto and Valentin 2016); (Kazadi et al. 2015); (Gassmann and Reepmeyer 2005); (Cardinal and

Category	
	Hatfield 2000); (Boasson and Boasson 2015); (Mohan et al. 2007)
<b>Intellectual Property Protection</b>	(Yang et al. 2014); (Iwasa and Odagiri 2004); (Boasson and Boasson 2015); (Allarakhia and Walsh 2011); (Sternitzke 2010); (Kale and Little 2005); (Hohberger 2016); (Chávez and Viquez 2015); (Russell 2016a); (Bollen, Vergauwen, and Schnieders 2005)
<b>Knowledge Culture and Organisational Structure</b>	(Wang, Ashleigh, and Meyer 2006); (Mehralian et al. 2016); (Magnier-Watanabe and Senoo 2008); (Magnier-Watanabe and Senoo 2010); (Magnier-Watanabe, Benton, and Senoo 2011); (Magnier-Watanabe and Senoo 2009); (Lindner and Wald 2011); (Guzman 2008); (Evans and Brooks 2005); (Ebrahimi, Saives, and Holford 2008); (Bigliardi et al. 2012); (Filiari et al. 2014)
<b>Knowledge Measurement and IC Disclosure</b>	(Vishnu and Kumar Gupta 2014); (Tahvanainen and Hermans 2005); (SubbaNarasimha, Ahmad, and Mallya 2003); (Singh and Kansal 2011); (Sharabati et al. 2010); (Palacios-Marques and Garrigos-Simon 2003); (Pal and Soriya 2012); Narula2016; Naidenova2013; (Mehralian et al. 2013); (Mehralian et al. 2013); (Kamath 2008); (Huang and Wu 2010); (Hine, Helmersson, and Mattsson 2008); (Ghosh and Mondal 2009); (Erickson and Rothberg 2009); (Chizari et al. 2016); (Bollen et al. 2005); (Boekestein 2006); (Boekestein 2009); (Abhayawansa and Azim 2014); (Sydler, Haefliger, and Pruksa 2014); (Russell 2016b); (Rossi, Thrassou, and Vrontis 2015); (Nito 2005); (Mehralian et al. 2012); (Mehralian et al. 2014); (Huang et al. 2011); (Boekestein 2009)

Publication years

The review shows that the majority of included articles have been published between 2004 and 2016 as shown in (Table 4).

*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								

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
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

### 3.1. 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).

### **3.2. *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 licensing (Allarakhia & Walsh, 2011). Although the exclusive licensing is more preferred in the pharmaceutical industry (2:1), non-exclusive licensing provides a strategic advantage to the company and 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 & Víquez, 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).

### **3.3. *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 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 standardized accounting guidelines on this vital asset results in unreporting of resources of billions in firm's annual reports with 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 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).

### 3.4. *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 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 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).

### ***3.5. 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 (Remy Magnier-Watanabe & 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 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 aging 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 (Rémy Magnier-Watanabe & Senoo, 2008). In fact, organisational characteristics can have

even more influence over KM than national culture (Rémy 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 (Rémy 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).

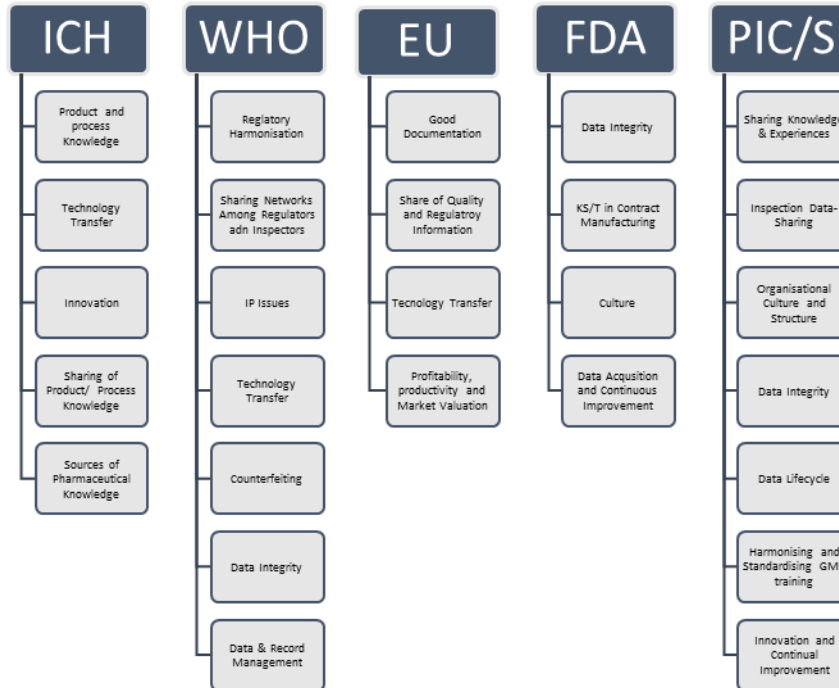
### **3.6. *Pharmaceutical Firm Performance:***

