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A Blueprint for Knowledge Management in the Biopharmaceutical Sector

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A Blueprint for Knowledge Management in the Biopharmaceutical Sector

By

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Abstract

This research examined current industry Knowledge Management (KM) methodologies and capabilities in order to gain insights into the level of maturity and understanding of KM within the biopharmaceutical sector. In addition, the researcher has developed models, tools and processes that can assist the sector to gain greater clarity of the value and merits that KM can offer to organizations. The researcher proposes that a systematic KM program can be used to "unlock" the knowledge and organizational capabilities necessary to convey real competitive advantage, but more importantly for the patient, to enable organizations to successfully develop and deliver the next generation of advanced therapeutics.

The research questions asked; What are the current levels of adoption of KM within the biopharmaceutical sector? How is 'critical knowledge' defined within organizations? What might represent the core elements of a *Pharma KM Blueprint* to better enable knowledge flow within organizations? The research approach adopted a *pragmatic* worldview which is most suited to a research topic that is both *real world practice orientated* and *problem-centered* and sought to examine the *consequences of actions* within the biopharmaceutical sector when knowledge is not managed effectively. There were three primary phases of inquiry employed in the thesis and a mixed methods approach was used to explore the problems addressed. The first phase involved quantitative and qualitative data analysis of relevant literature sources, including available international KM benchmarking data. The second phase involved a biopharmaceutical industry consultation phase comprising of focus groups, polls and philosophical dialogues with KM experts, sector KM practitioners and knowledge workers. The third and final phase of inquiry involved the adaptation and development of the *Pharma KM Blueprint* including practical KM tools, frameworks and models for use within the biopharmaceutical sector. This phase also included a detailed case study executed within one large biopharmaceutical organization of a KM diagnostic tool and process developed as part of this research.

The research findings have established a core principle that knowledge must be valued and managed as a critical asset within an organization, in the same manner as physical assets. In addition, the research identified that in order to realize the ambitions of ICH Q10, stated as, 'enhance the quality and availability of medicines around the world in the interest of public health', (ICH Q10, 2008), there is a crucial need to enhance the effective and efficient flow of knowledge across the product lifecycle within organizations.

The research finds that in order to extract value from this organizational knowledge there must be practical, integrated and systematic KM approaches implemented for the identification, capture, curation and visibility of the critical knowledge assets before the matter of enhancing the flow of knowledge can be addressed. The research indicates that while these concepts are important to any business within the traditional biopharmaceutical sector planning on remaining competitive, they represent a "game changer" (or "game over") opportunity for any organization planning to develop, manufacture or market advanced therapeutic products, personalized medicines or next generation products. A key output of the research is the *Pharma KM Blueprint* that illustrates the holistic integration of core KM principles, models and tools to deliver the real benefits to the patients and the business.

Authors 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 Dublin Institute of Technology and has not been submitted in whole or in part for another award in any other third level institution.

The work reported on in this thesis conforms to the principles and requirements of the DIT's guidelines for ethics in research. The Institute has permission to keep, lend or copy Volume I of this thesis in whole or in part, on condition that any such use of the material of the thesis be duly acknowledged.

Signature 

Date 31 AUG 2018

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Glossary of Terms and list of Abbreviation

API = Active Pharmaceutical Ingredient

CAPA = Corrective and Preventive Action

CFR = Code of Federal Regulation (US)

CMO = Contract Manufacturing Organization

DIA = Drug Information Association

DIKW = Data, Information, Knowledge, Wisdom hierarchy

DIT = Dublin Institute of Technology

DP = Drug Product

DS = Drug Substance

EFPIA = European Federation of Pharmaceutical Industries and Associations

EMA = European Medicines Agency

E2E = End to End

EU = European Union

FDA = Food and Drug Administration (US regulatory body)

GMP = Good Manufacturing Practice. Also cGMP, "current" Good Manufacturing Practice to denote the expectation for continual learning and current standards

GxP = Used to denote all Good Practices in the Pharmaceutical Lifecycle, e.g. GCP Good Clinical Practice; GDP Good Distribution Practices etc.

HPRA = Health Products Regulatory Authority (formerly Irish Medicines Board; Ireland)

ICH = International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (formerly International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use)

ISPE = International Society for Pharmaceutical Engineers

KM = Knowledge Management

MAH = Marketing Authorization Holder

M&A = Mergers and Acquisitions

Medicinal Product (Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use)

> (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
>
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

NCA = National Competent Authorities

NDA = New Drug Application

OPEX = Operational Excellence

PDA = Parenteral Drug Association

PhRMA = Pharmaceutical Research and Manufacturers of America

PIC/S = Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme:

PLM = Product Lifecycle Management

PQS = Pharmaceutical Quality System

PRST = Pharmaceutical Regulatory Science Team (DIT)

TT = Technical Transfer

QbD = Quality by Design

QIWG = ICH Quality Implementation Working Group

QRM = Quality Risk Management

SOX = Sarbanes–Oxley (Act of 2002)

VTN = Virtual Technical Network

Chapter One

Introduction and Context

"The time is now right for the Biopharmaceutical industry to embrace the journey towards knowledge excellence"

Editors – A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry
(Calnan, Lipa, Kane, & Menezes, 2018)

1 Research Background and Context

The global biopharmaceutical sector[1] supplies medicines to patients around the world, enhancing the quality of lives and, in many cases, saving lives. According to Friend et al., developing and manufacturing medicines presents many challenges, including: complexity, cost, market competition, and an ever-changing regulatory landscape (Friend, Arlington, Marshall, & Bailey, 2011). As new and novel therapies emerge and markets expand, patients gain greater access to life-improving and lifesaving medicines, however, a 2017 report commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA) suggests 'lack of equitable and consistent access to essential medicines represents one of the most pressing global health challenges of our time' (Pugatch Consilium, 2017, p. 7). Furthermore, a recent report by a global industry research organization, EvaluatePharma®, suggests the global biopharmaceutical sector is trending to reach a value of $1.2 trillion by 2024, largely fueled by novel therapies addressing unmet patient needs, as well as increasing access

[1] The term "Biopharmaceutical Sector" for the purpose of this thesis incorporates the life cycle of a medicinal product from discovery to patient (including, Chemical and Biological entities)

to medicines globally. The report warns that pressures will continue from payers[2] as the demand for real world evidence (RWE) intensifies, accelerating cost challenges for the industry and potentially limiting access to those who need it most (EvaluatePharma® World Preview, 2018). Traditionally, the biopharmaceutical sector has been driven by a regulatory and compliance focus, however in the face of these recent environmental forces, this research has been undertaken to explore the role that knowledge management can play in assuring the availability of high quality, innovative therapies globally.

In these politically charged times, the high cost and continued availability of medicines attracts media attention on both sides of the Atlantic, in the US and EU, in particular with BREXIT looming in the near future. This focus comes from a range of stakeholders, including governments, media and patient advocacy groups. High profile news articles highlighting the cost of medicines are commonplace, with many focusing on the human cost that stems from the lack of affordable, available therapies (Boseley, 2018). Despite this, the biopharmaceutical sector is not renowned as an industry leader in the field of operational excellence (St. Gallen University, 2017).

Seeking to understand these global health access challenges, the aforementioned PhRMA report identified barriers that limit access to medicines in five high level categories: healthcare and medicines funding, trade and supply chain (cost-related), healthcare workforce, regulatory system, and the distribution infrastructure.

[2] insurers and governments

Indeed, the burden associated with regulatory challenges was identified as far back as 2006 when a survey by the Economist Intelligence Unit (EIU) found that respondents cited 'escalating regulatory costs' as the biggest threat over the coming 15 years (Economist Intelligence Unit, 2006, p. 52).

To address this regulatory burden, representatives of the regulatory agencies and industry associations of Europe, Japan and the USA met, primarily, to plan an International Conference on Harmonisation in April 1990, however the meeting also discussed the wider implications and terms of reference of what has become known as ICH (now referred to as the International Council for Harmonisation).

> *The urgent need to rationalise and harmonise regulation was impelled by concerns over rising costs of health care, escalation of the cost of R&D and the need to meet the public expectation that there should be a minimum of delay in making safe and efficacious new treatments available to patients in need.(ICH, 1990)*

Twenty-eight years later, this aspiration has still to be realized despite ICH's trojan efforts in developing and publishing a range of quality guidance documents. This suite of companion quality guidelines ICH Q8[3], Q9[4], Q10[5], Q11[6] and (draft) Q12[7] were

[3] ICH Q8 Pharmaceutical Development
[4] ICH Q9 Quality Risk Management
[5] ICH Q10 Pharmaceutical Quality System
[6] ICH Q11 Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/ Biological Entities)
[7] ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

developed with a view to embedding the concepts of science-based, risk informed decision-making at all stages across the pharmaceutical product lifecycle.

From the perspective of this research, in 2005, ICH published a concept paper for ICH Q10 *Pharmaceutical Quality System* (International Conference on Harmonisation, 2005a) , where the topic of *knowledge management (KM)* made a formal entrance to the global regulatory landscape for the first time, and was identified as one of the two enablers underpinning an effective Pharmaceutical Quality System (PQS), along with quality risk management (QRM).

Even though KM only found its way formally into the biopharmaceutical sector regulatory guidance in 2005, in fact, KM concepts have been widely discussed in many other sectors for a quarter of a century or more. Its appearance in an official regulatory guidance document placed additional weight to the topic within the sector, as noted by one EU regulator, "If something isn't specifically required by some type of regulatory guidance (financial, safety, good manufacturing practice, etc.), even if it's good for business, it is often difficult to drive adoption" (O. Donnell, K., personal communication, June 3, 2018).

In 2014, evidence that the biopharmaceutical sector is becoming increasingly aware of the value of KM, not only as a PQS enabler but also for "good business" reasons, was signaled by senior executives from a leading Biopharmaceutical Global Manufacturing Division (Marty Lipa, Bruno, Thien, & Guenard, 2014). Nevertheless, despite the

passing of more than a decade, ambiguity still exists regarding the PQS enabler of knowledge management.

This research examined current industry KM methodologies and capabilities in order to gain insights into the level of maturity and understanding of KM within the biopharmaceutical sector. In addition, the researcher proposed models, tools and processes that can assist the sector to gain greater clarity of the value and merits of KM and how it can be used to "unlock" the knowledge necessary to deliver the next generation of therapeutics.

While a thorough literature review found no shortage of academic references related to the broad field of knowledge management, a clear gap emerged between academic exploration and practical utilization specifically in the Biopharmaceutical Sector. This research focused on addressing this gap. The ambition was to evaluate the available theory and move it into practice by identifying and developing practices and tools that can be utilized across the biopharmaceutical sector to enable the flow of knowledge.

1.1 Key Concepts of Knowledge Management (KM)

Before exploring key KM concepts, it is first worthy to explore the definition of "knowledge", and perhaps more importantly, what is not defined as knowledge.

To aid in the articulation of knowledge, the *Data, Information, Knowledge, Wisdom* (DIKW) hierarchy is commonly used. The DIKW hierarchy is considered foundational in

many information science curriculum and its development is often credited to Ackoff (Ackoff, 1989; Rowley, 2007). The DIKW hierarchy is commonly represented as a pyramid with the foundational base of *data*, see Figure 1-1.

Figure 1-1 DIKW Hierarchy as described by Rowley (Rowley, 2007)

In the context of this thesis the following definitions are useful to consider:

- Data: Symbols that represent the properties of objects and events. (Ackoff, 1989)
- Information: Information consists of processed data, the processing directed at increasing its usefulness. (Ackoff, 1989) e.g. data with context
- Knowledge: as defined by the Cambridge Dictionary[8] can be described as: *awareness, understanding, or information that has been obtained by experience or study, and that is either in a person's mind or possessed by people*. However, in the context of an organization, knowledge can be a combination of content (explicit knowledge), information, as well as tacit knowledge.
- Wisdom: Wisdom is the ability to act quickly or practically in any given situation. It is based on ethical judgement related to an individual's belief system (Jashapara, 2005).

In the course of this research study, a commonly held definition for "knowledge management" had proven difficult to find. Indeed, in 2015, Girard et al. analyzed over 100 definitions for knowledge management that were available via open sources

[8] Cambridge Business English Dictionary © Cambridge University Press)

(Girard & Girard, 2015), and presented findings of the most common verbs and nouns in use with respect to KM as presented in Table 1-1.

Table 1-1 Top Verbs and Nouns in KM Definitions (Girard & Girard, 2015)

Verbs	Nouns
Use (40)	Knowledge (112)
Share (36)	Organization (69)
Create (33)	Process (50)
Manage (30)	Information (44)
Improve (15	Assets (19)
Capture (14)	People (18)

(x) = number of instances

Within the context of this research three prominent definitions of knowledge management emerged and are presented in Figure 1-2.

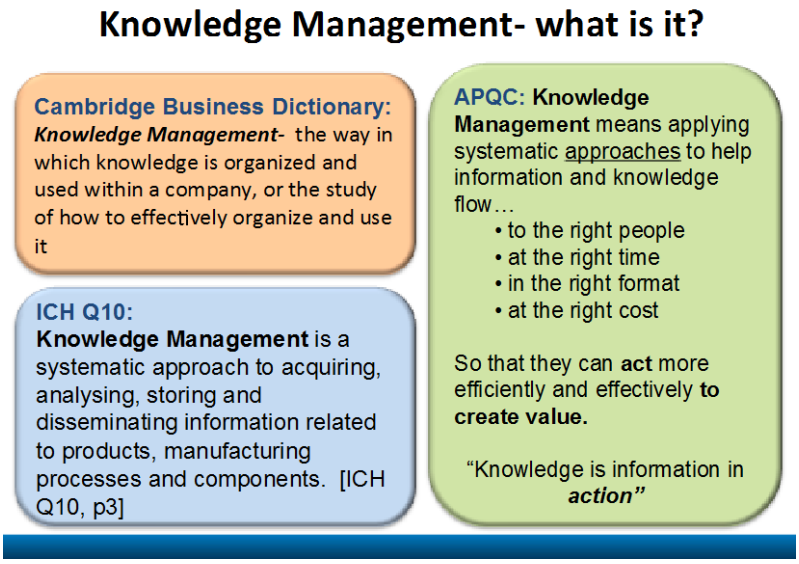

Figure 1-2 Knowledge Management Definitions (Kane, 2015)

The first definition from the Cambridge Business Dictionary highlights *organization* and *use*. The aforementioned ICH Q10 definition, leans toward a data lifecycle approach, focusing on *information* related to [biopharmaceutical] products, manufacturing

processes and components. Whereas, the American Productivity and Quality Center (APQC) definition presented above highlights systematic *approaches* to help knowledge and information flow when it is needed, to those that need it, how they need it, keeping in consideration the cost to do so. In the course of this project the research of APQC has proven to be invaluable and will be discussed in detail in the literature review and referenced throughout the research.

Each definition examined brought merit to the research and helped to focus this study. APQC have particular experience in bridging the research-application gap, and this is reflected in their definition of KM. It speaks to the pragmatic and applied nature of this research, reflecting on the business driver of KM; enabling employees to act more 'efficiently and effectively' to create value.

The inclusion of knowledge management in the ICH Q10 Product Lifecycle, depicted below in Figure 1-3, while not described in detail in the ICH Q10 guidance document, is a forward-looking concept. This diagram is provided here for illustrative purposes and is discussed in detail in the literature review in Chapter Two.

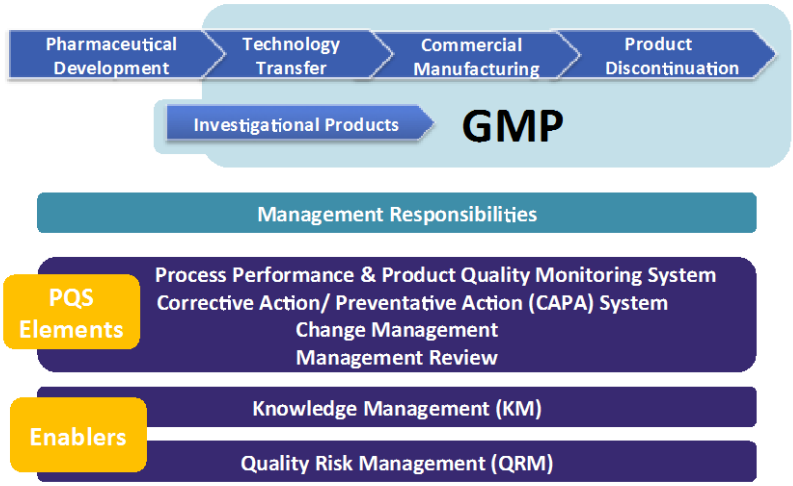

Figure 1-3 ICH Q10 Pharmaceutical Quality System (PQS) Model (International Conference on Harmonisation, 2008a)

The authors of *Enabling Knowledge Creation* advise that strategic implementation of KM not only leads to continual improvement (a principal goal of ICH Q10) but also radical innovation and competitive advantage (Von Krogh, Ichijo, & Nonaka, 2000, p. 72).

Linking back to the APQC KM definition, Figure 1-4 shown below (Wurmann, 2000) builds upon the concept of knowledge 'in motion or in use'. This diagram distinguishes between the *producers* of knowledge and the *consumers* of knowledge as the level of understanding and context increases.

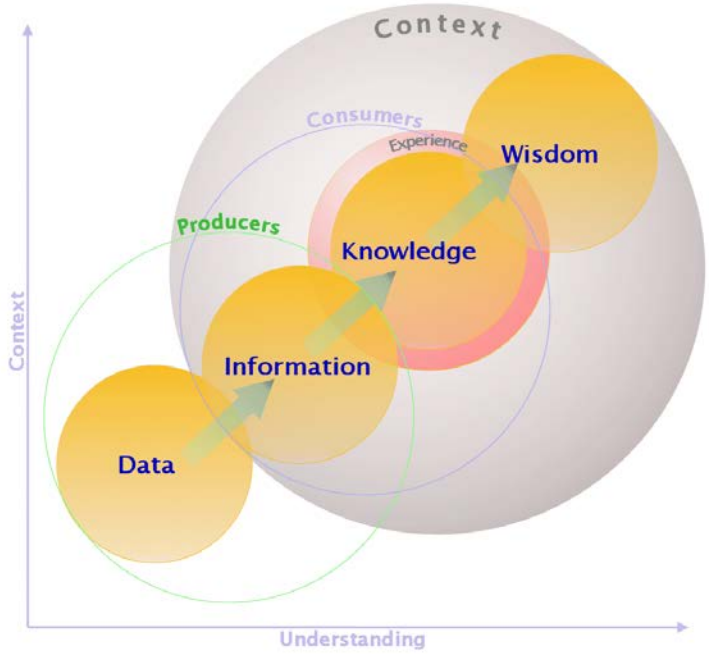

Figure 1-4 Diagram by Juan C. Dürsteler, adapted from "An Overview of Understanding" by N. Shedroff in the book Information Anxiety 2 by R.S. Wurman (Wurman, 2000)

While the depiction in Figure 1-4 is more representative of 'knowledge in motion' than the DIKW example, the researcher believes the circle highlighting *wisdom*, while academically important to the model, is difficult to socialize in a business setting. Therefore, the researcher suggests an amendment to this diagram replacing the element containing *wisdom* to one which represents "*insights*", as depicted in the adaptation shown in Figure 1-5 below.

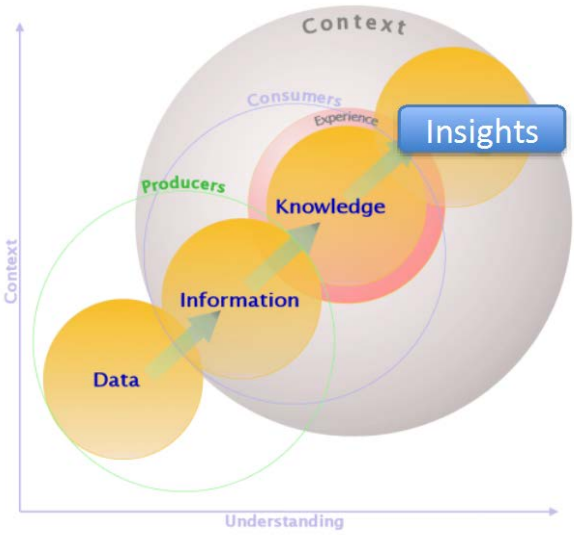

Figure 1-5 Diagram by Juan C. Dürsteler, adapted from "An Overview of Understanding" by N. Shedroff in the book Information Anxiety 2 by R.S. Wurman (Wurman, 2000) – Adapted by the researcher to replace Wisdom by "insights"

The researcher believes *insights* is more fitting, as wisdom is widely agreed as a "uniquely human" characteristic (Jeste et al., 2010). Whereas, insights may be derived by people with knowledge and experience. Furthermore, new trends in the field of KM suggest that insights may also be derived by new computing or artificial intelligence (AI) models that identify trends and correlations previously not possible to see with experience alone. A new era of "data-to-information-to-insights" is emerging and has been described as Knowledge Engineering and/or Cognitive Computing (Earley, 2016; O 'Dell & Trees, 2016).

To continue the exploration of KM terminology, additional key definitions are described in Table 1-2. These have been compiled by the researcher as relevant to the practice of knowledge management and will be referred to throughout this thesis.

Table 1-2 Key definitions related to knowledge management

Content	Topics or matter treated in a written work (ref Merriam Webster)
Tacit knowledge[9]	Knowledge that you gain from personal experience, for example when working in a particular organization. Often referred to as "know-how"
Explicit knowledge[10]	Knowledge that can be expressed in words, numbers, and symbols and stored in books, computers, etc.
Functional Knowledge	Knowledge created within a specific function within an organization e.g. specifications created by the engineering organization, batch record review processes created by the quality organization (definition offered by the resercher)

However, in the experience of the researcher, practically speaking, within a biopharmaceutical manufacturing environment, *Data, Information, Content, Tacit* and *Explicit knowledge* are often referred to generically as "knowledge", and in fact, the terms are used interchangeably by users.

1.2 Analysis of the current Biopharmaceutical Industry Landscape

> *In the current landscape, expectation from the pharmaceutical industry is rising; demand is higher, capabilities and resources must expand to accommodate diverse and multifaceted customer needs and standards must be met at varying levels- products that may meet standards for one regulatory body may not necessarily match those of another.* (CPhI Pharma Insights, 2016a)

This section introduces the current challenges facing the biopharmaceutical sector, namely:

- Outsourcing and Mergers & Acquisitions
- Building Trust
- Sourcing and Retaining Talent

[9] **Cambridge Business English Dictionary** © Cambridge University Press)
[10] **Cambridge Business English Dictionary** © Cambridge University Press)

1.2.1 Outsourcing and Mergers & Acquisitions

Traditionally, research and development (R&D) and commercial production of pharmaceutical products has been largely based in the western economies of the United States and Europe, supplying markets worldwide. However, the last decade has seen a sharp increase in the emerging markets, primarily China and India, building pharmaceutical production capabilities. This has led directly to cost pressures on US and European operations and indirectly to the transition towards the use of outsourced or contract manufacturing operations (CMOs).

The recent spate of mergers and acquisitions (M&A) has also changed the landscape of the industry. Drivers for M&A activity includes organizations seeking to consolidate their capabilities to counter threats from generic[11] brands, acquire new and existing product pipelines or technologies, or enter new markets. Indeed, the M&A activity undertaken in the first two quarters to July 2015 exceeded the full year totals seen in 2014 (Hirschler, 2015) and this trend was acknowledged to continue (PwC, 2015). The 2016 USA Markets reports (CPhI Pharma Insights, 2016b) outlined the following changes in US pharmaceutical operations and this is not dissimilar for European markets:

- Mergers and acquisitions
- Outsourcing

[11] A generic drug is identical--or bioequivalent--to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. (US FDA website) accessed 15Dec2016 http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm

- Adoption and implementation of new technologies
- Concerns regarding trade agreements, generics fees and the affordable healthcare act
- Adoption and implementation of the principles Quality by Design (QbD) and of performance management using quality metrics, i.e. responding to recent regulatory drivers

To understand the impact from the rapid growth within the emerging markets, it is useful to consider India as an example. Over the last 20 years the Indian pharmaceutical industry has shifted from producing high volume, low value, raw materials and Active Pharmaceutical Ingredients (APIs) to more complex formulations such as biologics. India now has the largest number of US FDA-approved facilities outside of the United States. Much of this growth is driven by an acknowledged 30-40% cost advantages (CPhI Pharma Insights/Global Business Reports (GBR), 2015) over western based US and European Manufactures. Listed below are examples of the impacts of this growth:

- The biggest growth area for the Indian industry is in producing *generics* (non-branded/ off patent) products for sale in Europe and USA.
- 40% of new drug approvals in the USA now belong to Indian companies
- Biologics and biosimilars[12] (i.e. generic versions of branded biological products) are expected to represent 15% of the Indian market value by 2020
- Indian companies continue to grow their technology base through overseas acquisitions and partnering with big pharma for R&D
- India's API producers have increasingly started to shift towards high value, low volume work with complex chemistry and Intellectual Property (IP) challenges

[12] Under the *Biologics Price Competition and Innovation Act* (BPCI Act), a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to

- The Indian government has committed to growing the sector and improving regulatory standards (CPhI Pharma Insights/Global Business Reports (GBR), 2015)

In a 2017 article highlighting current thinking on competing globally, published by the World Economic Forum, Chief Operating Officers were surveyed and identified their top four globalization concerns (Moritz, 2017). Although not specific to the biopharmaceutical sector, these concerns parallel current industry challenges, as follows:

1. Ability to be flexible in a world economy, citing global competition
2. Building and maintaining trust with customers and stakeholders
3. Sourcing and retaining talent – recognizing the human factor in a growing age of technology
4. Reimagining the leadership model – noting the importance of wide collaboration and the need to leverage more decentralized decision-making

Of these top four concerns it is useful to consider, in the context of this research, challenges two and three identified above, for the biopharmaceutical sector.

1.2.2 Building Trust

In the business of developing, manufacturing and supplying medicines, it is critical to put the patient at the center of decision making. One unique and confounding aspect of the biopharmaceutical sector is the ambiguity for many as to who the "customer" is within a complex array of stakeholders, including; regulatory health authorities, insurance payers, government funding agencies, prescribers, patients, and their carers (Calnan, 2014) .Although medicines are developed and manufactured to benefit

patients, the customer closest to the manufacturing organization is often the health authority that grants the Marketing Authorization (MA) to sell the medicinal product or the Manufacturing Authorization for the facility to manufacture the product. In addition, in many instances 'payers' (insurance companies or government procurement agencies) are also considered front-line customers and must be satisfied with the quality and cost of the product before they will purchase or reimburse patients. One additional hurdle, for prescription medications is that 'prescribers' must also have trust in the product and the company before they will recommend a specific product for their patient. All of this must be in place before the patient gains access to the medication.

The complexity of stakeholders results in a chain of trust in the biopharmaceutical sector which is long, fragile and convoluted. Historically, the response to failures has prompted the introduction of more regulation rather than the building and maintaining of trust with customers and stakeholders.

Reflecting back to 1937, over 100 people died in the United States resulting from chemical poisoning from a solvent used in a medicine that had not been tested (Rägo & Santoso, 2008). This event resulted in the introduction of the Federal Food, Drug and Cosmetic act of 1938 that granted the U.S. Food and Drug Administration (FDA) authority to oversee the safety of food, drugs, and cosmetics. In 1956, in Western Germany, Thalidomide was marketed. By 1960, it was introduced in over 46 countries resulting in over 10,000 babies being born with birth defects (ibid.). These events ultimately drove regulatory agencies worldwide to develop regulations to ensure

medicines and medical products were *safe and efficacious* for patients, prior to being approved for sale, and that quality systems were in place to ensure the *reliable manufacture* of safe and efficacious products.

In 1982, an unsettling incident involved seven deaths in the US when bottles of Tylenol[13] were tampered with at the point of sale. Most tragically this incident cost lives; in addition it also cost Johnson & Johnson (J&J) a tremendous loss in trust, as only 40% of respondents to a survey conducted a year later indicated they were likely to try Tylenol again (Kleinfield, 1983). Johnson & Johnson [14]responded to customer concerns by providing additional security measures to consumers via visual indications of tampering. This unfortunate incident led the US FDA to establish new guidelines in 1982 and 1989 for tamper-resistant packaging for over-the-counter and human drug products (US FDA, 2015). Trust is slow to earn and, and as evidenced in the J&J case, takes little time to lose. The researcher queries whether regulation in lieu of trust adds any greater protection for the patient.

1.2.3 Sourcing and retaining talent

> *By 2025, 60% of the US's pharmaceutical industry jobs could be vacant, the result of a lack of effective education policies coupled with growing competition from other countries, according to a series of reports released in June by industry trade group Pharmaceutical Research and Manufacturers of America (PhRMA)* (Earls, 2017)

[13] Tylenol is an over the counter product manufactured by McNeil Consumer Products a subsidiary of Johnson & Johnson (J&J)

[14] The tragedy also cost Johnson and Johnson over $100 Million in sales

Above is a recent headline from a pharmaceutical industry article which identifies that by 2025, 60% of US pharmaceutical industry jobs could be vacant. With this increase of employment vacancies, also comes the loss of deep knowledge of products and processes in the traditional US drug manufacturing base. The biopharmaceutical sector involves many levels of complexity, with a wide range of technology platforms from small molecule, traditional chemistry to large molecule vaccines and biologic therapeutics. When the variety and range of dosage forms and new combination delivery systems are factored in, the researcher proposes that it is very difficult to be a 'generalist' within this industry. To succeed, the industry requires a highly technical, specialized and educated workforce as evidenced by recent reports published in the UK, Ireland, and the USA (Earls, 2017; Expert Group on Future Skill Needs, 2016; Grey, 2016).

In an environment of fast-paced M&A activity, intense international competition, increasing regulatory expectations, all coupled with a potential 'brain drain' in the western economies as baby boomers retire; taking a fresh perspective of these challenges through the lens of KM is not just helpful – but essential.

The skills and capabilities needed to drive the pharmaceutical industry forward include building deep knowledge and expertise to not only develop new and novel medicines, but also to continue to improve and innovate on traditional, legacy medicines. Speaking of skills capabilities and experience this would appear to be an appropriate point to introduce the researcher's position.

1.3 Research Positionality

The researcher brings over 25 years of biopharmaceutical sector experience gained in multiple organizations, involving a variety of roles across the product lifecycle. The researcher spent the bulk of her career working in large, global pharmaceutical organizations, in roles including: Quality, Engineering, Strategy, and Technical Operations. In addition, the researcher has been involved in multiple facility startups focused on manufacturing new pharmaceutical products for patients in global markets. In addition to the manufacturing experience, the researcher also brings seven further years' experience working for two US Federal Government agencies in regulatory roles. This first hand understanding of regulatory expectations linked with 25 years of direct manufacturing experience has informed the researcher's industry focus of this research topic.

Experience drawn from multiple companies, multiple products, multiple countries and multiple regulatory environments, has highlighted the difficulties in executing many everyday tasks in the absence of effective knowledge management. This is not only the experience of the researcher, but other industry professionals have also shared similar experiences during numerous dialogues, details of which are discussed in further chapters. From the researcher's own experience, lack of access to the necessary knowledge can result in deviations, rework, ineffective investigations, additional expense, frustration of employees, and in an extreme case shared with the researcher, an inability to file an existing product in a new market due to lack of knowledge retention- thereby limiting patient access.

Therefore, the researcher has a passion for identifying practical solutions, which will enable the industry to deliver and improve safe, effective medicines to patients.

Finally, from a personal perspective, the researcher is also a patient. Due to a chronic disease, requiring daily life-sustaining medications, the researcher committed to:

- Understand key academic concepts of knowledge management
- Explore and focus proven knowledge management practices that are industry agnostic
- Explore the challenge of articulating the importance of KM for the biopharmaceutical sector
- Identify pragmatic approaches that can be utilized and are fit for purpose for the biopharmaceutical sector

1.4 Shaping the Face of Knowledge Management in the Biopharmaceutical Sector

When considering KM, in particular as a key enabler in delivering the objectives of ICH Q10, three key questions that arise for this researcher based on the 25 years of direct experience in the sector. These are:

1. What are the opportunities for KM to have a meaningful impact in the Biopharmaceutical sector?
2. How can KM help biopharmaceutical companies deliver medicines and other therapies to patients more rapidly?
3. How could an effective KM program support operational efficiencies for the company, improve employee engagement, and help address the many other challenges that face the sector?

To begin to these questions the researcher reached out to her network and convened a group of KM practitioners working within the biopharmaceutical sector to conduct a

focus group. Further details of the attendance and purpose of this focus group, and other industry engagement activities undertaken as part of this research, can be found in Chapter Four.

However, while setting the context, it is worth reviewing the findings of the focus group at this stage in the thesis. The group identified common challenges, trends and drivers facing the sector today, coupled with business strategies and objectives that are typically invoked to address these challenges. The challenges, drivers and objectives summarized in Table 1-3 form the business case for the House of Knowledge Excellence Framework discussed in Chapter Seven.

Table 1-3 Challenges, Trends and Drivers Facing the Biopharmaceutical Industry

(a) Challenge, Trend or Driver	(b) Strategy or Objective to address
Regulatory Driver(s)	
Regulatory expectation that knowledge is applied to improve patient outcomes (e.g. ICH Q10)	More efficient post approval changes Product innovations
Regulatory expectation for improved understanding of risk	Improved risk assessment process & outcomes (standard process, routine frequency, etc.)
Business Environment Driver(s)	
Global Competitiveness (pricing pressures, generic competition)	Operational Excellence (process capability, cost savings, etc.)
Increased therapeutic area competition	Shorten time to market/accelerate development timelines
Mergers and Acquisitions	Increase technical capabilities, optimizing product portfolios
Pressures to innovate to sustain growth	Operational Excellence (process capability, cost savings, etc.)
Shift to outsourcing in multiple stages of the product lifecycle (e.g. clinical studies, product collaborations, contract manufacturing, supply)	Leveraging external collaborations and 3rd parties for competitive advantage
Supplying Products into Emerging Markets against local competition	Effectively and efficiently supplying products to emerging markets while satisfying evolving requirements in that market
People/Talent Driver(s)	
Baby Boomer retirement	Maintaining business continuity, succession planning, knowledge retention
Evolving workforce expectations, (Millennial's entering the workforce)	Innovation, attracting new and diverse talent
The rise of Virtual/Remote workers	Reduction of facility footprints, maintaining connectivity and knowledge transfer between remote teams

When examining the challenges, trends and drivers within the sector, it was apparent that there is no one standardized KM approach available to address each of them.

1.5 Principle Ambitions at the Commencement of the Research

This research set out to examine current KM methodologies and capabilities in order to gain insights into how to best utilize existing, new and emerging biopharmaceutical knowledge to realize the ambitions of ICH Q10, stated as, 'enhance the quality and availability of medicines around the world in the interest of public health', (ICH Q10, 2008).

In addition, the research also sought to identify the critical aspects necessary to achieve effective knowledge management within a highly regulated environment, to facilitate not only the utilization, but also the flow, of this knowledge throughout organizations in order to reduce the risk of failures affecting the business or the patient.

The first stage of the research involved carrying out an extensive literature review, presented in Chapter Two, which informed the development of specific research questions that are outlined in Chapter Three.

In conclusion of this introductory chapter it is perhaps useful to the reader to introduce the main research output, which is presented as a new *Pharma KM Blueprint* and outlined in the final section of this chapter.

1.6 Introducing the Pharma Knowledge Management Blueprint

The main output from this research, developed as a result of the insights gained from the research work conducted over the course of the study, is introduced in Chapter Five and is presented as a new framework entitled, *The Pharma KM Blueprint*. The first element of the *Pharma KM Blueprint* is founded on the need to value and maintain *knowledge assets* in the same way as physical assets. With a view of bridging the gap from the theoretical field of knowledge management to the practical, the researcher presents the key findings, as follows

- Chapter Five- **Managing Knowledge as an Asset** – Addresses the need to value and maintain *knowledge assets* in the same way as physical assets within an organization
- Chapter Six – **The Pharmaceutical Product Knowledge Lifecycle Model** - Addresses the challenge of enabling knowledge flow in order to increase visibility, access and use of the product and process knowledge assets across the product lifecycle
- Chapter Seven - **The House of Knowledge Excellence Framework** – Demonstrates a framework developed to implement a systematic KM program linked to strategic objectives of an organization, incorporating KM practices, pillars (people, process, technology, governance), and enablers to support the effective management and flow of knowledge assets.
- Chapter Eight – A **Knowledge Management Effectiveness Evaluation** - Provides a practical KM diagnostic tool that may be used to identify and evaluate areas of opportunity and track progress on closing knowledge gaps.

The Pharma KM Blueprint as described across Chapters Five through Eight is represented in Figure 1-6.

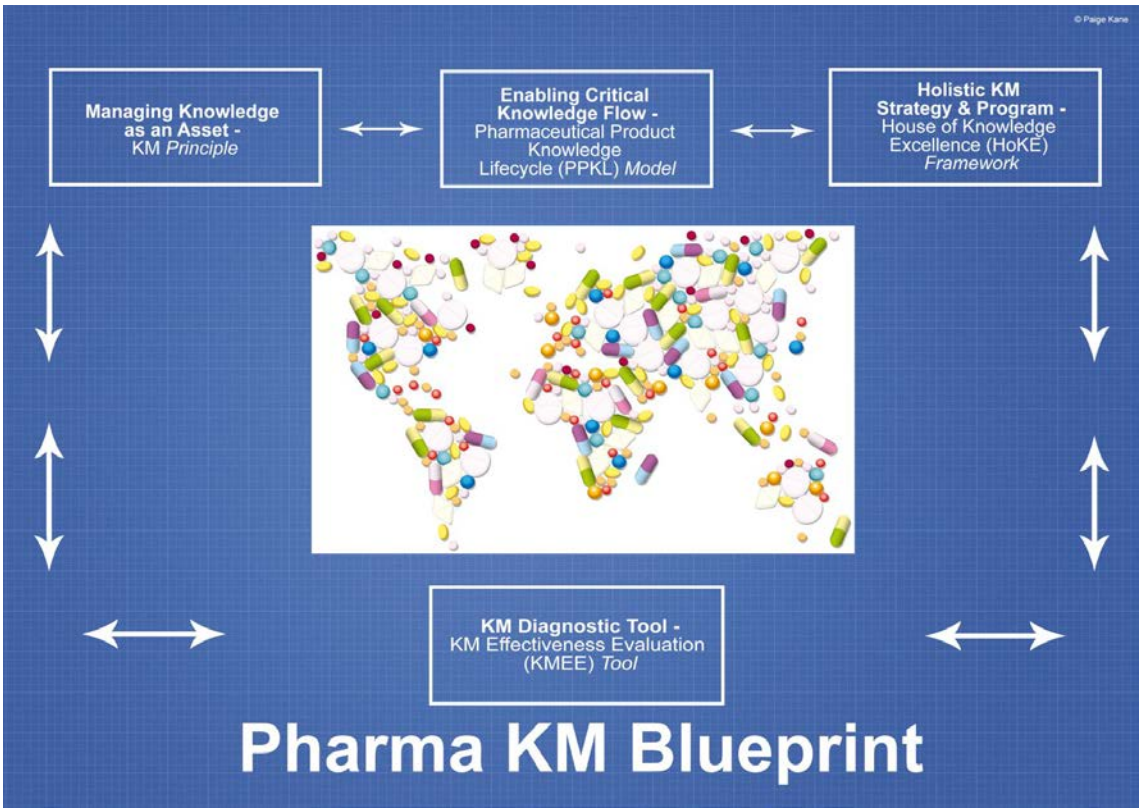

Figure 1-6 The Pharma KM Blueprint- Kane 2018

This chapter has outlined the context and motivation of the research, provided an overview of the biopharmaceutical sector including the current industry challenges and has provided a brief overview of the discipline of knowledge management. The chapter concludes by presenting a brief overview of the main research output, the *Pharma KM Blueprint*. The next chapter provides a review of the main literature sources considered as part of this research study.

Chapter Two

Literature Review

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2 Introduction

> *The pharmaceutical industry has a strong belief in its own uniqueness.* (Trees & Hubert, 2017)

As the topic of knowledge management in the biopharmaceutical sector is still emerging, the resources for this literature review continued to develop over the span of the research. Relevant sources reviewed included regulatory guidance, books, whitepapers, peer reviewed articles, reports, online periodicals, as well as presentations from biopharmaceutical sector personnel, regulators and knowledge management thought leaders.

In addition, a number of the research references were also generated through the researcher's own practitioner networks, through biopharmaceutical sector engagement, actively seeking case studies from organizations and attending multiple consultation events.

This chapter opens with a history of knowledge management, highlighting key concepts to provide a foundation for the practice of knowledge management, agnostic of any industry specific requirements, presented in section 2.1.

Section 2.2 examines literature associated with international benchmarking models, assessment of KM maturity within organizations and the current state of KM across a range of non-biopharma sectors. In particular, data and insights were reviewed from two different leading KM sources:

- APQC a not-for-profit KM research organization
- Knoco, a consulting firm specializing in knowledge management.

Section 2.3 discusses the regulatory landscape of the biopharmaceutical sector. First linking selected regulations to the biopharmaceutical product lifecycle phases and then advancing to explore the specific ICH guidance that introduces knowledge management as an enabler to a Pharmaceutical Quality System (PQS).

Section 2.4 explores literature specific to KM as it pertains to the biopharmaceutical product lifecycle phases of Technology Transfer and Commercial Manufacturing.

In addition to the literature reviewed within this chapter, literature relevant to Chapters Four through Eight is also included in those respective chapters.

2.1 The History of Knowledge Management

The history of *knowledge management* is relatively short in comparison to other management theories and practices that emerged in the mid 20th century (McGrath, 2014). While Peter Drucker is long credited with coining the term 'knowledge worker'

(Drucker, 1959), knowledge management was not widely discussed as a *Practice*[15] until the early 1990's.

In the late 1960's Drucker shared his insights regarding the importance of knowledge within organizations and expanded on the role of the knowledge worker; going on to discuss the transition from an industrial economy to what would later be referred to as a knowledge economy (Drucker, 1969). In these early publications, Drucker shared five *knowledge realities*, which are shown in Table 2-1, that established the need to be more systematic with respect to organizational knowledge (Drucker, 1964).

Table 2-1 Knowledge Realities (Drucker, 1964)

1. A valid definition of the specific knowledge of a business sounds simple – deceptively so.
2. It takes practice to do a knowledge analysis well.
3. Knowledge is a perishable commodity. It has to be reaffirmed, relearned, re-practiced all the time
4. Every knowledge eventually becomes the wrong knowledge. It becomes obsolete.
5. No company can excel in many knowledge areas.

These knowledge realities remain important tenants that will be revisited later in Chapter Five as the researcher explores the definition of *critical knowledge* within the biopharmaceutical sector.