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).

**3.7. Regulatory Insights:**

A through 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).



*Figure 4 Key themes in regulatory guidelines*

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

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 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.

### 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 minimizing 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 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 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, 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, 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 Annex 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).

### 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, 2004; ICH, 2000; PIC/S, 2017; WHO, 2010b). 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

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 (Services & FDA, 2011).

### 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).



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.); 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.)

#### 1 **4. Discussion and Implications:**

2 The pharmaceutical industry is not only one of the knowledge-intensive sectors, but also  
3 an industry with a direct effect on health promotion (Mehralian et al., 2016). It comprises  
4 distinct characters making pharmaceutical knowledge management a unique process. Being  
5 research-intensive, highly innovative and a great source of IC (Kamath, 2008), building  
6 networks of R&D personnel with research institutions, providing ultimate protection of IP  
7 rights, having high influence of political, legal and administrative factors on technology  
8 acquisition (Hemmert, 2004), achieving high level of maturity in project management  
9 (Wakefield, 2005), involving suppliers in product development activities (Lawson & Potter,  
10 2012), involving collaborative research with universities and governments (Dooley & Kirk,  
11 2007), presenting sophisticated drug discovery and development systems (Criscuolo, 2005),  
12 facing challenges of regulated prescription drugs (Pedroso & Nakano, 2009), being one of the  
13 fast growing economic sector (Singh & Kansal, 2011), together with huge economic  
14 productivity and high number of employees (Bigliardi et al., 2012) are some of reasons for  
15 choice of pharmaceutical industry as empirical research field in KM literature.

16 Based on an in-depth review of the literature, few trends emerge. Domination of academic  
17 authorship (93% of authors) and empirical research (>70%) in 36 countries along with 20%  
18 increase in co-authorship reflects the academic maturity of the research area. Participation of  
19 practitioners is relatively limited (7%) in spite of the colossal investments in KM by pharma  
20 companies (Riddell & Goodman, 2014). This also validates the notion that the role which  
21 “*knowledge*” plays in the pharmaceutical industry is still immature and disabling the ICH Q  
22 10 desired pharmaceutical quality system (Calnan et al., 2018). This can also accentuate what  
23 has been described by Ragab and Arisha (2013) as a theory-practice gap in KM literature in  
24 general.

1 Since R&D is considered the key space for knowledge creation (Ingelgård et al., 2002;  
2 Parisi et al., 2006), most of the studies ignored other functions (e.g. manufacturing, sales or  
3 quality) or other sources of knowledge in pharmaceutical organisation (e.g. process validation  
4 studies; manufacturing experience, continual improvement, and change management  
5 activities). From a regulatory perspective, managing the knowledge throughout  
6 commercialisation and manufacturing phases until product discontinuation is supposed to be  
7 as important as managing drug development knowledge (ICH, 2009).

8 Taxonomical analysis of literature affirms six main knowledge processes/ themes  
9 extensively covered by researchers (Figure 3). In spite of that, the research in some other  
10 potential areas is relatively scarce (e.g. knowledge acquisition). In addition, the current  
11 thinking of the pharmaceutical regulatory bodies doesn't match the trending themes in  
12 business literature. For example, technology transfer and method/process transfer are  
13 regulated practices under pharmaceutical quality systems (ICH, 2009; WHO, 2011); case  
14 studies or empirical research is quite limited in this area.