As early as 1986 Wiig, delivered a seminal conference presentation entitled *Management of knowledge: perspectives and opportunity*. Then in the 1990's Wiig identified that the language was beginning to shift from the 'management of knowledge' to 'Knowledge Management' (Wiig, 1993). In his publication entitled *Knowledge Management Foundations: Thinking about Thinking - how People and*

[15] The field of Knowledge management Knowledge management is often referred to as an area of "practice", such as accounting, project management or other profession.

Organizations Represent, Create, and Use Knowledge, Wiig introduced eight important knowledge management concepts which are depicted below in Table 2-2.

Table 2-2- Knowledge Management Focus areas (Wiig, 1993)

1. Survey, develop, maintain, and secure the intellectual and knowledge resources of the enterprise.
2. Promote knowledge creation and innovation by everyone.
3. Determine the knowledge and expertise required to perform work tasks, organize it, make the requisite knowledge available, "package" it (in training courses, procedures manuals, or knowledge-based systems, for example), and distribute it to the relevant points-of-use.
4. Modify and restructure the enterprise to use knowledge most efficiently, take advantage of opportunities to exploit knowledge assets, minimize knowledge gaps and bottlenecks, and maximize the value-added knowledge content of products and services.
5. Create, govern, and monitor future and long-term knowledge-based activities and strategies - - and particularly new knowledge investments -- R&D, strategic alliances, acquisitions, important hiring programs, etc., based on the determined opportunities, priorities, and needs.
6. Safeguard proprietary and competitive knowledge and control use of knowledge to ascertain that only the best knowledge is used, that valuable knowledge does not atrophy, and that it is not given away to competitors.
7. Provide KM capabilities and a knowledge architecture so that the enterprise' s facilities, procedures, guidelines, standards, examples, and practices to facilitate and support active KM as part of the organization' s practices and culture.
8. Measure performance of all knowledge assets and account for them -- at least internally -- as capitalized assets to be built, exploited, renewed, and otherwise managed to fulfill the organization's mission and objectives.

It is worthy of note that based on research conducted in this study; these eight focus areas identified by Wiig in 1993 still resonate in a modern biopharmaceutical business. Indeed, the idea of treating Knowledge as an asset, suggested by Wiig, is one of the first key stages in the Biopharma KM Blueprint what was produced as an output from this research work, and is discussed in detail in Chapter Five.

In addition to the KM focus areas above, Wiig also described *knowledge flow* models as being 'the most important tool for charting how knowledge is used in the business' (Wiig, 1993). Since, then a wide variety of knowledge flow models are discussed in literature, from theoretical models that focus on elements such as the flow associated with knowledge creation (Nonaka, Toyama, & Hirata, 2008) to knowledge flow tools,

such as knowledge mapping techniques, that practitioners may utilize to identify knowledge flow issues (APQC, 2016). These important concepts relating to the need to maintain an effective flow of knowledge throughout organizations are further discussed in Chapter Six.

In 1995, with the publication of *The Knowledge Creating Company* (Nonaka & Takeuchi, 1995), Nonaka and Takeugchi discussed how Japanese companies had learned to harness their skills and expertise using organization knowledge creation techniques that focused on capturing tacit knowledge and codifying it. *The Knowledge Creating Company* is a key publication that brought the discipline of *Knowledge Management*, and more specifically the importance of tacit knowledge, to the forefront. As a result of this Nonaka is hailed as one of the leading researchers in the field of knowledge management. This is evidenced by the finding that, for the years of 1998-2007, Nonaka was the most cited author in KM publications (Ma & Yu, 2010).

As interest in knowledge management continued to grow, more publications followed, and in 1997 the journal *Expert Systems with Applications* (Elsevier Ltd.) produced its first special edition focusing solely on knowledge management (Volume 13, Issue 1, Pages 1-84 (July 1997). This increase in knowledge management literature continued through the 2000's. Published proceedings from the *European Conference on Knowledge Management* (ECKM) alone, exceeded 750 papers between the years of 2006- 2013 (Fteimi & Lehner, 2016). In addition, a systematic review of peer reviewed journal articles revealed that there were over 350 publications on the subject up to the year 2013 (Ragab & Arisha, 2013).

Therefore, although as evidenced above, there is no shortage of academic references on knowledge management, finding literature on bridging the gap between academic exploration and practitioner's utilization has proved to be more challenging. This gap was identified by Schütt in 2003, suggesting that the Nonaka model is flawed as 'the codification hype, even then, did not meet expectations' (Schütt, 2003). The premise of bridging this gap, shaped the researcher's ambition to evaluate the available theory and move it into practice by identifying and developing practices and tools that can be utilized by practitioners in the biopharmaceutical sector to harness the KM enabler described in ICH Q10(International Conference on Harmonisation, 2008a).

The next section reviews the available literature related to the practice of benchmarking KM tools and approaches.

2.2 Benchmarking Knowledge Management

Benchmarking is a performance management tool commonly used across all industrial sectors, academia, and not for profit organizations. Benchmarking[16] can be defined as:

> [verb] Evaluate (something) by comparison with a standard: e.g. *'we are benchmarking our performance against external criteria'*

Stroud discusses three primary classifications of benchmarking (Stroud, 2010): internal, competitive, and strategic. *Internal* benchmarking is conducted internal to the

[16] English Oxford Dictionary Online (accessed 2016-11-25) https://en.oxforddictionaries.com/definition/benchmark

organization only, *competitive* benchmarking demonstrates the position within a given industry sector or peer group and *strategic* benchmarking can be used for identifying world-class performance and may not relate to a given industry sector or given peer group.

Benchmarking is widely considered a key management tool for organizational performance improvement (Rigby, 2015). The rationale and purpose for undertaking benchmarking is often varied and this is described by Rigby in Table 2-3:

Table 2-3 Benchmarking Rationale - Bain 2015 (Rigby, 2015)

Benchmarking Purpose	Rationale
Improve performance	Benchmarking identifies methods of improving operational efficiency and product design.
Understand relative cost position	Benchmarking reveals a company's relative cost position and identifies opportunities for improvement.
Gain strategic advantage	Benchmarking helps companies focus on capabilities that are critical to building strategic advantage.
Increase the rate of organizational learning	Benchmarking brings new ideas into the company and facilitates experience sharing.

Within the field of knowledge management benchmarking is useful as a means of gaining understanding about the approaches and tools in use within organizations and also as a means of mapping the maturity of these KM approaches. In the experience of the researcher, topics typically benchmarked with respect to knowledge management are:

- Evidence of a programmatic approach to KM

- Levels of KM Maturity
- Use of specific KM tools/approaches e.g. Communities of Practice
- Examining the span or penetration of KM practices across the various levels of organizations

One organization with a rich history of KM research and benchmarking is the American Productivity and Quality Center (APQC) which:

> 'helps organizations work smarter, faster, and with greater confidence. It is the world's foremost authority in benchmarking, best practices, process and performance improvement, and knowledge management. APQC's unique structure as a member-based nonprofit makes it a differentiator in the marketplace' (APQC[17])

APQC have been conducting formal KM benchmarking on behalf of their members and clients for nearly ten years and conducting general KM research for over 20 years. APQC maintain an extensive database of *KM Maturity Benchmarking* data, which is further discussed in the next section.

2.3 KM Maturity Measurement

When seeking to measure the effectiveness of KM within organizations, maturity is a key aspect central to many models. An early example of measuring knowledge management Maturity (KMM) from 2003 was found in the literature from a team involving Arizona State University and Intel employees. The objective of the KMM survey was to identify the level of Knowledge management maturity for an organization and to provide guidance on how to improve and progress to the next level

[17] www.APQC.org

(Kulkarni & St. Louis, 2003). The survey measured maturity levels 1-5 across four key areas of: lessons learned; expertise; data; and structured knowledge. The survey results offered great potential with respect to organizational self-assessment for knowledge management as the level of knowledge management maturity for each key maturity area was clearly articulated and could subsequently be acted upon.

A further example of a maturity measurement tool found in the literature is the *Knowledge Management Maturity Assessment Matrix* (KMMAM) (Kruger & Snyman, 2007). This tool was developed in an academic setting with the intent of providing a pragmatic tool for assessing KM Maturity; it is worth noting that the authors report:

> '*It is clear that the inability to bridge the gap between theoretical propositions and practical usability is not only hindering knowledge management practitioners from successfully assessing the level of knowledge management maturity reached within organizations but, more importantly, is making managers lose faith in knowledge management as a strategic enabler'.* (Kruger & Snyman, 2007)

The KMMAM tool contained four levels of maturity and 101 questions. Kruger and Snyman tested the tool on students at the University citing the challenge of obtaining access within a company to pilot the tool as a limiting factor in its testing.

Also, in 2007, APQC developed their *Knowledge Management Capability Assessment Tool* (KM-CAT^{TM}), which is industry agnostic (i.e. not industry specific) and measures KM capabilities and their respective level of maturity. The KM-CAT^{TM} measures 5 levels of maturity over 4 categories inclusive of 12 sub-categories with 146 questions.

Since its inauguration, The KM-CAT™ has been used by many diverse organizations (corporations, nonprofit and governmental) and to date, over 200 companies have benchmarked their knowledge management maturity using this model.

Furthermore, in 2015 APQC carried out a detailed analysis of the KM Capability Assessments in their database (n=218) to explore insights the broader implication of the KM Capability data collected since 2007 might present (Trees, 2016). From this study, APQC identified that only 23% of participants regularly assess benchmark and analyze their respective programs. They found that organizations that benchmark and analyze their KM capability outperform organizations that do not report such activities. To illustrate examples of this, Figure 2-1 below depicts five capability measures where organizations that systematically benchmark and analyze outperform their peers.

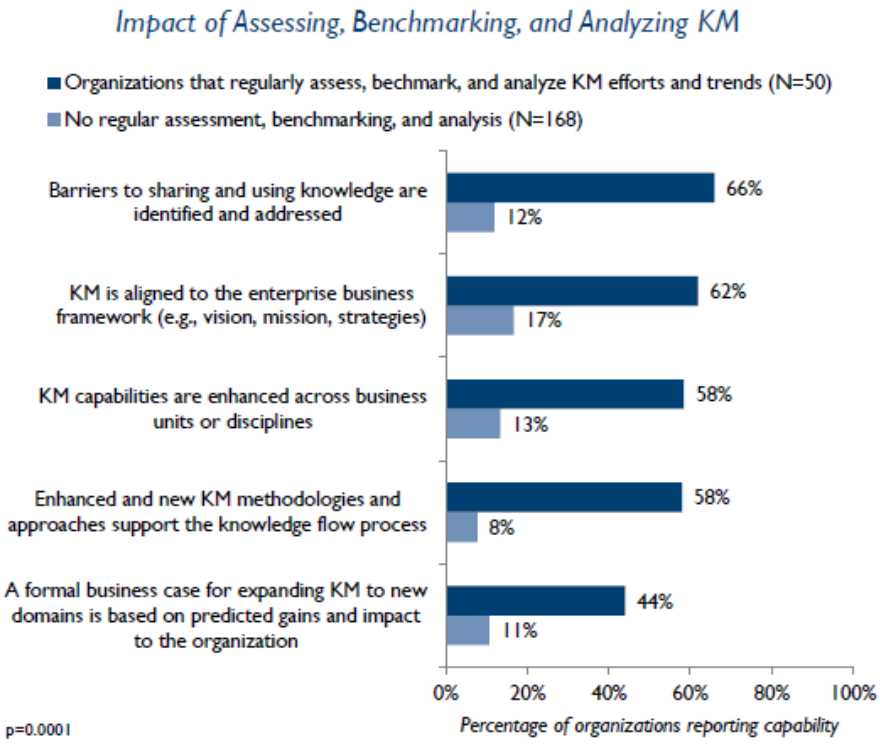

Figure 2-1 Impact of Assessing, Benchmarking, and Analyzing KM (Trees, 2016)

Within the biopharmaceutical sector, benchmarking of knowledge management programs and approaches are not widely conducted. In 2014, at the request of the researcher, APQC specifically reviewed the data from biopharmaceutical companies that have benchmarked KM via the APQC KM-CAT™ and identified that only 21 companies from the sector had done so (see Figure 2-2). It is acknowledged that biopharmaceutical companies might have benchmarked against other tools; however, the KM-CAT™ is the only known data source that breaks out the pharmaceutical sector available at this phase of the research and is likely indicative of the level of uptake within the sector. In addition to noting the low uptake of benchmarking by the biopharmaceutical sector, it is also worth observing that those that did, demonstrated low levels of KM Maturity.

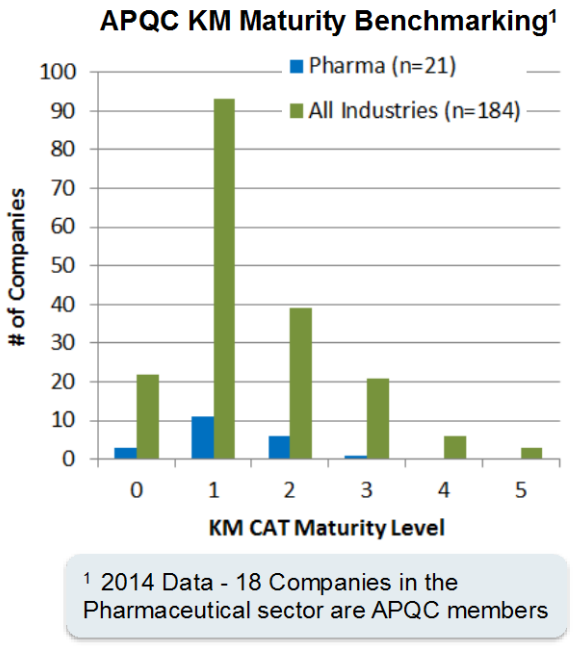

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Figure 2-2 APQC Data -Pharmaceutical Companies Benchmarked KM via the KM-CAT (Kane, 2014b)

Even before the 2014 analysis was published, as far back as 2009; the *BioPhorum Operations Group* (BPOG)[18], a well-established biotechnology industry forum, initiated a working group with a view to developing a knowledge management maturity model for use within the Biopharmaceutical sector. The BPOG KM working group, citing the unique nature of the industry, sought to develop a biopharmaceutical industry specific KM maturity model. After reviewing literature and learning about the APQC KM-CAT™, the group elected to use the APQC model to conduct their benchmark. This decision was based on the opportunity to further benchmark with biotechnology companies that were not members of BPOG as well as against other industries. As a result, seven

[18] More information on the BPOG can be found at www.biophorum.com

biopharmaceutical companies benchmarked[19] against the APQC KM-CAT™. The specific results were confidential to each company, however the members of the KM working group participated in rich discussions, sharing KM approaches and exploring challenges and success stories. The researcher was a member of this BPOG KM working group, and much of these discussions and insights informed her research.

In 2014, Lin et al. evaluated KM Maturity models to understand how KM maturity relates to barriers to knowledge flow. Their analysis evaluated seven popular maturity models (including the APQC KM-CAT™) and determined that barriers to knowledge flow were inherently different at different KM maturity levels. They concluded that organizations should proactively address specific barriers to knowledge flow in order to develop greater KM maturity. (Lin, Wu, & Yen, 2012). This researcher will further discuss these concepts in Chapters Five through Eight, sharing new research conducted to date with respect to KM maturity and knowledge flow.

Meanwhile, in an attempt to understand the current state of KM approaches globally, Knoco, a consulting firm based in the United Kingdom, developed a *Global Knowledge Management Survey* in 2014 and repeated the study in 2017 (Knoco, 2014, 2017). Knoco are:

> *'leading knowledge management consultants helping organisations of any size to deliver tangible business value from their knowledge; by designing knowledge management strategies and frameworks, delivering knowledge management initiatives, and providing essential knowledge management*

[19] The researcher was employed by one of the companies participating in the BPOG KM benchmarking work stream. This case study has not been published outside of the 7 companies that participated in the BPOG KM work stream/ benchmarking activity.

toolkits. Knoco's know-how, honed by working with world leaders in knowledge management over the past 20 years, helps clients in any sector improve performance and increase profitability through KM. (Knoco[20])

While not specifically designed as a formal benchmarking study, Knoco's study is one of the most comprehensive reports on the state of knowledge management executed to date and it, together with a 2015 focused study carried out by APQC will be further discussed in the next section 2.4.

2.4 Current State of Knowledge Management

To assess the current state of KM, a literature review was performed using two primary sources:

- Knoco *Global Knowledge Management Survey* (2014 and 2017)
- *APQC Member Study* -i.e. KM practitioners (2015)

In addition to the above-mentioned sources, in seeking to understand the current global demographic of KM practitioners, the researcher was regrettably unable to locate any further sets of verifiable data in the literature. In order to seek further insights into the global adoption of KM, the researcher explored social media platforms in particular the widely used professional application LinkedIn, where an analysis of LinkedIn members, currently claiming to be practitioners("KM Practitioners Search," 2015). In addition, from the analysis, it is noteworthy that one group on LinkedIn, entitled "Knowledge Management", has nearly 25,000 members, indicating

[20] www.Knoco.com

considerable interest in KM. Several other KM groups on LinkedIn have membership in the ~5,000 range (e.g. Knowledge Management Experts, Gurteen Knowledge Management Community, etc.). While the researcher does not purport LinkedIn data as a typically academic verifiable data source, in the absence of other published data, it was considered interesting to explore, in particular in light of the topic under review *Knowledge Management*.

Turning attention to the Knoco *Global Survey of Knowledge Management* (Knoco, 2014, 2017), data from world-wide KM practitioners was compiled via Knoco's own opt-in mailing list of over 3,000 practitioners as well as leveraging KM groups on LinkedIn, Twitter, and personal contacts. The survey obtained responses from 369 participants in 2014 and with an additional 48 responses received in 2017 to total 417, with Western Europe and the USA & Canada making up the largest proportion of respondents resulting in 34% and 29% respectively in 2014 and little change in 2017 (34% and 27%). Twenty-one industry sectors were represented in the survey; however, biopharmaceuticals were not delineated as a stand-alone sector. However, an interview by the researcher with survey developer Dr. Nick Milton (Director and VP, Knowledge Management consulting at Knoco), it was confirmed that participants from the pharmaceutical sector did respond, however their data were not segregated from the other respondents. In the course of this interview Dr. Milton noted the lack of specific biopharmaceutical sector data as a potential research opportunity, which prompted the researcher to develop the KM Pharma survey, which is discussed in Chapter Four.

Reviewing specifically the finding of the 2017 Knoco study, the demographics revealed that 91% of respondents were involved in some type of KM role within their organization, 53% of which were leading the KM initiative followed by an additional 20% that had a full time KM role. Some indication of the KM Maturity of an organization could be determined by number of years the company has been involved with KM, and the results shown in Figure 2-3 indicate that over 200 organizations has less had than four years' or less experience of KM, but over 150 respondents claimed 8-16 years of experience

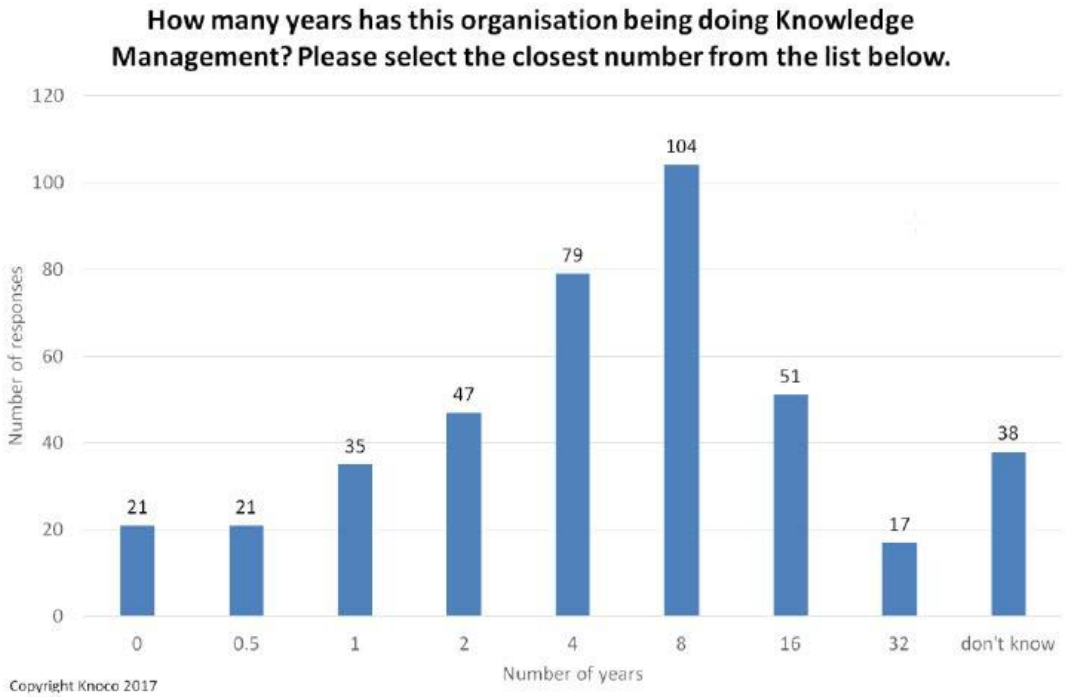

Figure 2-3 The Number of years respondent companies have been involved with KM (Knoco, 2017)

However, unlike maturity models that describe maturity in levels of 1-5, the Knoco survey captured a practitioner's view of maturity by asking specific questions to glean insights, which together with the responses are shown in Figure 2-4 below:

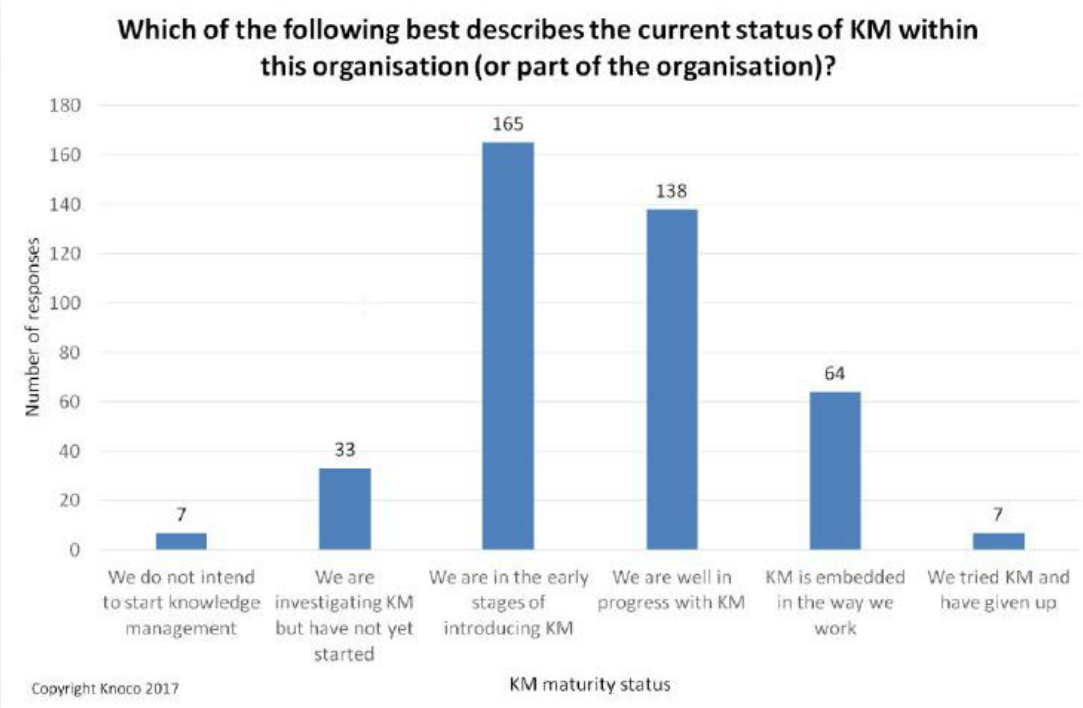

Figure 2-4 KM Maturity Levels (Knoco, 2017)

The responses indicate good interest in KM, with the largest number reporting to be in the early stages of introduction, but an encouraging number indicating KM to be well in progress and embedded in the 'way we work'. While the biopharmaceutical sector may be lagging behind, these numbers should give the sector encouragement to embrace KM and provide a comparative lens of the KM landscape from a practitioner's standpoint. As noted previously, this researcher, with permission from Knoco and APQC, further developed the KM Pharma survey specifically for the biopharmaceutical sector.

Turning our attention now to APQC to provide another vantage point of the current state of KM (APQC, 2015). In 2015 APQC surveyed their members to understand the outlook and focus for the year ahead, to identify external trends in knowledge sharing

and to explore expected impact on new tools and techniques. 524 respondents participated in the survey.

In contrast to the Knoco data, APQC demographics presented in figure 2.5, were more geographically diverse, and included responses from Asia Pacific, Africa and South America; however North America emerged in both surveys as the leading region for respondents with 34% in the Knoco survey and 30% in the APQC survey.

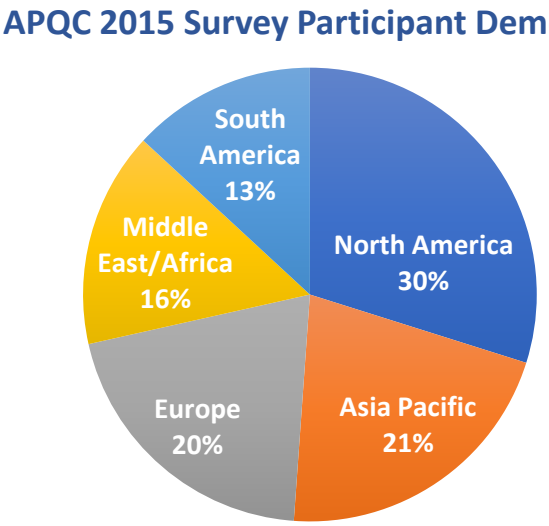

Figure 2-5 APQC 2015 Member Survey demographics (APQC, 2015a)

The APQC report identified *enabling collaboration* as a top priority with 87% of respondents listing it as important or very important, followed by more than 80% of participants listing the following items as important, or very important:

1. Capturing content and *explicit* knowledge
2. Promoting a knowledge sharing *culture*
3. Eliciting and transferring *tacit* knowledge

In addition, more than 70% of respondents indicated it was important, or very important, to increase the maturity of their KM program (APQC, 2015).

Interestingly, the researcher had previously identified these topics for further research prior to completion of this literature review. Exploration of these three topics is further described in the research objectives section in Chapter Three.

In examining specific KM initiatives within organizations in 2015, the APQC survey identified the following items depicted in Figure 2-6.

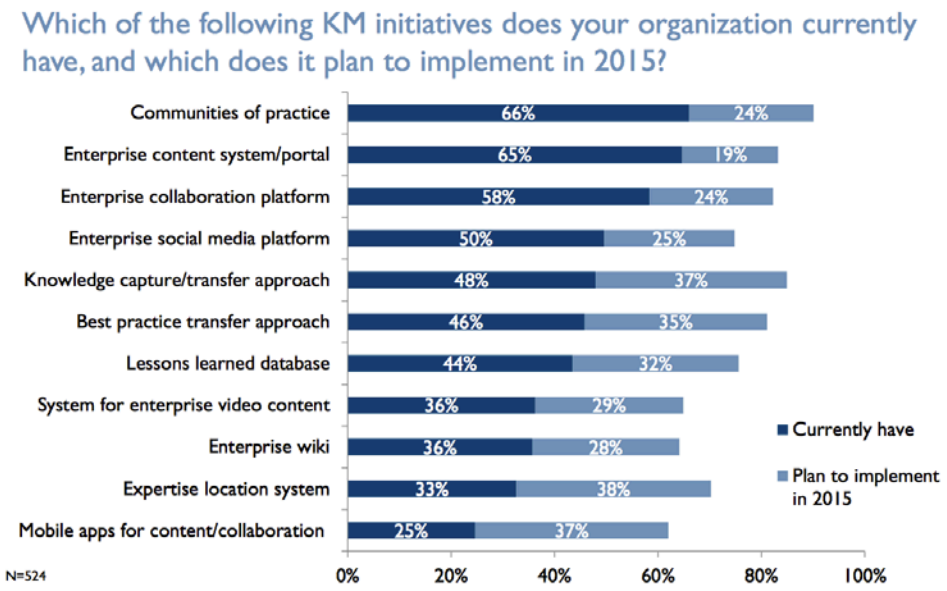

Figure 2-6 APQC 2015 KM Survey: KM Initiatives, as found and planned (APQC, 2015a)

Communities of Practice (CoPs), enterprise content portals and enterprise collaboration platforms were identified by more than 50% of participants as current KM initiatives at the time. Factoring in the 2015 implementation plans shared by the respondents, Communities of Practice should now be a KM practice used by 90% of APQC members and over 80% should now have capabilities in either searchable *enterprise content portals* for accessing explicit knowledge and *enterprise collaboration*

platforms for connecting colleague's tacit knowledge across their organization (i.e. the know-how).

The largest focus for APQC survey participants in 2015 were in the following areas:

- Expertise location system (i.e. 'Find an Expert') (38%)
- Knowledge capture/transfer (37%)
- Mobile apps for collaboration (37%)
- Best Practice transfer approaches (35%)

APQC also explored collaboration and knowledge sharing with partners and suppliers from the third-party network (APQC 2015). This is an area on increasing importance to the biopharmaceutical sector in particular as a result of the mergers and acquisitions described in Chapter One. 95% of survey participants indicated their organizations share knowledge with external partners and 34% expect a significant increase in knowledge sharing in the next three years. Figure 2-7 describes the findings.

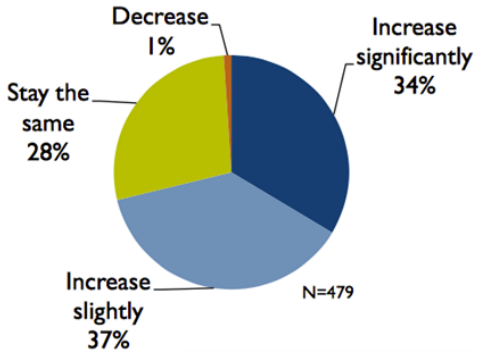

Figure 2-7 APQC 2015 Survey - External partner knowledge sharing in the next 3 years (APQC, 2015a)

On the other hand, the plans for knowledge sharing with suppliers looked somewhat different. In this case 47% of survey respondents expected knowledge sharing to stay the same and only 14% believed there would be a significant increase (Figure 2-8).

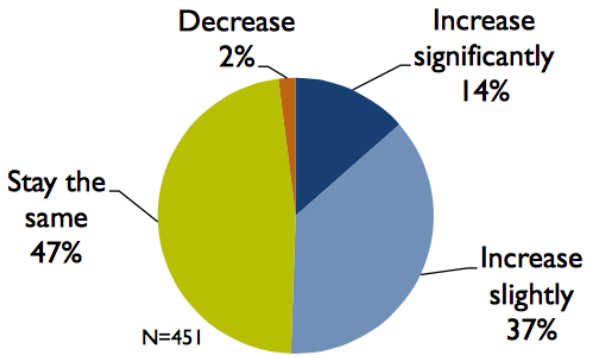

Figure 2-8 APQC 2015 Survey - Supplier knowledge sharing in the next 3 years (APQC, 2015a)

Based on the current biopharmaceutical sector trend of outsourcing, mergers and acquisitions (CPhI Pharma Insights, 2016b) it could interesting for further research in this area to analyze data specific to the sector regarding current and future knowledge sharing with both external partners and key suppliers.

Finally, of note, the APQC survey explored the impact expected by organizations on KM programs from emerging technological and methodological developments between 2015-2018. Big data and analytics as well as crowd sourcing/open innovation ranked the highest in terms of future impact on the focus of KM programs. This is shown in Figure 2-9 below.

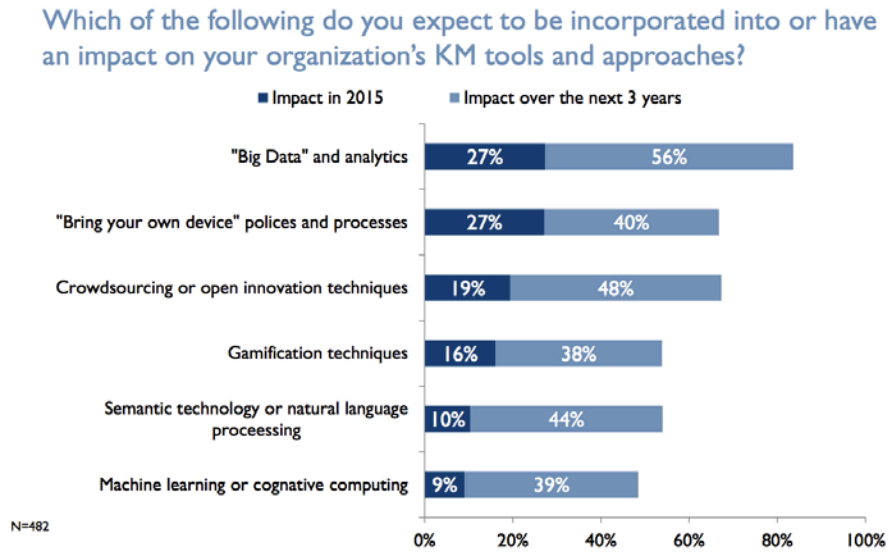

Figure 2-9 APQC 2015 Survey - Emerging KM technological and methodological developments (APQC, 2015a)

In summary, although not directly comparable in all aspects, both the survey data from Knoco in 2014 and the APQC member survey in 2015 provided a solid comparative foundation on which the survey specifically designed in this research to extrapolate data from the biopharmaceutical sector, was built upon. The KM Pharma survey is discussed in Chapter Four.

2.5 Pharmaceutical Regulatory Guidance

This section will review the published biopharmaceutical regulatory guidance and supporting literature as it relates to KM.

2.5.1 Pharmaceutical Regulatory Background and Overview

The biopharmaceutical sector operates globally and is highly regulated. Regulations take the form of:

1) Environmental health and safety (e.g. employee and environmental protection)

2) Businesses and accounting (e.g. SOX[21]) International Safe Harbor Privacy Principles)
3) Regulation of Pharmaceutical Products (cGMP, cGCP, cGLP, etc)

As the focus of this research study is related to the biopharmaceutical products themselves, the discussion in this section of the literature review will focus on item three above, i.e. *Regulation of Biopharmaceutical Products*. There are three primary types of regulations enforced across the regulated product lifecycle, as listed in Table 2-4:

Table 2-4 Pharmaceutical Lifecycle Regulations

Regulation	Scope/ Intent
GLP: Good Laboratory Practices	Applies to the Safety Studies – non-human – undertaken during the research & development of a new drug
GCP: Good Clinical Practices	Applies to the Safety and Efficacy Clinical Studies – may be human – undertaken as part of the approval and testing of a new drug
GMP: Good Manufacturing Practices	Applies to the control and management of the manufacturing activities for an approved drug to assure consistent and safe manufacture that meet the requirements of the approved manufacturing authorization

Each set of regulations pertains to a particular component of the overall product lifecycle. Figure 2-10 depicts a typical pharmaceutical product lifecycle and the applicable phase for each regulation

[21] SOX: Sarbanes–Oxley (Act of 2002)

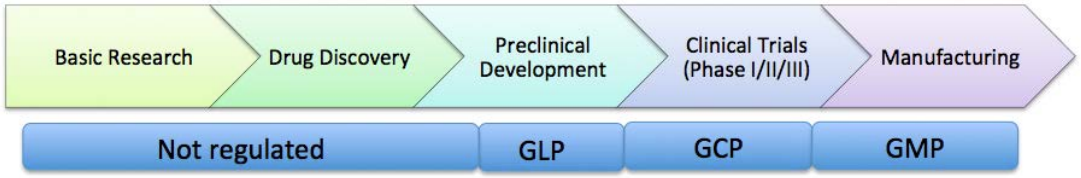

Figure 2-10 Typical pharmaceutical product lifecycle depicting regulation applicability

Biopharmaceutical regulatory bodies, typically referred to as national competent authorities (NCAs) worldwide develop and enforce the GLP, GCP and GMP guidance as described above. These regulatory bodies have a legal mandate to protect the public via guideline development, approval of medicinal products for sale and distribution within their respective regions. In addition, they carry out compliance audits and undertake legal enforcement actions, if necessary.

The worldwide biopharmaceutical regulatory landscape is complex, not only do individual countries have national competent authorities (nearly 200 globally), there are also several other key international organizations such as the World Health Organization (WHO) and the World Trade Organization (WTO). In addition, the sector itself plays a role in influencing the regulators via not-for-profit organizations such as PhRMA (Pharmaceutical Research and Manufacturers of America), EFPIA (European Federation of Pharmaceutical Industries and Associations, PDA (Parenteral Drug Association) and ISPE (International Society for Pharmaceutical Engineering), to name but a few.

Although there are nearly 200 national competent authorities (NCA's), it should be noted that some countries have multiple organizations responsible for regulating different aspects of biopharmaceutical products (e.g. in Europe each country has an NCA, but they are also members of the European Medicines Agency (EMA)). While some countries do not have regulators of their own, the World Health Organization (WHO) advocates on behalf of these countries which are mainly based in Africa. As a result, WHO has published a series of GLP, GCP and GMP guidance documents, which are part of the body of global regulatory expectations.

In the spirit of international regulatory collaboration, WHO has also sponsored the International Conference of Drug Regulatory Authorities (ICDRAs) for the past 46 years to 'provide drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration[22]

In addition to WHO, two other key organizations are noteworthy in the drive to harmonize biopharmaceutical regulations

- **ICH** (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), introduced in Chapter One
- **PIC/S** [23]Pharmaceutical Inspection Co-operation Scheme)

In terms of scope, ICH focuses on scientific and technical aspects of *drug registration* whereas PIC/S collaborates in the *GMP regulatory* space as a non-binding, informal co-operative arrangement between medicinal product regulators. To better understand

[22] http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en
[23] Pharmaceutical Inspection Co-operation Scheme (PIC/S) https://www.picscheme.org

the scope of each collaborating regulatory authority group, the diagram in Figure 2-11 has been created to provide a visual reference.

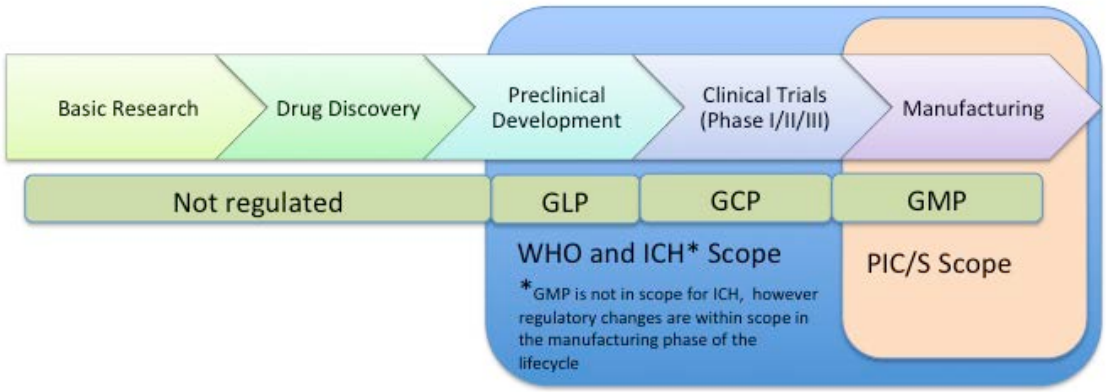

Figure 2-11 Typical pharmaceutical product lifecycle depicting regulation applicability

Traditionally, many NCAs had varying levels of requirements; ICH has endeavored to align these requirements. The regulatory agencies from US, EU and Japan are founding members of ICH, with its membership now extended to South Korea and Canada while several other countries are involved as observers. The perceived benefits of alignment of requirements include:

- Preventing duplication of clinical trials in humans and minimizing the use of animal testing without compromising safety and effectiveness
- Streamlining the regulatory assessment process for new drug applications
- Reducing the development times and resources for drug development

ICH publishes guidelines to four categories: **Q** (Quality), **S** (Safety), **E** (Efficacy) and M (Multidisciplinary Guidelines). As outlined in Chapter One the ICH guideline which specifically mentions knowledge management is ICH Q10 – Pharmaceutical Quality System guideline (International Conference on Harmonisation, 2008a), and will be discussed in detail later in this chapter.

PIC/S is open to any NCA, which has a *comparable GMP Inspection System*, and there are currently 49 participating authorities from all over the world (Europe, Africa, America, Asia and Australasia). PIC/S aims to harmonize inspectional procedures by developing common standards in the field of GMP inspection and by providing training opportunities to inspectors. Many companies when developing internal policies and procedures for their Quality Management System (QMS) refer to the PIC/S guidance as minimal GMP standards, indicating the importance of distinguishing international standards from guidance documents.

2.5.2 ICH Regulatory Guidance and Knowledge Management

Knowledge management, is a new topic introduced into the biopharmaceutical regulatory environment with the publication of ICH guidance *Q10 - Pharmaceutical Quality System (PQS)* (International Conference on Harmonisation, 2008a). The development of ICH Q10 was initiated in 2005 and the document was finalized in June 2008. ICH Q10 states three primary objectives:

1. Achieve product realization
2. Establish and maintain a state of control
3. Facilitate continual improvement

As described in Chapter One of this thesis, objectives one and three provide the basis of this research.

The ICH Q10 guideline introduces the concept of a four-phase product lifecycle, as follows: Pharmaceutical Development, Technology Transfer, Commercial Manufacturing and Product Discontinuation, depicted in Figure 2-12.

Figure 2-12 ICH Q10 Pharmaceutical Quality System (PQS) Model (International Conference on Harmonisaiton, 2008)

2.5.3 The Twin Enablers

Knowledge Management, together with *Quality Risk Management (QRM)* are listed as the two key enablers to an effective Pharmaceutical Quality System (PQS). The PQS enabler of Quality Risk Management is discussed at length in a dedicated ICH guideline entitled, ICH Q9: Quality Risk Management (International Conference on Harmonisation, 2005b), which was published in 2005. In contrast, ICH has not developed a companion document outlining expectations for the *Knowledge Management* enabler.

Also, worth noting is that when a new ICH document is drafted, the US FDA release the document for public comment. When the document is approved it becomes new guidance. This is in marked contrast to undertaking an update to the existing US FDA Code of Federal Regulations (CFRs), which is a far more challenging task. In the case, of

ICH Q9, the US FDA accepted it June of 2006, making it an official regulatory guidance for the US, which created greater regulatory expectations regarding the application of QRM. Furthermore, it is now not unusual to find regulatory observation citing the lack of QRM within organizations following an FDA inspection (Waldron, Greene, & Calnan, 2015).