15 IC is the most frequently used keyword and research theme in pharmaceutical KM  
16 literature. The influence of pharmaceutical IC on profitability, productivity and market value  
17 is addressed in several papers (e.g. Pal and Soriya, 2012). Pharmaceutical IC reporting in BS  
18 suffers from inconsistency and lack of standardised guidelines. Yet, Intellectual Capital,  
19 knowledge measurement or disclosure are not recognised by cGMP guidelines. While M&A  
20 implications were a subject of academic research in pharma companies, regulatory  
21 publications focus on knowledge transfer after product/process acquisition or data acquisition  
22 during product lifecycle (FDA, 2004a).

23 Although KM at product and process level is explicitly required in ICH Q10 1.6.1.(ICH,  
24 2008), regulatory authorities didn't suggest any framework for either measurement or  
25 disclosure of IC. With poor reporting and disclosure of IC in pharma (Abhayawansa & Azim,

1 2014), further research is needed to induce industry-specific measurement frameworks not  
2 only at organisational IC level but also at the individual knowledge level. As a part of  
3 company intangible capital, patent-related keywords are mentioned 10 times in the review  
4 pool (e.g. patent citation, analysis, research, count, etc.) reflecting the importance of IP rights  
5 as a research subject.

6 Governmental role in innovation, either through the outputs of basic science or public  
7 funding of growing industry R&D, is emphasised in the literature. Dynamics of innovation as  
8 managed by the Triple Helix model can be a meticulous explication of this phenomenon  
9 (Etzkowitz & Leydesdorff, 2000; Leydesdorff & Meyer, 2006). When the FDA announced  
10 the Pharmaceutical cGMPs for the Twenty-first Century in 2006; corrective actions,  
11 innovation and continuous improvement were considered as three complementary  
12 improvement approaches in Pharmaceutical Manufacturing (FDA, 2004b). However, only  
13 innovation has received enough attention in the surveyed literature. It is worth nothing that  
14 the term “creation” was mainly used by the regulators to signify creation of data and/or  
15 electronic records (FDA, 2016b).

16 The review explored the role of pharmaceutical organisational culture and structure in  
17 knowledge management. The review confirmed the notion that some values are found to be  
18 associated with the prosperity of knowledge within workspace (Remy Magnier-Watanabe &  
19 Senoo, 2009) and a new technology is not able alone to bring about a successful KM system  
20 (Chatzkel, 2007). The KM performance of the company was found in general related to its  
21 market performance. **Unlike pharmaceutical quality system** (ICH, 2008), organisational  
22 performance as a function of its KM practices was not considered by any of the four  
23 regulatory bodies.

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## 1 **5. Conclusion and Limitations of Research:**

2 According to the pharmaceutical regulatory guidelines, personnel must be qualified and  
3 knowledgeable with functions related to their work activities (FDA, 2006; WHO, 2014). It is  
4 a requirement to manage product and process knowledge throughout the product lifecycle  
5 (ICH, 2008). However, the academic research interests in pharmaceutical knowledge as  
6 presented in the extant KM literature partially overlap with the regulatory concerns. This  
7 incomplete overlap offers an opportunity for business researchers to design their future work  
8 to help industry meet regulatory expectations. Regulatory bodies recommended knowledge  
9 management but did not provide comprehensive frameworks to manage knowledge of  
10 pharmaceutical firms at the time industry practitioners refrain from serious contribution to  
11 academic research. This supports the notion that knowledge management in pharmaceuticals  
12 is still a growing research area, particularly in non-research and development functions.

13 The review has the limitation of being restricted to articles extracted from the *Emerald*  
14 *Insight* and *Science Direct* databases. Knowledge management conference proceeding and  
15 other academic portals can be explored in future studies. Despite the limitations, this paper  
16 offers an integrative and comprehensive taxonomy of KM literature in an industry-specific  
17 context that offers valuable insights for future research.

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