Another example of the ambiguity of the KM enabler, is illustrated when looking at the section-detailing KM within ICH Q10. It is five sentences long, inclusive of the definition, as follows:

> '*Use of knowledge management and quality risk management will enable a company to implement ICH Q10 effectively and successfully. These enablers will facilitate achievement of the objectives described in section II.D (1.5) above by providing the means for science- and risk- based decisions related to product quality.*

Knowledge Management (1.6.1)

> *Product and process knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. For example, development activities using scientific approaches provide knowledge for product and process understanding.* ***Knowledge management is a systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes, and components.*** *Sources of knowledge include, but are not limited to, prior knowledge (public domain or internally documented); pharmaceutical development studies; technology transfer activities; process validation studies over the product lifecycle; manufacturing experience; innovation; continual improvement; and change management activities'.* (International Conference on Harmonisation, 2008b)

Although ICH Q10 was approved in 2008 and adopted by the EU in 2008, by the USA in 2009 and by Japan in 2010, little recognition has been given to the KM enabler. Dubbed as the "orphan enabler" (Calnan, Greene, & Kane, 2017), it is proposed that the lack of maturity within the industry regarding the role that *knowledge* plays in delivering the necessary quality risk management, continuous improvement and innovation is actually *disabling* the achievement of the ICH Q10 desired state.

Since 2008, the biopharmaceutical sector has seen an increase in software vendors offering biopharmaceutical companies a "knowledge management system". For further clarification ICH issued a Q8/Q9/Q10 Questions & Answers document in 2010 (International Conference on Harmonisation, 2010), two years post ICH Q10 approval, to dispel the growing concern of the need for a specific KM "system" and to clarify other questions about the KM enabler.

The five questions that related to KM within this ICH Q&A document (ibid.) are listed below and are worthy of review at this point:

> '***Question 1: How has the implementation of ICH Q8, Q9, and Q10 changed the significance and use of knowledge management?***
>
> ***Question 1 answer****: Q10 defines knowledge management as: 'Systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components'. Knowledge management is not a system; it enables the implementation of the concepts described in ICH Q8, Q9 and Q10. Knowledge management is not a new concept. It is always important regardless of the development approach. Q10 highlights knowledge management because it is expected that more complex information generated by appropriate approaches (e.g., QbD, PAT, real-time*

data generation and control monitoring systems) will need to be better captured, managed and shared during product life-cycle. In conjunction with Quality Risk Management, Knowledge Management can facilitate the use of concepts such as prior knowledge (including from other similar products), development of design space, control strategy, technology transfer, and continual improvement across the product life cycle.

Question 2: Does Q10 suggest an ideal way to manage knowledge?

***Question 2 answer**: No. Q10 provides a framework and does not prescribe how to implement knowledge management. Each company decides how to manage knowledge, including the depth and extent of information assessment based on their specific needs.*

Question 3: What are potential sources for knowledge management?

***Question 3 answer**: Some examples of knowledge sources are:*

Prior knowledge based on experience obtained from similar processes (internal knowledge, industry scientific and technical publications) and published information (external knowledge: literature and peer-reviewed publications); Pharmaceutical development studies; Mechanism of action; Structure/function relationships; Technology transfer activities; Process validation studies; Manufacturing experience e.g.: Internal and Vendor audits; Raw material testing data; Innovation; Continual improvement; Change management activities; Stability reports; Product Quality Reviews/Annual Product Reviews; Complaint Reports; Adverse event reports (Patient safety); Deviation Reports, Recall Information; Technical investigations and/or CAPA reports; Suppliers and Contractors; Product history and /or manufacturing history; Ongoing manufacturing processes information (e.g., trends).

Information from the above can be sourced and shared across a site or company, between companies and suppliers/contractors, products and across

different disciplines (e.g., development, manufacturing, engineering, quality units).

Question 4: Is a specific dedicated computerised information management system required for the implementation of knowledge management with respect to ICH Q8, Q9 and Q10?

Question 4 answer*: No, but such computerised information management systems can be invaluable in capturing, managing, assessing and sharing complex data and information.*

Question 5: Will regulatory agencies expect to see a formal knowledge management approach during inspections?

Question 5 answer*: No. There is no added regulatory requirement for a formal knowledge management system. However, it is expected that knowledge from different processes and systems will be appropriately utilized.'*(International Conference on Harmonisation, 2010)

Questions four and five respectively discuss the requirement for a specific KM computerized "system" and possible inspection activity related to the *Knowledge Management* enabler. Certainly, in the opinion of the researcher, the ongoing ambiguity and limited level of guidance related to expectations for KM is disabling the development of systematic approaches for this enabler within the industry. It is acknowledged that one must be careful in developing regulatory guidance, especially if the industry is not prepared, educated, or equipped to implement such guidance.

However, there is clear evidence that interest in KM has increased across the industry. May of 2014 saw a workshop on KM organized by one of the leading industry associations, the PDA (Washington DC, USA), and also brought the publication of the

KM e-Supplement by the other leading association, ISPE (Various, 2014). Knowledge management featured in the joint ISPE/FDA Quality Manufacturing Conference in 2015("ISPE/FDA Joint Quality Conference," 2015), and again in the DIA (Drug Institute of America) Annual meeting in 2015("DIA Annual Meeting," 2015), and in 2016 the ISPE Annual European conference ("ISPE European Confernce," 2016) featured a keynote on KM delivered by this researcher. In 2017, the researcher developed a Pharmaceutical KM survey, vetted by the ISPE KM Task Team that further explored KM adoption and maturity. Survey highlights (demographics, survey design) were presented by the researcher at the 2017 ISPE Annual Meeting (Kane, 2017). The survey is discussed in Chapter Four.

2.6 Understanding the Role of Knowledge Management Across the Product Lifecycle

Building awareness of the importance of the role of managing critical knowledge, end-to-end (E2E)[24], across the product lifecycle has emerged as a critical element of this research. This is discussed further in Chapter Six and a knowledge lifecycle model is proposed, adapted from the ICH Q 10 product lifecycle, the *Pharmaceutical Product Knowledge Lifecycle* (PPKL).

ICH Q8 - Product Development (International Conference on Harmonisation, 2009), ICH Q9- Quality Risk Management (International Conference on Harmonisation, 2005b)

[24] E2E refers to the product lifecycle from product development through product discontinuation

and ICH Q10 - Pharmaceutical Quality System are closely linked by their common thread of the application of robust science and risk-based decision-making.

Figure 2-13 provides a visual representation of the relationship between the regulations, typical pharmaceutical product lifecycle phases, the regulated product lifecycle phases as described in ICH Q10, and the ICH Q10 expected outcomes of 'achieve product realization' and 'facilitate continual improvement' (International Conference on Harmonisation, 2008a).

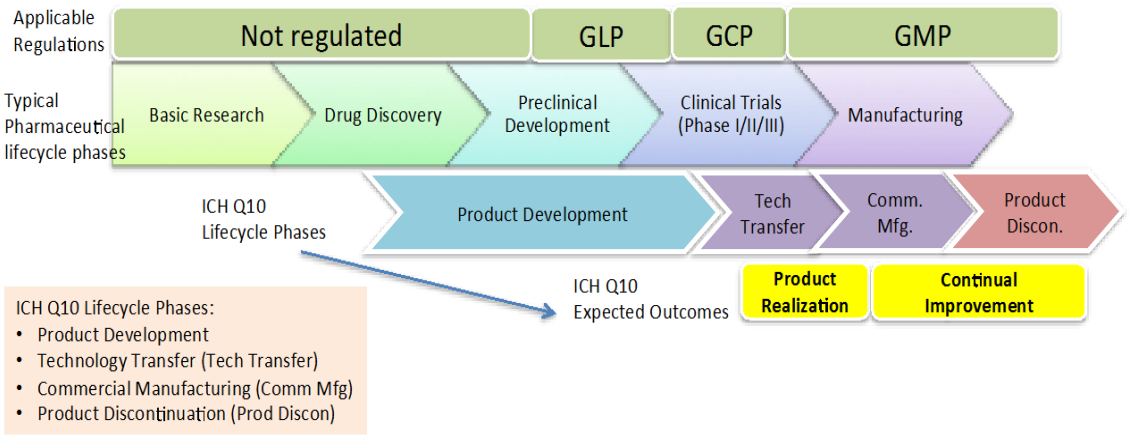

Figure 2-13: Regulations, Lifecycle and ICH Q10 Expected Outcomes

Although multiple guidance documents have been published the researcher found a lack of connectivity in practice that links product and process knowledge across the lifecycle. Draft ICH Q12 entitled *Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management* was introduced, to help realize the intended benefits of ICH Q8-11 and provide additional focus to the commercial manufacturing / post-approval phase of the lifecycle. This KM gap was acknowledged in the statement of the perceived problem in the ICH Q12 concept paper:

'There is currently a lack of a harmonised approach on technical and regulatory considerations for lifecycle management. While the concepts in ICH Q8, Q9, Q10 and Q11 provide opportunities for a more science and risk-based approach for assessing changes across the lifecycle, several gaps exist which limit full realisation of intended benefits. The envisioned post-approval 'operational flexibility' has not been achieved. The main emphasis at ICH to date has focused on early stages of the product lifecycle (i.e., development through launch)'.(International Conference on Harmonisation, 2014)

The development of the draft ICH Q12 guidance has sought to address this. However, in the opinion of the researcher, it falls short of achieving this due to the intense focus on established conditions coupled with a risk-based classification of post-approval changes. The researcher fully acknowledges that established conditions and greater flexibility for post-approval changes should deliver benefits to patients. In reality, the researcher suggests as the current paradigm operates a less than effective End to End (E2E) lifecycle management of critical knowledge. The required level of risk-based justification is difficult to demonstrate in the absence of the necessary supporting knowledge and consequently a vast set of opportunities will remain beyond the reach of many organizations. These opportunities are the very things that KM aims to enable, such as operational efficiencies, more effective knowledge capture, transfer and sharing of tacit knowledge, building organization capabilities, etc.

Furthermore, the researcher has identified the *Technology Transfer* (TT) phase as one of *the* critical phases of knowledge creation. The literature review and discussions regarding *Technology Transfer* will be explored in detail in Chapter Six, as a central knowledge creating component of the *Pharmaceutical Product Knowledge Lifecycle* (PPKL).

2.7 Biopharmaceutical Sector Knowledge Management Publications

Academic literature with a focus on the biopharmaceutical product lifecycle was not found to be plentiful during the literature, and when focusing on the technology transfer (TT) and commercial manufacturing phases of the lifecycle this lack of literature was even more pronounced. Although over 45 publications were identified from 1998- present, only six were relevant for the scope of this research and can be found in Appendix I (Guebitz, Schnedl, & Khinast, 2012; Herwig, Garcia-Aponte, Golabgir, & Rathore, 2015; Junker et al., 2011; Meneghetti et al., 2016; Qureshi & Evans, 2015; Rathore, Garcia-Aponte, Golabgir, Vallejo-Diaz, & Herwig, 2017).

Publications of relevance were found in the May 2014 ISPE Pharmaceutical Engineering Knowledge Management Supplement (ISPE, Various, 2014) and in conference proceedings from PDA, ISPE and DIA mentioned in the previous section. Of note, two books have been published specifically focused in toward the pharmaceutical industry: *Knowledge Management in the Pharmaceutical Industry* (Goodman & Riddell, 2016) and *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry* (Calnan, Lipa, et al., 2018) that incorporated many case studies from across the industry and from related industries. Table 2-5 provides an overview of the other sources included in this literature review.

Table 2-5 Other Sources for literature review and industry case study evaluations

Date	Name	Papers*	Audience/Contributors
May 2014	PDA Knowledge Management Workshop, Bethesda, MD USA	8	Industry KM Practitioners and learners
March 2015	KM Dublin 2015, Dublin, Ireland	13	International Regulators, Industry KM Practitioners and learners
June 2015	DIA 51st Annual Meeting, Washington, DC USA	3	International Regulators, Industry KM Practitioners and learners
June 2015	ISPE/FDA/PQRI Quality Manufacturing Conference, Washington DC, USA	3*	International Regulators, Industry KM Practitioners and learners
March 2016	ISPE European Conference- Frankfurt, Germany	2	International Regulators, Industry KM Practitioners and learners
June 2016	DIA 52nd Annual Meeting, Washington, DC USA	3*	International Regulators, Industry KM Practitioners and learners
June 2016	ISPE/FDA/PQRI Quality Manufacturing Conference, Bethesda, MD USA	3	International Regulators, Industry KM Practitioners and learners
September 2016	ISPE Annual Meeting, Atlanta, GA USA	2	International Regulators, Industry KM Practitioners and learners
Published July 2017	Knowledge Excellence in the Pharmaceutical Industry- CRC Press	27	Industry KM Practitioners, International Regulators, globally recognized KM thought leaders
October 2017	ISPE Annual Meeting	2	Industry KM Practitioners, globally recognized KM thought leaders
January 2018	CASSS CMC Strategy Forum – Washington D.C., USA, January 2018	1	International Regulators, Industry KM Practitioners and learners
February 2018	IFPAC - N. Bethesda, Maryland USA, February 2018	1	International Regulators, Industry KM Practitioners and learners
April 2018	APQC 2018 Annual KM Conference – Houston Texas USA April 2018	1	KM Practitioners and learners, globally recognized KM thought leaders (industry agnostic)
June 2018	2018 PDA Europe Conference – Berlin Germany, June 2018	1	Industry KM Practitioners and learners
2014/ 2018	General Literature Review- Pharmaceutical KM case studies scoped to Product Realization/ Technology Transfer and Commercial Manufacturing	14	Note: 8 of the 14 relevant articles in the literature review were from the ISPE Pharmaceutical Engineering KM Supplement, May 2015

*As this is an emerging topic, some papers were shared across multiple venues from 2014-2016

From the literature review conducted by the researcher of relevant peer reviewed articles, two papers in particular are of interest to discuss here as they relate directly

to KM in the product lifecycle phases of Product Realization/TT and commercial manufacturing. Guebitz, et al, presented *A risk management ontology for Quality-by-Design based on a new development approach according to GAMP 5.0* (Guebitz et al., 2012). The authors share a new ontological methodology based on the concepts of GAMP 5 (*GAMP 5 A Risk-Based Approach to Compliant GxP Computerized Systems*, 2008) that provide important insights on how the twin ICH Q10 enablers of KM and QRM are inherently linked within the Quality by Design (QbD) concept. The second article by Herwig, et al, is entitled *Knowledge Management in the QbD Paradigm: Manufacturing of Biotech Therapeutics* (Herwig et al., 2015). Two of the tables included in this article provide examples of key sources of knowledge and associated technological categories for the application and support of KM tools relevant to the biopharmaceutical sector. In the opinion of the researcher, this article is an excellent start in identifying both knowledge sources and associated KM tools that are suitable for the biopharmaceutical sector, however any references to specific supporting KM processes (e.g. lessons learned, communities of practice, knowledge mapping, etc.) are absent.

In the course of this research study, the researcher has furthered the canon of knowledge in this specific field by identifying KM tools *and their associated supporting processes* that could benefit the biopharmaceutical sector. These tools and processes are summarized in the *House of Knowledge Excellence Framework* described in Chapter Seven of this thesis and based on a book chapter (Kane & Lipa, 2018) contributed to *A Lifecyle Approach to Knowledge Excellence in the Biopharmaceutical Industry* (Calnan, Kane, Lipa, & Menezes, 2018). The House of Knowledge Excellence

(HoKE) Framework forms the third component of the overall *Pharma KM Blueprint* developed from this research. In addition, the researcher analyzed 13 biopharmaceutical company case studies included in *A Lifecyle Approach to Knowledge Excellence in the Biopharmaceutical Industry,* categorizing these case studies by lifecycle phase and by knowledge management practice espoused. The analysis is discussed in further detail in Chapter Four of this thesis and serves as an easy reference for practitioners to indicate the range of approaches that can be applied to address some of the knowledge gaps identified. In all, 27 biopharmaceutical sector case studies were presented in the 2018 book, however not all were cases that could be attributed to a product lifecycle phase as they were academic in nature or broader in theme, provided by health authorities, or views presented by knowledge management thought leaders. The full listing of these cases can be found in Appendix I. The body of work presented in the book represents the most comprehensive view of current adoption of KM within the biopharma industry.

In summary, the literature review revealed no shortage of academic references for knowledge management, however, peer reviewed journal articles addressing current practices related to the pharmaceutical lifecycle phases of *new product introduction/technology transfer and pharmaceutical manufacturing* were not plentiful. Review of industry symposia and conferences within the scope of new product introduction/technology transfer and pharmaceutical manufacturing yielded 43 cases, of which 25 were from industry, eight were presented from the view of a health authority and ten that were either academic in nature or shared by globally recognized KM thought leaders.

Chapter Three

Research Methods and Materials

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3 Methodology Introduction

This body of research investigated the level of understanding, maturity and the inherent challenges of implementing an effective knowledge management program within the biopharmaceutical sector. The intent of this study was to evaluate the current level of understanding of KM within the sector, and then to examine the opportunities to leverage available learning and insights to develop practical tools and approaches which could be used as a means to further progress the maturity of knowledge management and deliver real benefits to the patient and the business.

Knowledge management as a practice is comprised of business and technical processes as well as cultural aspects. This blend of factors is commonly referred to as the trilogy of 'People, Process and Technology' (Collison & Parcell, 2004). Utilizing this combination of people, process and technology as an underpinning framework, the research is primarily qualitative in nature with some aspects of quantitative research. Therefore, the researcher has employed a mixed methods research approach.

This chapter describes the research design, methodology and methods selected to conduct this research and seeks to:

- Describe the researcher's perspective
- Review the research question and its evolution

- Provide an overview of the research timeline of key activities
- Outline the research design principles and methodology
- Describe the progression of research, including research limitations

3.1 The Researchers Worldview

Undertaking any research project requires the researcher to identify with the genesis of the research topic. Furthermore, describing the philosophical ideals of the researcher helps to inform the context not only of the research topic chosen but also of the research methodologies selected (Creswell, 2014).

Philosophical ideals can also be described as ontologies and epistemologies or as paradigms (Creswell, 2014). The epistemology evaluates 'what is the relationship between the knower and the known', (Guba & Lincoln, 1994, p. 195) and 'how we know what we know' (Crotty, 1998, p. 3). Guba also describes the worldview as 'a basic set of beliefs that guide action'. Creswell goes onto to describe four possible worldviews in Table 3-1:

Table 3-1 Four Worldviews (Creswell, 2014)

Postpositivism	**Constructivism**
• Determination • Reductionism • Empirical observation and measurement • Theory verification	• Understanding • Multiple participant meaning • Social and historical construction • Theory Generation
Transformative	**Pragmatism**
• Political • Power and justice oriented • Collaborative • Change oriented	• Consequences of actions • Problem- centered • Pluralistic • Real-world practice oriented

The worldview of *pragmatism* is most suited for examining this research topic as the researcher is focusing on the problem of the current lack of understanding of KM as a real-world practice and looks to the consequences for the expected role of KM within a new regulatory paradigm and in light of advances in novel therapeutics. As noted in Chapter One, although there is an expectation for KM to be leveraged as an enabler to an effective Pharmaceutical Quality System (PQS), there is currently limited formal guidance of what is required or expected. This presented a research topic area that is both *real world practice orientated* and *problem-centered*, for which a pragmatic approach is appropriate.

Although the regulations for the biopharmaceutical sector are issued and enforced by either national or international government organizations, this researcher has elected not to pursue the 'transformative' worldview as the research paradigm. While, the transformative worldview would typically be appropriate for research interwoven with politics or a political change agenda, in this case the researcher intends to primarily focus on the change actions required by the biopharmaceutical sector stakeholders and not the governmental regulatory organizations.

Exploring the world view of pragmatism in the context of KM an enabler to an effective PQS this researcher has focused on 'what works' (Teddlie & Tashakkori, 2009) currently within the sector and as KM is still an emerging practice the researcher will look at the *pluralistic* or multiple approaches currently in use in order to collect and analyze the findings.

Typically, in scientific disciplines, either quantitative methods, those that are primarily interested in numerical data and analysis or qualitative methods, those focusing on the capture, analysis and interpretation of narrative information, are selected singly as a research methodology framework. However, based on the chosen research topic in this case and the pragmatic research paradigm, the researcher believed a mixed methods research methodology was best suited for this research study. Section 3.4 will further discuss the mixed methodologies to be used in this study.

3.2 Researcher's' Insider Perspective

As noted in section 1.4, the researcher is actively employed within the biopharmaceutical sector, with over twenty-five years of direct experience spanning right across the product lifecycle. The researcher has spent the bulk of that career working in global pharmaceutical organizations, in multiple roles, including: Quality, Engineering, Strategy, and Technical Operations. In addition, the researcher has been involved in a number of new facility startups focused on delivering new products to global markets and ultimately the patient and plays an active leadership role in a number of industry associations and professional bodies, such as ISPE and BPOG. This real world, insider experience has informed the manufacturing industry focus of the research, as described by Costley et al., 'your professional life, professional bodies, partner organizations and colleagues will have an influence'.

Based on real world experience the challenges presented by poor knowledge flow have been evident to the researcher in many everyday situations. The researcher therefore has a passion for delivering and improving medicines as espoused in the goals of ICH Q10 'product realization and continual improvement' (International Conference on Harmonisation, 2008a). This motivation focused the scope of the research to:

- Explore and focus on 'what works' in the practice of knowledge management
- Identify pragmatic approaches that are fit for purpose for the pharmaceutical industry
- Provide clarity for what is possible for KM to become a true enabler of the ICH Q10 ideals.

It is acknowledged that this insider perspective can bring both advantages and disadvantages to the research study. As noted by Costley et al., 'Organizational, professional and personal contexts will affect the way a piece of research and development is undertaken'(Costley, Elliott, & Gibbs, 2010). These advantages and disadvantages are described below in Table 3-2 as discussed by Greene (Greene, 2014)

Table 3-2 Advantages and disadvantages of the Insider perspective, adapted from Greene, 2014

Advantage	Disadvantage
Knowledge: less time to orient, ability to ask more meaningful questions, more apt to understand the viewpoints of participants	**Overly subjective:** The perspective of the researcher may be narrowed, researcher may make assumptions, participant may defer details due to the researchers familiarity
Interaction: As the researcher has more familiarity group and social setting, the participants may be more willing to engage	**Biased:** The researcher may be considered too close to the culture to surface provocative questions and/or the researcher may select participants that share beliefs, experiences or values that could influence the methodology or results.
Access: Access to key participants may be expedited due to contacts within the social group	

Therefore, the researcher's rich history within the biopharmaceutical sector may be viewed as an advantage as well as a disadvantage. Taking this into account, the researcher utilized the expertise and broader views of the academics, regulators and other industry personnel involved in the DIT Pharmaceutical Regulatory Science Team (PRST) to counterbalance any potential bias throughout the research project.

One final note regarding the insider's perspective: Although the researcher is employed full-time by a biopharmaceutical manufacturing company, no part of the researcher's academic fees are being paid for or reimbursed by the company. This research is self-funded out of a passion for learning and a desire to share learning's across the sector. The researcher's inside perspective pertains to the broader sector, and not to a specific company.

3.3 The Research Questions

The original research proposal was submitted to the College of Sciences and Health, School of Chemical and Pharmaceutical Sciences in June 2014 and accepted in August 2014 (Kane, 2014a). The research proposal was based on the following primary hypothesis:

Primary Hypothesis:

> *Traditionally, the pharmaceutical industry has emphasized the expectation for **explicit knowledge** due to regulatory requirements (e.g. SOP's, specifications, batch records, formal documentation, etc.). The primary hypothesis of this study is that this skewed focus has been to the detriment of the effective utilization of **tacit knowledge** for decision making when bringing products into the commercial domain (product realization). In addition, this focus on explicit knowledge creates barriers for effective knowledge flow that hinders implementation of continuous improvement activities.*

In addition, a secondary hypothesis was developed to compliment the researchers desire to gain more understanding of the level of maturity of KM, as realized in the biopharmaceutical sector.

Secondary Hypothesis:

> *There are very few biopharmaceutical companies that have benchmarked internal capabilities for knowledge management. As a result, the industry lacks understanding of the necessary elements of an effective knowledge management program, this is impacting the implementation of the concepts embodied in ICH Q10.*

Although these two hypotheses presented an appropriate starting point, as the literature review progressed and the preliminary observations from the philosophical dialogues were analyzed; the researcher came to the realization that in order to meet the intent of the study (i.e. identifying learning's that can be better leveraged within the sector), the hypotheses required modification. This led directly to the development of three further concepts with associated queries to help to focus the direction of the research questions.

Table 3-3 below describes these three additional concepts. The concepts were gleaned from learning's gained from expert focus groups that were undertaken as part of the initial phase of the research. Associated queries were also developed to further explore these concepts.

Table 3-3 Research Concepts and Associated Queries

Concept	Associated Query
Characterize the current levels of adoption of KM within the sector	• How is the biopharmaceutical sector adopting KM? • What benchmarks exist for adoption? • What is the current status of the sector with regards to adoption?
Regulatory requirements drive the perception of what knowledge is critical for product realization and continual improvement, as such, critical tacit knowledge is not captured proactively as a matter of routine operations for product realization and continual improvement lifecycle phases	• What are examples of critical knowledge that may not be considered a "regulatory requirement"? • Can critical knowledge be easily accessed? • What are examples of critical tacit knowledge? • How is tacit knowledge identified and captured?
Benchmarking KM Maturity drives greater understanding of approaches that can be utilized for implementing effective knowledge sharing in the product realization and continual improvement lifecycle phases	• What methods are used to benchmark KM maturity? • What approaches were implemented based on benchmarking?

This led directly to the development of the following three research questions that this study sought to address.

1. What are the key characteristics related to the current levels of adoption of KM within the biopharmaceutical sector?

2. How is 'critical knowledge' defined in the *product realization* and *continual improvement* product lifecycle phases within organizations?
3. Using the insights gained from question 1 and 2 above, what might represent an optimal design for a Pharma KM Blueprint to better enable knowledge flow within organizations, suitable for staff supporting activities within the *product realization* and *continual improvement* product lifecycle phases?

3.4 Research design, methodologies and methods

With respect to the research design, a mixed methods approach was selected for this research topic. More specifically, an *embedded mixed methods* approach was utilized, as appropriate for the phased/ step-wise approach of the research (Creswell, 2014; Teddlie & Tashakkori, 2009). For an outline of the phases and associated research activities please see Table 3-4.

The research methodologies include: *explanatory sequential mixed methods* and *exploratory sequential mixed methods* as well as standard qualitative methodologies.

- *Explanatory sequential mixed methods* is where quantitative research approaches are subsequently followed by qualitative methods (QUAN ➔ qual), in order to assist with the interpretation of the findings (Creswell, 2014). *Explanatory sequential mixed methods* were used in this research to gain a better understanding of the current levels of adoption of KM within the industry.
- *Exploratory sequential mixed methods* were utilized in this research where qualitative research approaches are subsequently followed by quantitative methods (QUAL ➔ quan) in order to further explore the findings related to 'critical knowledge' and to validate the design of the Pharma KM Blueprint.

Table 3-4 below describes the methodology and methods that will be applied to each research question across the three phases of the research program.

Table 3-4 Research Methodology

Research Question	Methodology	Phase 1 Methods	Phase 2 Methods	Phase 3 Methods
Characterize the current levels of adoption of KM within the industry	Explanatory sequential mixed methods	• Data analysis • Survey polls • Focus groups	• Data analysis • Structured benchmarking survey • Philosophical dialogues	• Data analysis • Philosophical dialogues • Focus groups
Explore the definition of 'critical knowledge' in relation to product realization and continual improvement lifecycle phases	Exploratory sequential mixed methods	• Literature review • Philosophical dialogues	• Literature review • Structured benchmarking survey	• Literature review/Data analysis • Semi Structured interviews • Philosophical dialogues
Design a Pharma KM Blueprint, to better enable knowledge flow, suitable for staff supporting the product realization and continual improvement lifecycle phases	Qualitative	• Literature review/ qualitative data analysis • Focus groups	Literature review/data analysis	• Literature review/Data analysis • Semi Structured interviews • Philosophical dialogues • Focus groups

Although the research was described and planned in three phases, it should be noted that due to the availability of subjects for participation in surveys, polls, focus groups, interviews, and philosophical dialogues, many of the research activities progressed in parallel to facilitate engaging with the participants.

3.5 Ethics and Privacy

The research plan was approved via the Dublin Institute of Technology Research Ethics Committee and all research was conducted in accordance with the Interim Policy on the 'Good Conduct' of Research in DIT (Dublin Institute of Technology, n.d.).

Specifically, the researcher:

- Informed individuals about all aspects of the proposed research
- Secured their voluntary agreement to participate - the principle of 'informed consent'
- Handled and stored personal information under conditions of the highest possible confidentiality
- Used such information exclusively for the purposes of the research.

In addition, each participant received copies of any reports developed from focus groups and it is intended that the research outcomes will be published at the conclusion of the study.

This research participants were, in the main, senior executives from within the biopharmaceutical sector, and as such are well-educated, professionals due to the scientific/technological nature of the topic area. The researcher had no power or influence over any research participants. As previously noted, the researcher was not being compensated or reimburse for educational expenses by any means and all research is intended to bring depth and understanding to the sector as a whole.

The researcher maintains all research material on a personal computer with password protection as well as encryption.

3.6 Progression of the research

In the course of the study, the researcher leveraged biopharmaceutical industry symposia and conferences to host focus groups, conduct philosophical dialogues and identify participants for semi-structured interviews as well as conducting a benchmarking survey. The timeline of research activities is depicted in Figure 3-1.

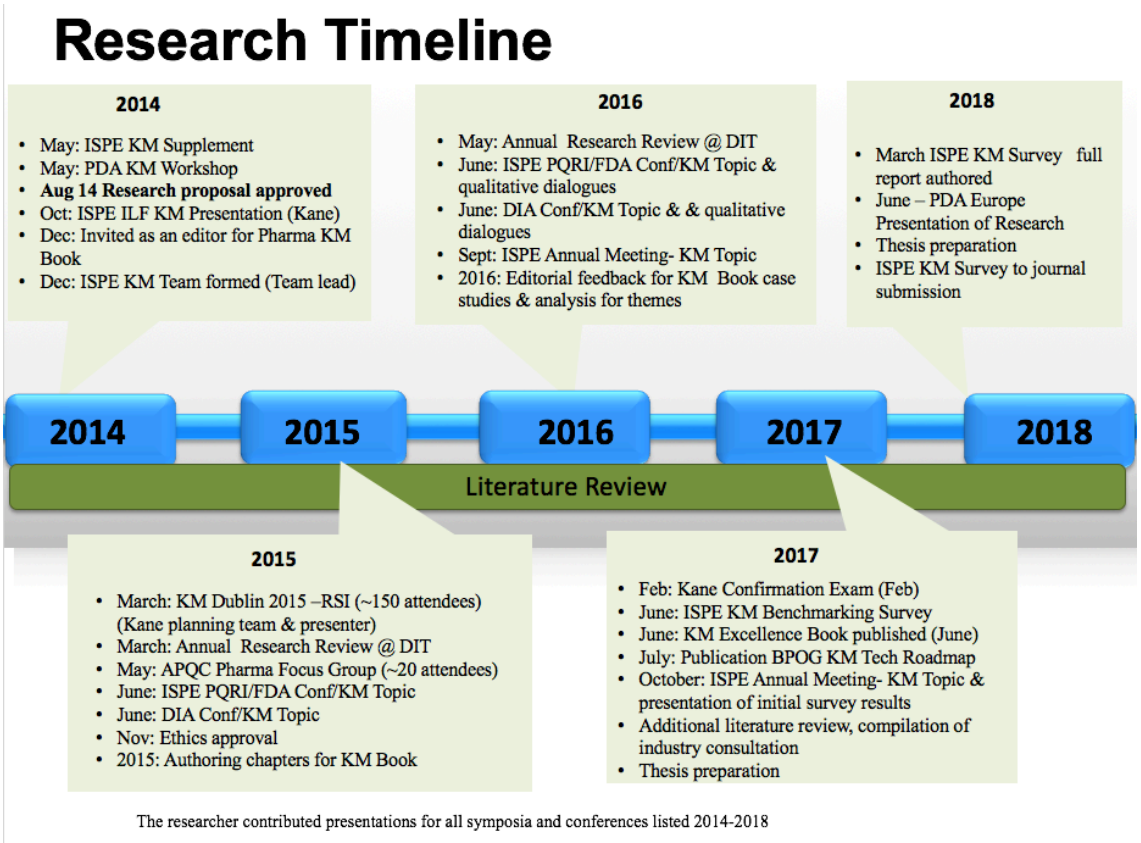

Figure 3-1 Research Timeline 2014-2018

The researcher has actively led and participated in industry forums, at the request of industry leaders, providing symposium topics for biopharmaceutical knowledge management as depicted in the research time line above. In parallel with this research study and in support of the work undertaken, the researcher was a contributing editor of a new Knowledge Management book written specifically for the biopharmaceutical sector entitled, *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry,* (Calnan, Lipa, Kane, Menezes, 2017). The development and editing of this work has facilitated deep engagement, in the form of philosophical dialogues, with over 18 biopharmaceutical companies who shared case-studies and insights on their knowledge management approaches. This was a key source of learning for the researcher.

Chapter Four now presents all of the research activities engaged in over the course of this study. Chapters Five through Eight then present the main research outcomes arising from the key findings and insights gained from these activities described in Chapter Four.

Chapter Four

4 Biopharmaceutical Sector Consultation – Characterizing the Challenge

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> *"In a rapidly changing world with increasing pressures, given the multifaceted benefits of effectively managing knowledge to the patient and the business, how could one not leverage knowledge management as a competitive advantage?"*
>
> *Yegneswaran, Thien & Lipa*
> *(Yegneswaran, Thien, & Lipa, 2018, p. 16)*

This chapter presents an overview of all of the qualitative and quantitative, mixed method research activities conducted over the course of this study. These methods include; engagement with senior leaders from within the sector at international industry symposia and conferences; hosting biopharmaceutical industry focus groups; conducting philosophical dialogues with KM practitioners from within the biopharmaceutical sector, and beyond to other sectors; conducting semi-structured interviews; designing and executing a KM benchmarking survey for the biopharmaceutical sector; data analysis of all of these sources.

4.1 Framing the Knowledge Challenge

In the 10 years since KM emerged as a Pharmaceutical Quality System (PQS) enabler in ICH Q10, little has been discussed on the topic of KM and as highlighted in Chapter One little additional specific regulatory or industry guidance has been published to promote understanding or drive adoption. One could suggest that knowledge

management is not well understood as a management practice because of the considerable focus that is placed on the science, technology and regulation necessary to deliver the sector's complex array of biopharmaceutical products. However, as this research project has progressed, so too has the level of industry interest in and discussion on the topic of knowledge management.

The literature review in Chapter Two also highlighted the fact that guidance and/or case studies for knowledge management in the biopharmaceutical sector are not plentiful. Therefore, in seeking to better understand the various industry challenges, the researcher, has sought out, led and compiled industry feedback and KM practitioner sentiment through a range of different mediums, specifically:

1. The PDA Knowledge Management Workshop, USA (2014)
2. The Knowledge Management Symposium, KM Dublin 2015, Ireland (2015)
3. The APQC 2015 Knowledge Management Conference, USA (2015)
4. ISPE Benchmarking Biopharmaceutical KM Survey, Online (2017)
5. Development and Analysis of 13 Biopharmaceutical Company Case studies, as contributed to the book co-edited by the researcher, *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry* (2018)
6. BPOG KM Technical Roadmap Working Team, Interactive Working Group (2017- Present)
7. ISPE KM Task Team, Interactive Working Group (2016- Present)

Items 1- 3 listed above were major international seminars and conferences in which the researcher participated in the capacity of either a group facilitator a speaker or a delegate. These forums provided an important platform for engagement with senior leaders and practitioners from within the biopharmaceutical sector and from other

industry sectors. In the cases of the *PDA Knowledge Management Workshop* (2014) and the *Knowledge Management Symposium, KM Dublin* (2015), the researcher captured the qualitative data recorded during the interactive breakout sessions, which was shared by the session leaders directly with the researcher. Findings from these events are described in sections 4.2 and 4.3 respectively.

In the case of the *APQC 2015 Knowledge Management Conference* (2015), the researcher chaired and facilitated a biopharmaceutical sector focus group with 20 participants. Findings from this event can be found in section 4.4.

Item 4 above, the ISPE Benchmarking Biopharmaceutical KM Survey, Online (2017), relates to the work undertaken by the researcher to design, develop and execute a biopharmaceutical sector specific *KM Benchmarking Survey*, which was made available online to afford a wider opportunity of response by the International Society for Pharmaceutical Engineering (ISPE) members and through the ISPE KM Task Team's personal *LinkedIn* network. In spite of this attempt to garner wide participation within the sector, the survey only attracted 25 responses from 20 unique organizations. This limits the usefulness of these results to support this doctoral research study, but perhaps more importantly, points towards a general lack of maturity and awareness of KM within the sector. A summary of the *KM Benchmarking Survey* questions is included in Appendix II, however, as the responses were not statistically relevant, and the initial data analysis proved to be inconclusive the results are not provided here for any further discussion. Therefore, the main outcome of this research activity pointed

towards the need for the development of practical KM approaches, tools and practices. This reinforced the decision to develop the *Pharma KM Blueprint.*

Section 4.5 outlines the insights gained from a review of the 13 case studies contributed to the KM Book, *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry* (2018), co-edited by the researcher during the course of this research study. The analysis of these case studies not only looks at the qualitative data shared in the book chapter contributions but also represents the range of philosophical discussions held with the case study authors throughout the development of the book.

Finally, items 6 and 7 listed above represent the ongoing participation and leadership role assumed by the researcher in two significant biopharmaceutical sector task teams actively working on addressing the challenges and opportunities for KM in the sector. Involvement in these two task teams has facilitated the researcher to engage in regular philosophical dialogues with a cohort of peers and stay abreast of drivers and developments affecting others in the sector. Further details of these activities can be found in Section 4.6.

4.2 2014 PDA Knowledge Management Workshop (2014)

May 2014 saw the first event solely focused on the topic of knowledge management for the biopharmaceutical sector. Seventy delegates from ten countries attended the workshop held in Bethesda, Maryland, USA. The byline for this works was aptly

entitled *Raising the Awareness*. The workshop was chaired by Dr. Christopher Smalley and Mr. Igor Gorsky, who worked diligently with the planning team to collect case studies and provide a forum for the industry to discuss the ICH Q10 enabler of knowledge management. The researcher, then in the role of Director of Knowledge Management within Pfizer Global Supply (Pfizer's commercial manufacturing and supply organization), was invited to speak and share a case study. Little did the researcher know at that time, that this event would ultimately be the catalyst for undertaking this doctoral research position at DIT and the beginnings of – *The Pharma KM Blueprint*.

The workshop was a two-day event consisting of four case studies from industry (Genentech, Shire, Pfizer and Accelrys); two papers representing the regulatory perspective, Dr. Tor Gräberg (Swedish Medicines Product Agency) and Dr. Stephan Rönniger (representing the ICH IWG); and two external perspectives shared by well-known KM thought leaders from outside of the pharmaceutical industry.

During the industry case study presentations, it emerged that each of the four companies had taken a different approach to managing their important product and process knowledge, however each had solved a specific business problem, enabling knowledge to flow to those in their organizations who needed it.

One of the KM expert talks, given by Dr. Ed Hoffman the then Chief Knowledge Officer (CKO) from NASA, linked Quality and Risk Management in the NASA KM Program, resonating directly with the twin enablers of ICH Q10 in the biopharmaceutical sector.

The other expert speaker, Ms. Cindy Hubert, Executive Director of KM Practice at APQC shared her presentation entitled, *Knowledge for the Future*. Hubert shared industry agnostic concepts about KM and gave a perspective as to what effective KM could look like when fully implemented throughout an organization. This presentation elicited robust conversation from the workshop delegates. One participant, in great frustration, reminded Hubert that the pharmaceutical industry was very complex, suggesting that the cross-industry comparisons were not valid. Hubert responded, linking to her direct experience with other biopharmaceutical companies, that the pharmaceutical industry has a strong belief in its own uniqueness[25] however the sector 'still has a great opportunity to accelerate its learning'. As the researcher listened to the highly engaging dialogue, the realization dawned of the need to further explore why the biopharmaceutical sector has failed to embrace KM as an enabler. This research and ultimately this thesis were directly borne out of this dialogue and the resulting engagement during the workshop with colleagues from the Dublin Institute of Technology (DIT).

In all, six breakout workshop sessions were offered to stimulate discussion on the topic of pharmaceutical knowledge management, linking to the workshop theme of *Raising the Awareness.* Workshop breakout session topics are listed in Table 4-1.

[25] This point was reiterated in a later publication (Trees & Hubert, 2017)

Table 4-1 PDA 2014 KM Workshop Breakout Sessions

2014 PDA Knowledge Management Workshop Breakout Sessions			
	Group 1	Group 2	Group 3
Breakout Session A	How are You Managing External Knowledge (CMO's)	Recognizing and Linking to Tacit Knowledge in the Organization	Linking Knowledge to Business Outcomes
Breakout Session B	Identifying Critical Knowledge in the Organization	The Role of Change Management in KM	ICH Q10 - Where are You and Where You Want to Be

Breakout session A was held day one and Breakout session B was on day two. Workshop attendees (n=70) were randomly assigned to one of three groups. At the conclusion of each day, breakout facilitators shared the output from their group. Workshop attendee names/affiliation as well as materials presented from the breakout sessions can be found in Volume Two of this thesis. The researcher analyzed the output from each breakout workshop session, and collated common themes and observations from the sessions. Table 4-2 captures the common themes from the six breakout sessions.

Table 4-2 PDA 2014 Knowledge Management Workshop – Common Themes and Challenges

Key Challenges as Identified across breakout sessions- PDA 2014

Lack of understanding about:

- Who the process owners are – e.g. for knowledge sources coming from PAT, Process Monitoring
- Who the 'experts' are
- How to measure knowledge transfer/ Evaluate effective Knowledge Management
- Which knowledge is critical/ the criteria for assessing knowledge criticality

Tacit Knowledge:

- Does tacit knowledge belong in a quality system?
- What does good tacit knowledge transfer look like?
- High impact problems need solutions that involve tacit knowledge
- It is often easy to ignore tacit knowledge as it is hard to quantify

Value of Knowledge:

- Users don't regard the value of product knowledge in addition to the products
- Users don't treat knowledge as an asset
- Large volumes of knowledge are developed during product development, but this is often not used further or accessible
- The need to focus on critical knowledge, cannot manage all knowledge in the same manner

Other themes emerging:

- There are a range of disparate systems employed across the sector
- Often is it only when a "burning platform" presents that there is a realization of the need to better connect the dots (fill in the gaps) [between product/process knowledge, people and systems]
- Why does biopharma not have Chief Knowledge Officers?
- The need to understand the clear distinctions between KM programs, tools, procedures
- KM Requires change management skills – to manage people change (behaviors), not regulatory change

A number of additional topics stood out for the researcher in analyzing the discussion output from this PDA industry consultation. Firstly, insights surfaced on the clear need to link managing knowledge to improved business outcomes for the biopharmaceutical

sector. Secondly, the need to align KM terminology with the PQS and regulatory expectations to ensure clarity of understanding. Thirdly, that there is a real need to prioritize the immediate KM opportunities for the sector in order to focus the initial development of KM to a few topics. Finally, and most resoundingly, those involved in the PDA breakout sessions expressed a clear need to develop a systematic approach to knowledge management and knowledge transfer for the biopharmaceutical sector. This has driven the researchers work, specifically, on the *House of Knowledge Excellence* (HoKE) framework, and more broadly, on the development of the *Pharma KM Blueprint*.

4.3 The Knowledge Management Symposium, KM Dublin 2015, (2015)

The second international symposium at which the researcher engaged in sector consultation was sponsored by Regulatory Science Ireland (RSI) and held in Dublin in March 2015. The researcher was a member of the organizing committee for the symposium and acted as a track leader and a speaker during the event. KM Dublin 2015 aimed to drive the knowledge management discussion forward for the biopharmaceutical sector and was themed *Enabling Knowledge Flow, Delivering Safe & Effective Products*. This symposium, attracted over one hundred forty attendees, double that of the PDA KM Workshop in 2014. It was the first of its kind to bring together international regulators, life science industry practitioners, academics and KM thought leaders to discuss and explore the integration of knowledge management and risk management in the development, manufacture, surveillance and regulation of biopharmaceutical and medical device related health products. This forum was

particularly interested in providing regulators (international health authorities) and those actively engaged in developing ICH regulatory guidance a venue to discuss and learn more about knowledge management. The attendee demographics of this symposium are provided in Figure 4-1.

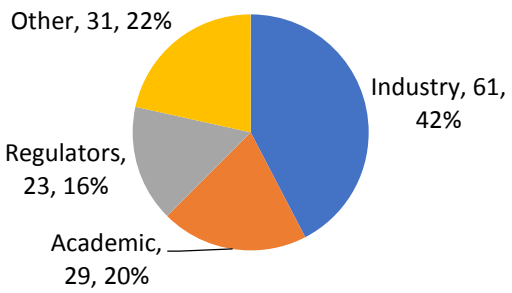

Figure 4-1 KM Dublin 2015 Attendee demographics – 144 attendees

At that time in March 2015, there was an international group working on the first draft of a new quality guidance document, ICH Q12 Technical *And Regulatory Considerations For. Pharmaceutical Product Lifecycle Management,* and members of that team were invited to attend and participate in a discussion panel with the delegates. Some delegates had hopes that ICH Q12 would provide additional guidance regarding knowledge management, others questioned if ICH Q12 should even be published given that, in their opinion, ICH Q8, Q9 and Q10 had not delivered the anticipated results and regulatory flexibility.

Over the two days, five regulators shared perspective from their respective agencies and experiences. In addition, the program was designed to facilitate opportunities to capture delegate opinion and experiences through three breakout sessions across four

different track topics. At the end of each breakout session, the track leaders shared the output with all delegates in the main conference hall. Figure 4-2 displays the four breakout tracks.

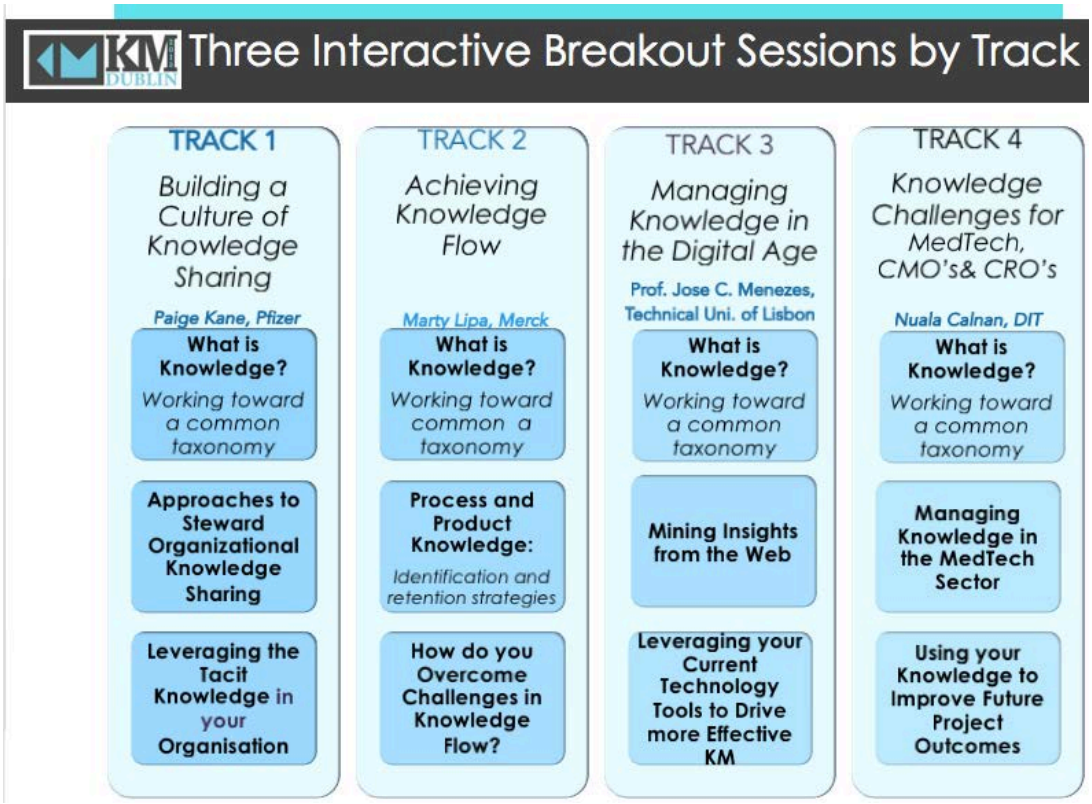

Figure 4-2 Breakout Discussion Tracks - KM Dublin 2015

The first breakout session across all four tracks opened with a discussion on "what is knowledge?". Interestingly, at *Track Four* it was identified that only one out of the thirty delegates present had a definition for knowledge in their organization at that time. Track Two delegates reported that less than 5% had a definition for either "knowledge" or "knowledge management". Furthermore, while 90% of the group present agreed it was important to have a knowledge management strategy in place, only approximately 25% present reported that their organizations indeed had a KM strategy in place. A key insight which arose from the dialogue about 'what is knowledge', is that it was observed that there was a marked absence of "people" in the ICH Q10 definition of KM shown on the next page. This was taken to indicate a

general lack of awareness within the sector on the value and role that tacit knowledge plays in the product lifecycle.

> *Knowledge Management: Systematic approach to acquiring, analysing, storing, and disseminating information related to products, manufacturing processes and components.* (International Conference on Harmonisation, 2008b, p. 14)

Continuing on the subject of the role of people, a common theme emerged from the discussions in Track One on *leveraging tacit knowledge* about the importance of sharing, capture and re-use of knowledge (by people).

Across the remaining KM Dublin 2015 breakout session the following common themes were recorded, as shown in Table 4-3:

Table 4-3 Knowledge Flow Barriers - Breakout Discussion Tracks - KM Dublin 2015

Knowledge Flow Barriers Identified across the KM Dublin 2015 Breakout Groups	
Organizational Hierarchy	Lack of trust between functional groups
Time	Lack of transparency around Individual Roles
Too many systems and repositories (lack of transparency)	Physical facility barriers (e.g. clean rooms, siloed functions, different geographical locations)
Regulatory barriers in transforming tacit knowledge to explicit	Cultural and mindset issues with the need to enable knowledge flow

In addition to the knowledge flow barriers which were identified, other key insights were shared in the Breakout Groups at KM Dublin 2015 were recorded in Table 4-4. These insights have led directly to many of the elements included in the development of the *Pharma KM Blueprint* and, where applicable these driver and links are noted in final column of Table 4-4.

Table 4-4 Other Key Insights gained from Breakout Discussion Tracks -KM Dublin 2015 - linked to Pharma KM Blueprint Elements

Breakout Group Subject	Key insights reported by breakout group	Driver/ links to key outputs in the Pharma KM Blueprint (Chapter 5-8)
Approaches to Steward Organizational Knowledge Sharing	Trust and Respect, value in sharing, need for defined KM infrastructures, KM embedded in the objective of employees- there are challenges with hierarchical barriers [to knowledge flow]	**Ch 7**: HoKE elements related to People, Roles, Systematic KM Program **Ch 8:** KMEE – Need to evaluate current state and progress
Leveraging the Tacit knowledge in your organization	Employees must realize the value of their tacit knowledge, challenges with tacit knowledge include: Technology Transfer, projects across boundaries, colleague turnover	**Ch 5:** Knowledge as an Asset **Ch 6:** PPKL Knowledge Flow Model– specifically the addition of a Technology and Knowledge Transfer lens **Ch 7:** HoKE Practices, CoPs
Process and Product Knowledge: Identification and retention strategies	What is critical knowledge, what are the needs of customer, regulatory, quality attributes. Focus on Technology Transfer, how to start, start small	**Ch 5**: Knowledge as an Asset **Ch 6:** PPKL **Ch 8:** KMEE – Assess current state
Mining insights from the web	Use of web search technology, quality of data and concerns with data sharing across firewalls	**Ch 7:** HoKE Practices, Taxonomy, Technology Pillar
Leveraging your current technology tools to drive more effective KM	Data available but the accessibility across organizations is difficult, ability to contextualize data, need tools to help do more knowledge intensive work, Taxonomy (building and using) is not straightforward.	**Ch 7**: HoKE Practices, Taxonomy, Technology Pillar
Managing knowledge in the MedTech Sector	Sharing patient experiences (tact knowledge from the patient), use of Device History File, complexities of combination products	**Ch 5:** Knowledge as an Asset **Ch 6:** PPKL - Additional opportunity for future research
Using your knowledge to improve Future Project Outcomes	Capturing lessons learned are important, also to include near miss [near knowledge miss), planned knowledge transfer must be included up front	**Ch 5**: Knowledge as an Asset **Ch 6:** PPKL **Ch 8:** KMEE – Assess current state

4.4 APQC 2015 Annual Meeting - Biopharmaceutical KM Focus Group (April 2015)

The 20th annual APQC Knowledge Management conference was held in April 2015 in Houston Texas, USA. This annual event attracts over 350 attendees across all industries. The target audience are KM practitioners, leaders and sponsors. APQC is a not for profit member-based research organization. The structure of the APQC membership is based on the organization, and individual memberships are not available. Cindy Hubert was an invited speaker at KM Dublin 2015 and experienced the robust pharmaceutical industry discussions, following which, APQC offered to host a dedicated focus group for biopharmaceutical sector attendees at the annual APQC meeting in Houston Texas, which the researcher led.

Based on the outputs from the sector consultation workshop sessions held at KM Dublin 2015, the researcher sought to further understand the KM gaps as relevant to the KM practitioners, their organization, and what specific help was needed to close the gaps. Sixteen participants from eight biopharmaceutical companies, and four participants from non-pharma companies, participated and participant names and affiliations are located in Volume Two of this thesis. Three questions were offered for discussion by the researcher:

- **What do you need for yourself / your company (Internal focus)?**
- **What is needed to help move industry forward?**
- **What questions would you ask your KM industry peers?**

Responses were categorized in two categories, *Program Enablers* and *Program Pillars* (Note: this informed two important elements of the *House of Knowledge Excellence*

examined later in Chapter Seven). Table 4-5 below provide the mapping of these categories, as follows:

Table 4-5 Categorization of feedback- APQC 2015 Pharma KM Focus Group

Program Enablers	Program Pillars
Strategy, KM Program and Guidance	People, Culture, and Change Management
Sponsorship and Governance	Process
Benchmarking and Best Practices	Content and Technology

In order of ranked need, Table 4-5 provides specific requests from industry for internal KM needs and Table 4-6 outlines top requests that the sector would find beneficial.

Table 4-6 Internal KM organizational needs – 2015 APQC KM Pharma Focus Group

What do you need that would help you/your organization in KM (Internal KM Focus)		
Program Enabler:	Strategy, Program, and Guidance	• More Industry Specific Guidance on how to implement a *systematic* KM Program • More dedicated KM resource so that people have time to think (create, teach, learn, innovate) • Articulate how IT can help innovate in KM and what is expected from IT • Easy/effective approaches to translate KM into improving operating metrics (prove it works, effectiveness evaluation)
Program Enabler:	Sponsorship and Governance	• A formal KM professional council where we could connect and steer our multitude of efforts • A senior sponsor that will create the strategic pull & resources (and provide 'air cover') • Executive level support
Program Enabler:	Benchmarking and Best Practices	• A database of what is out there in the industry and what worked • Understand best KM practice
Program Pillar:	People, Culture, and Change Management	• Understanding of what KM is and how to influence colleagues/peers on why it is important to the patient and the business
Program Pillar:	Process	• Knowledge capture and communication via story boarding • A blending of business acumen with a heavy use of technology 'out of the box'
Program Pillar:	Content and Technology	• Is there a KM technology platform?

Table 4-7 External/ Industry KM needs – 2015 APQC KM Pharma Focus Group

What could help the biopharmaceutical sector in the KM Space?		
Program Enabler:	Strategy, Program, and Guidance*	• A forum for doing KM across regulators, sponsors, vendors so that we can make medicines more affordable to develop, manufacture, and distribute to patients • White paper on the interpretation of the pending ICH guidelines • Guidance documents on KM – something a little more prescriptive, what are the expectations • Clearly articulate what the GMP/GxP requirements are for KM, "IT" solutions, HR, IM/IT, and quality integration • Help defining the relationship between product lifecycle (PLM) and KM
Program Enabler:	Benchmarking and Best Practices	• A Lessons learned by agencies or global regions • A benchmark reports for companies using KM maturity matrix • Standardized best practices for the 'noncompetitive advantage' activities (documentation formats, data standards, etc. (Transcelerate is an attempt at this) • Approaches for handling legal constraints around community discussions without narrowing scope • Quality Management system and KM integration standards to reduce human error

As revealed in Table 4-7, top requests include an opportunity to develop guidance documents on KM, as well as help understand product lifecycle and KM relationships. The *Pharma KM Blueprint* introduced in Chapters Five through Eight seek to provide initial guidance and tools for KM practitioners.

The third question that was posed to the focus groups participant was designed to elicit general questions and provide opportunities for the focus group to connect and interact over the course of the KM conference. Ample opportunities were provided for this interaction.

4.5 Development and Analysis of Biopharmaceutical Case Studies

Following the success of the KM Dublin 2015 event the organizing team were invited by Taylor and Francis to develop a book specifically directed at KM in the biopharmaceutical sector. The editorial team was composed of two academics and two industry KM program leaders. Through years of industry contribution with ISPE and BPOG, the researcher was able to assist in identification of potential case studies and chapter authors for the book. After deep canvassing, the editorial team was able to share 'first in kind' cross industry views of biopharmaceutical knowledge management from the lens of sector leaders, manufactures (large molecule, small molecules and contract manufacturing organizations), academia (pharmaceutical and knowledge management), regulatory and even one contribution from the point of view of a patient. Fifty contributors converged from 24 different organizations across the globe to share case studies and insights in KM.

A Lifecycle Approach to Knowledge Excellence in the biopharmaceutical Industry was published June 16, 2017 by CRC Press with a copyright date of 2018. The text explores the role of knowledge management in the delivery of safe and effective products to patients. Included in the book is a practical approach to a KM program, the House of Knowledge Excellence Framework (a key deliverable from the researcher and discussed further in Chapter Seven of this thesis) outlining a systematic approach to implementing KM showing the relationships between knowledge and the associated enablers, pillars, practices and strategic objectives. The book is divided into four sections:

Section I: Making the Case for Knowledge Excellence in the Biopharmaceutical Industry

Section II: Perspectives on Knowledge

Section III: Practices, Pillars and Enablers: Foundations for Successful KM

Section IV: Practices and case studies and enabling knowledge flow

Case studies of KM *in practice* from organizations across the pharmaceutical industry can be found in sections III and IV of *A Lifecycle Approach to Knowledge Excellence in the biopharmaceutical Industry*. The researcher analyzed the thirteen case studies reflecting KM activities in the biopharmaceutical product lifecycle, to understand the lifecycle phase as well as identify the practices, pillars and enablers that have been demonstrated across the various companies. With respect to the lifecycle phases, as articulated in ICH Q10, some case studies crossed multiple lifecycle phases. Of the thirteen case studies, three highlighted KM activities in the product development space, six in the technology transfer phase and eight included details of KM practices related to the commercial manufacturing phase. The topics and associated product lifecycle phases addressed in the case studies are mapped in Table 4-8

Table 4-8 Mapping of Case Studies to Product Lifecycle Phase

Case Study		Lifecycle Phase			
Chapter #	Chapter Title	Pharmaceutical Development	Technology Transfer	Commercial Manufacturing	Product Discontinuation
13	A Holistic Approach to Knowledge Management: Pfizer Global Supply		X	X	
14	KM Evolution at Merck: Managing Knowledge in Merck Manufacturing Division		X	X	
18	Let's Talk About Knowledge Management - Learning from the Library of Alexandria Disaster			X	
19	Rapid & Robust Product Development Powered by Knowledge Management Capability	X	X		
20	KM Case Study: Using Near Real-Time Data Analytics and Performance Metrics to Ensure a Robust and Resilient Supply Chain			X	
21	KM Elements in Support of Generation of CMC Regulatory Documentation	X			
22	A People Approach to Managing Knowledge: Who Are You Working For?			X	
23	Developing a Lessons Learned Process - where lessons are learned: A case study of Pfizer Pharmaceutical Sciences	X	X		
24	Capturing Critical Process and Product Knowledge: The Development of a Product History File			X	
25	Communities of Practice: A Story about the VTN and the value of community		X	X	
26	Identification of Critical Knowledge: Demystifying Knowledge Mapping		X	X	
27	The Practical Application of a User-Facing Taxonomy to Improve Knowledge Sharing and Reuse across the Biopharmaceutical Product Lifecycle: A Case Study		X	X	
28	Knowledge based Product and Process Lifecycle Management for Legacy Products			X	

"X" indicates an area of focus

Table 4-9 expands on these case studies to illustrate and identify the knowledge management *practices* utilized by the companies in the respective case studies.

Table 4-9 Mapping of Case Studies to KM Practices

Case Study		Knowledge Management Practices						
Chapter #	Title	Communities & Network	Content Management	Taxonomy	Lessons Learned	Expertise Location	Expertise, Transfer & Retention	*Other KM Practices*
13	A Holistic Approach to Knowledge Management: Pfizer Global Supply	++	++			++		++
14	KM Evolution at Merck: Managing Knowledge in Merck Manufacturing Division	++	++	++	++	+	++	+
18	Let's Talk About Knowledge Management - Learning from the Library of Alexandria Disaster	+	+	+	+			+
19	Rapid & Robust Product Development Powered by Knowledge Management Capability	+				+		+
20	KM Case Study: Using Near Real-Time Data Analytics and Performance Metrics to Ensure a Robust and Resilient Supply Chain							++
21	KM Elements in Support of Generation of CMC Regulatory Documentation		++	+				++
22	A People Approach to Managing Knowledge: Who Are You Working For?	+	+			+		+
23	Developing a Lessons Learned Process - where lessons are learned: A case study of Pfizer Pharmaceutical Sciences				++			
24	Capturing Critical Process and Product Knowledge: The Development of a Product History File		++					+
25	Communities of Practice: A Story about the VTN and the value of community	++				+		
26	Identification of Critical Knowledge: Demystifying Knowledge Mapping		+					++
27	The Practical Application of a User-Facing Taxonomy to Improve Knowledge Sharing and Reuse across the Biopharmaceutical Product Lifecycle: A Case Study		+	++				
28	Knowledge based Product and Process Lifecycle Management for Legacy Products	++	++				++	++

'+' indicates degree relevance (none, + low, ++ high)

This analysis of the current state of KM within the biopharmaceutical sector indicates that there are still only a relatively small number of biopharmaceutical organizations well advanced in the development of their KM programs. Furthermore, from the details shared in the case studies, it was evident that while each company was solving a different and diverse range of business challenges they each recognized that KM was a key enabler to the solutions required. The researcher has highlighted the variety of KM practices and approaches employed which reinforces that there is no 'one size fits all' KM practice or approach in use. This underpins the importance of creating cross industry knowledge networks to share good practice examples in order to drive greater awareness and adoption within the sector. The researchers continue to work in this capacity in her role within the ISPE KM Task Team and the BPOG KM Technical Roadmap Working Team.

4.6 BPOG KM Technical Roadmap Working Team (2015 to present)

The Biopharma Operations Group (BPOG) is a member-based industry consortium specifically focused on the biotechnology sector of the biopharmaceutical industry. The BPOG set out to deliver a ten-year technology roadmap for biotechnology based therapeutic products. The Technical Roadmap (TR) is intended to be a dynamic and evolving collaborative technology management process to determine pre-competitive critical needs and drivers and identify technological and/or manufacturing targets in the next ten years.

The BPOG TR has six components (individual documents) inclusive of:

- Process Technologies
- In-line Monitoring & Realtime Release
- Modular & Mobile
- Automated Facility
- **Knowledge Management (KM)**
- Supply Partnership Management

The researcher is a founding member of the team developing the KM TR consisting of contributors from nine biotechnology organizations. In this role, the researcher provided thought leadership and was able to 'pressure test' many of the ideas and assumptions explored in this research project. One thought leadership contribution that was discussed at length with the team members includes the researcher's key principle that *knowledge must be treated as an asset* (see Chapter Five of this thesis for further details). To the delight of the researcher, this principle was accepted as a core principle and included as a highlighted observation in the BPOG KM TR published in 2017 (BioPhroum Operations Group, 2017). It should be noted that the scope of this document is directed specifically at biopharmaceutical companies who develop, and manufacture *Biotechnology* or *Biologics* based therapeutics and therefore other biopharmaceutical companies may not be aware or have access to this roadmap. The formal publication of the BPOG KM TR represents a first step in articulating the KM challenge for the Biotechnology sector. The document seeks to define the "what" but lacks the "how", and the BPOG organization will continue to work on materials beneficial to their biotechnology members. To address the "how" the researcher presents the novel research output in the form of the *Pharma KM Blueprint* in Chapters Five to Eight to begin to bridge the gap from the theoretical to the practical.

The researcher continues to contribute as a member of the BPOG KM TR Working Team.

4.7 Conclusions

Chapter Four has endeavored to demonstrate the breadth of qualitative and quantitative industry consultation activities undertaken as part of this research study. This included involvement in and analysis of two international industry symposia of nearly 200 delegates (PDA 2014 KM Workshop, KM Dublin 2015), a specific KM biopharmaceutical sector focus group held at the APQC annual conference in 2015 with twenty participants, and the development of a formal biopharmaceutical sector *Benchmarking KM survey* in 2017. In addition to these more formal, structured activities the researcher also engaged in informal dialogues and semi-structured interviews in her capacity as a leader/member of the ISPE KM Task Team and the BPOG KM Technical Roadmap working team.

A high-level summary of industry consultation activities suggested a real opportunity to better define KM for the biopharmaceutical sector, showing the relationships between *KM Strategy, Program, Benchmarking and Best Practices*, as well as specific tools and supporting processes to ensure knowledge is managed as an asset and to help enable knowledge to flow. This reflects the need to overcome the problems associated with isolated "knowledge islands" within organizations which was identified in the PDA 2014 workshop. The focus group participants and workshop delegates continue to request guidance for implementing KM, inclusive of tools and supporting processes as a means to more effectively meet the regulatory expectations.

Chapter Four has also sought to demonstrate that although the practice of knowledge management is not at the forefront within the biopharmaceutical sector, there are many other industries that have embedded KM, not for just to meet regulatory expectations but for good business reasons (Yegneswaran et al., 2018). According to Goodman and Riddell, although knowledge is generally considered as "the other product" from the biopharmaceutical industry (Goodman & Riddell, 2016, p. 43) and, when compared to other sectors, the biopharmaceutical sector continues to lag those other sectors in terms of KM maturity (APQC, 2018).

The field of knowledge management, as discussed in Chapter One and as researched in the literature review in Chapter Two, continues to present an elusive and ambiguous topic for many. The researcher proposes that this ambiguity arises as a result of two confounding factors. The first factor is that knowledge management is considered by many as a management discipline and therefore holds little interest to those operating within the technical arena. The second factor has led the researcher directly to the hypothesis that, at least within the biopharmaceutical sector, knowledge is not valued as a *critical asset* or as an equivalent asset to physical manufacturing assets. This realization forms the basis of the core principle of this research, specifically the need to manage knowledge as an asset, and forms the first element of the *Pharma KM Blueprint* developed by the researcher. Chapter Five will now introduce the blueprint and discuss this principle in detail. Chapter Six, Seven and Eight will then address the other elements of the blueprint.

Chapter Five

Pharma KM Blueprint Part One: Knowledge as an Asset

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5 Introducing the Blueprint for Knowledge Management in the Biopharmaceutical Sector

Of central importance is the changing nature of competitive advantage - not based on market position, size and power as in times past, but on the incorporation of knowledge into all of an organization's activities.

Leif Edvinsson, Swedish Intellectual Capital guru in Corporate Longitude (2002)

The ability of a biopharmaceutical organization to capture, collate and retain the knowledge it has gained over the design, development and testing of its therapeutics, is a key success factor for the business. More specifically, the ability to coherently convey in the submission dossier, or common technical document (CTD), the knowledge gained across the design and development of the product, through to the design of the clinical trials in order to demonstrate the safety and efficacy of the product, and to subsequently demonstrate the capability to consistently manufacture the product, is crucial in the overall marketing authorization approval process. All of these elements are founded on the bedrock of the organization's knowledge and, if done well, convey significant competitive advantage.

Speed to market is also considered to be a competitive advantage, with first-to-market pharmaceuticals shown to have a six percent market share advantage over later entrants (Cha & Yu, 2014, p. 1). This advantage highlights even more the opportunities and benefits that effective lifecycle management, founded on sound scientific data and knowledge, can yield. Furthermore, effective lifecycle management coupled with a robust *Pharmaceutical Quality System* is envisioned in the Draft of ICH Q12 to enable firms to prospectively manage future changes to medicinal products in a more strategic manner (International Conference on Harmonisation, 2017).

For these competitive reasons, the biopharmaceutical sector applies significant effort to identify and develop new drug candidates and technologies and improve marketed products to extend their exclusivity, indications or market reach. All of these activities create both tacit and explicit knowledge, which can either be technical in nature or business process focused. Yet, the benchmarking data, insights and survey results examined and presented as part of this research study confirm that biopharmaceutical organizations have not invested a commensurate level of effort in managing what they know.

In a seminal publication from 2014, Merck[26] described the paradox of how the ability to transfer and apply knowledge is acknowledged as a competitive advantage, however, "knowledge is seldom treated like a crucial asset"(Marty Lipa et al., 2014). This insight from Merck begs deeper exploration of the *knowledge asset* concept and

[26] Merck & Company, Inc., d.b.a. Merck Sharp & Dohme (MSD) outside the USA and Canada, is a large global pharmaceutical company

greater understanding of what constitutes crucial or *critical knowledge*, as it is often referred to in biopharmaceutical industry guidance.

This exploration by the researcher has led directly to defining the *Pharma KM Blueprint,* (Introduced in Chapter One) the principal output of this research, the first element of which is **Valuing Knowledge as an Asset**.

5.1 Valuing Knowledge as an Asset

Linking quality and knowledge management has been, and remains, a foundational component of the mission of APQC[27]. APQC's founder Jack Greyson was one of the creators of the *Malcolm Baldridge National Quality Award* [28](MBNQA). The MBNQA recognizes US organizations for performance excellence. Not surprisingly then, knowledge management is a core capability included in the evaluation process for the MBNQA award. Furthermore, a definition for "knowledge assets" can be found in the supporting materials. The definition of a knowledge asset provided by the Malcolm Baldridge Glossary is, in the opinion of the researcher, the most comprehensive definition noted in the literature review undertaken for this body of research. The definition and description are shared below:

> *'The term "knowledge assets" refers to the accumulated intellectual resources of your organization. It is the knowledge possessed by your organization and its workforce in the form of information, ideas, learning, understanding, memory, insights, cognitive and technical skills, and capabilities. Your workforce, databases, documents, guides, policies and procedures, software, and patents are repositories of your organization's knowledge assets. Knowledge assets are*

[27] American Productivity and Quality Center - APQC
[28] http://asq.org/learn-about-quality/malcolm-baldrige-award/overview/overview.html

> *held not only by an organization but reside within its customers, suppliers, and partners as well. Knowledge assets are the "know how" that your organization has available to use, to invest, and to grow. Building and managing its knowledge assets are key components for your organization to create value for your stakeholders and to help sustain overall organizational performance success.'*(Steel, n.d.)

Building on this concept of knowledge assets, Martin Ihrig, in a discussion with MacMillian, points out that knowledge assets can be described as either 'structured (codified knowledge), or unstructured e.g. tacit knowledge' (MacMillian, 2015). Moreover, in a paper linking quality management practices and knowledge management, Lim, et al., noted that for organizations to succeed, they 'have to view knowledge as an asset and manage it effectively' (Lim, Ahmed, & Zairi, 1999, p. S616).

Based on 25 years of personal experience in the industry, validated by the themes elicited from the industry consultations examined in Chapter Four, a key observation for this researcher is that:

> **The biopharmaceutical sector has not yet come to the realization that knowledge is an asset, as demonstrated by the lack of formal processes and/or resources to manage its knowledge as an asset. Knowledge assets are not treated equivalent to physical assets, such as plant equipment or lab bench technologies.**

In valuing knowledge assets, the researcher considers that in fact physical assets and knowledge assets have several characteristics in common:

- **Both classes of assets can appreciate or depreciate**: Not all knowledge has the same value over time.
- **The more the asset is used, the more value it creates**: When a bioreactor is run at high capacity, it brings more value to the business than when sitting idle. Similarly, if a knowledge asset is not used, it provides little value to the person who captured and stored it or to the business.
- **Both physical and knowledge assets can be traded**: For example, in the form of sharing explicit knowledge (a report or training program) or sharing an expert that has deep tacit knowledge about a topic within your network.
- **There is a market value for a knowledge asset**: In the case of tacit knowledge, when tacit knowledge is needed, and it isn't available, it is possible (in some cases) to purchase that knowledge, such as by hiring experts to troubleshoot a critical utility system, engaging consultants or the addition of knowledgeable/experienced new full-time staff. Conversely, organizations that build up a deep internal knowledge, often sell their services to others e.g. in 1991 NNE (Novo Nordisk Engineering) began selling their pharmaceutical engineering services to others outside of their own company. In the instance of explicit knowledge, it is possible to purchase standards, reports or other forms of codified knowledge to enhance the body of knowledge within an organization.

Dr. Nick Milton of Knoco has written on the theme of knowledge assets and describes the traditional field of physical asset management as 'well studied' and suggests learning opportunities in linking the methodologies of physical asset management to knowledge asset management, (Milton, 2014). Milton outlines the four stages of an asset lifecycle, citing the *Asset Management Accountability Framework* developed by the State of

Victoria (AUS), as a starting point to consider when managing knowledge assets see Figure 5-1 below.

Figure 5-1 Four stages of the asset lifecycle (State of Victoria Department of Treasury and Finance, 2016, p. 11)

The four stages outlined in the framework include: *Planning, Acquisition, Operations and Disposal*. Reflecting on these stages, the researcher presents in Table 5-1 what this might mean in terms of KM for a biopharmaceutical organization. Key questions to address in the four stages for knowledge assets are outlined below.

Table 5-1 Key questions to address in the four stages for knowledge assets

Planning (including strategy and risk assessment)
• What knowledge is critical? • Where does it fall within the regulatory framework (GLP, GCP, GMP)? • Is it tacit or explicit ? • What is the risk of losing this knowledge? • Do we have the systems we need to ensure this knowledge can flow to who needs it, when they need it?
Acquisition: process of procurement
• How will this knowledge be generated? • Will this knowledge creation occur via a business process (e.g. change management, deviation management, technology transfer, business development activities)? • Will this knowledge creation occur via a technical process (e.g. experiments, technical scale up, lab-testing, manufacturing, data analytics/ SPC review etc.)? • What mechanisms are available to capture and store this knowledge once created?
Operation
• Applying the KM lens to this stage requires a focus on capturing knowledge in the flow of work during operations. • KM approaches such as Communities of Practice (CoPs) and lessons learned activities greatly enhance the ability to capture and share knowledge assets in the flow of work. • For physical assets it is the norm to have dedicated roles for personnel to maintain these assets on a regular basis. This maintenance role, or knowledge curation role, is not yet commonplace in regard to knowledge assets. • While there may be an information technology person responsible for a system that contains explicit knowledge, but who maintains the knowledge assets to ensure they are timely, relevant, and accessible?
Disposal
• Like physical assets, knowledge assets too have an end of life. • Processes should exist to identify and remove knowledge assets that are no longer relevant[29] not only is it costly to manage old assets, it also could make it more difficult to find relevant / current assets in a timely manner. • As per maintenance, a role should exist to manage the whole lifecycle of the knowledge asset and that includes a systematic process for disposal

Having presented the rationale that knowledge is an important asset and should be considered on par with a physical asset, the next important step forward in knowledge

[29] Removal of knowledge assets may be subject to corporate records retention policies

as an asset component of the *Pharma KM Blueprint* explores the concept of *critical* knowledge.

5.2 Critical Knowledge

ICH Q10 *Pharmaceutical Quality System (PQS)* defines the product life cycle stages of a pharmaceutical product as: Product Development, Technology Transfer, Manufacturing, and Product Discontinuation. Throughout these individual product lifecycle stages a variety of data, information, and knowledge are created and used. A plethora of pharmaceutical GxP regulations[30]outline minimum expectations regarding the management of the variety of data and information related to product safety and efficacy as well as manufacturing and testing operations.

As the industry and technology has matured, companies have increased their organizational capabilities for capturing and processing their day-to-day data and information. Advances in terms of Continued Process Verification (CPV), Statistical Process Control (SPC), smart manufacturing, data analytics, and now even artificial intelligence (AI) capability, have all contributed to the growing "data lakes" across the sector. Oliver notes that pharma data is doubling every five months and that;

[30] (i.e. Good Manufacturing Practices (GMPs), Good Clinical Practices (GCP) and Good Laboratory Practice (GLP) – collectively referred to henceforth as "GxP")

> *In recent years, the pharma industry has invested heavily in "data lake" style technologies. Essentially, capture the data first and hope to find a use for it later. While the amount of data captured has increased, we're still waiting for the outcomes.* (Oliver, 2018)

The key question for the researcher remains what – if any- of this data might be considered *critical?*

Furthermore, if technology has not delivered the desired outcomes, what about the people? While the 1990's brought an early focus on the role of people in the knowledge creation process (Nonaka & Takeuchi, 1995), more than 20 years later, despite an increasing regulatory attention on the need for effective risk based decision- making, the biopharmaceutical sector is still lagging in terms of unlocking and connecting tacit knowledge across their organizations. The question remains as to how well the sector actually performs in regard to leveraging its knowledge; in short, how well is the sector using what it already knows!

Reflecting on how well the sector is doing in identifying its critical knowledge, one does not need to look further than the ISPE *Drug Shortages Survey Report* (ISPE, 2013, p. 6), where a significant number of respondent noted that 'production system issues leading to drug shortages or near misses were present during technology transfers or product development'. Indeed, Professor. Jose C. Menezes, an expert in Quality Risk Management from the Technical University of Lisbon also highlights the lack of "using

what we know" as a case of institutional amnesia and evidence of why we continue to see repeated FDA 483's and Warning letters [31]within organizations:

> *"The [biopharmaceutical] industry has no memory, we keep repeating the same mistakes again and again." Prof. Jose C. Menezes. September 16, 2016 ISPE Annual Meeting, Atlanta GA USA*

The APQC benchmarking report, presented in Chapter Four, also confirms that the biopharmaceutical sector has been slow to adopt KM approaches. It reports that only 4% of biopharmaceutical KM programs have reached a standardized maturity level of "3" or better, in comparison to 18% across all other sectors. (Trees & Hubert, 2018, p. 50). In contrast, a non-pharma specific survey, this time conducted by KPMG, reported that 79% of respondents believed that KM can play an "extremely significant" or a "significant" role in improving competitive advantage (KPMG, 2000, p. 15). For other sectors, KM approaches embedded in to the flow of work have been credited with employee engagement as well as considerable sources of cost savings. A specific example comes from El Paso, an oil and gas company, where KM efforts were focused to foster expertise within the firm and share technical knowledge across the organization. El Paso targeted first-year savings of $500,000, but in fact delivered over $1.2 million in savings in the first year (APQC, 2012b).

Slow KM adoption also featured in the researchers own 2017 ISPE Pharmaceutical KM Survey[32], where only 25% of respondents indicated that KM was embedded in the way

[31] FDA 483's and Warning letters are written notices of non-compliance with federal regulations. A Warning letter may be issued for a significant infraction and could result in the loss of licensure and other penalties.

they work. Therefore, with KM adoption in the biopharmaceutical sector clearly lagging other sectors and the blight of an industry-wide case of amnesia, one could question if product and process knowledge is delivering value to either our businesses, or more importantly, our patients.

Arguably, a key challenge inherent in this data and information capture is the conversion of that data and information into knowledge, and the identification, retention and perhaps most importantly of all – the **use** of the *critical knowledge* (that may be explicit or tacit) in order to speed decision-making, enable greater insights to support risk management and drive operational excellence through continuous improvement.

Linking back to the development phase of the biopharmaceutical lifecycle, ICH Q8 - Pharmaceutical Development (International Conference on Harmonisation, 2009), placed an emphasis on product and process understanding, however it is clear from this research that there are many more sources of organizationally critical knowledge beyond that knowledge which is directly related to the development, or even manufacture, of a given product and process, such as patient usage, post-market surveillance, knowledge of business processes, etc.. This is further discussed in the next section.

[32] As discussed in Chapter Four although not statically relevant, low participation in the survey may also point towards a general lack of maturity and awareness of KM within the sector

5.3 Stemming the Loss of Critical Knowledge

It is the opinion of the researcher, that in addition to product and process knowledge highlighted in the ICH Guidance documents and GxP regulations, critical knowledge may also come from sources beyond the traditional "GxP" lens; this includes capturing lessons learned, expertise or 'know-how' of how things work, whether it be sourced as a technical element or an input or output from a complex business process and even knowledge gained from continual improvement programs and projects.

The knowledge of *how things work* and *how things get done* is also critical to an efficient and effective workflow and often has a direct impact on the ability of the organization to consistently deliver high quality medicines to the patient. Often times this knowledge is not recognized or valued as 'critical' until someone leaves their role or even more challenging, exits the company. By which point it is often difficult or impossible to recover or reconfigure the original knowledge asset(s). This dilemma of *knowledge loss* is not specific to the biopharmaceutical sector; however, there may be a false sense of security regarding the ability to recreate such knowledge within the sector due to the traditional focus on retention of regulated data, records, and information. However, "know-how" often provides the key necessary to unlock the critical knowledge from within these retained records. Without the "know-how", retained data and information may never progress up the hierarchy to be converted into useful knowledge. Therefore, in the biopharmaceutical sector it is important that knowledge retention strategies should never be mistaken for record retention policies and procedures. Knowledge retention is a much broader organizational capability,

never more so when the outsourced supply chain is also considered. Davenport et. al remind us that if you are 'renting knowledge, make sure you take steps to retain it' (Davenport & Prusak, 1998, p57.). Supplier Technical Agreements (TAs) should, but often don't, incorporate clauses related to the knowledge that emerges over the course of the contractual arrangement with a supplier.

Knowledge mapping is one valuable KM practice that may be utilized to help identify knowledge and its relative importance to the organization. A proven knowledge mapping tool, specifically designed for use within the biopharmaceutical sector, has been developed and used successfully by the researcher (Kane, 2018), a discussion and template of which can be found in Appendix III. Finally, knowledge mapping is one of the core KM practices identified in the overall *House of Knowledge Excellence Model* (Kane & Lipa, 2018), which is described in detail in Chapter Seven which is the third element of the *Pharma KM Blueprint.*

5.4 Conclusion

In conclusion, the researcher fully acknowledges the complications which arise in the biopharmaceutical landscape, specifically in respect to the regulatory expectations to capture, store, and validate a range of explicit knowledge. As discussed previously, not all knowledge or content, are of equal value or regulatory importance. This concept is aligned with the recommendation in the ISPE GAMP© Electronic Records & Signature guidance (ISPE Guide, 2005) noting the need for, *'*application of appropriate controls commensurate with the impact of records and the risks to those records*.'* Pragmatic KM guidance in this field would also advocate that the manner in which explicit

knowledge and content is stored and curated[33] should be commensurate with the relative importance/criticality of that knowledge.

This chapter has presented the need to manage knowledge as an asset and shown how physical assets and knowledge assets have several characteristics in common. Including the necessity to have dedicated roles for personnel to maintain these knowledge assets on a regular basis. This maintenance role, or "knowledge curation" role, is not yet commonplace in this sector. Chapter Six will outline the next key element blueprint*, entitle the Pharmaceutical Product Knowledge Lifecycle (PPKL) Model,* which discusses the importance of enabling knowledge assets to flow across the product lifecycle.

[33] **curate something** (especially on the Internet) to collect, select and present information or items such as pictures, video, music, etc. for people to use or enjoy, using your professional or expert knowledge. Oxford Learners Dictionary online

Chapter Six

Pharma KM Blueprint Part Two: Pharmaceutical Product Knowledge Lifecycle (PPKL) Model

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"Knowledge is sticky. Without proper processes and enablers, it will not flow" – Dr. Carla O'Dell, APQC

6 Understanding Knowledge Flow

This chapter is grounded in the knowledge management concept of *knowledge flow*. The nuances of knowledge flow have been widely discussed by knowledge management thought leaders such as Nonaka, O'Dell, Hubert, Milton and Leistner, and can be summed up succinctly by O'Dell's quote, 'knowledge is sticky, without proper processes and enablers, it will not flow'. From the perspective of the researcher, lack of knowledge flow is manifested when organizations are either unable to find the knowledge it knows that it has, or knowledge is not available in a timely manner. Leistner advocates that the term "*knowledge management*" is in fact a misnomer and a more appropriate terminology is "*knowledge flow management*" (Leistner, 2010). The result of ineffective knowledge flow may surface as rework (e.g. repeating experiments, reanalyzing data to create new reports), delays in submission of regulatory dossiers, inability to provide timely response to health authority questions (from inspections or regulatory submissions), challenges locating the knowledge needed to resolve manufacturing deviations, or simply not finding the internal expertise to resolve a problem. Larry Prusak, founder of the *Institute of Knowledge*

Management, states that *"Knowledge is better understood as flow"* (O'Dell & Hubert, 2011, p. xii).

Dr. Reid G. Smith, an engineer and a knowledge management expert with deep experience in the petroleum industry, offers the following analogy of knowledge and flow:

> *Knowledge flow and fluid flow obey analogous laws. The analogy suggests that the knowledge productivity of an organization can be increased by changes in three variables: organizational permeability, knowledge viscosity and business pressure gradient.* (Smith, 2005)

Smith introduced the notion of using the concepts in Darcy's Law [34]for knowledge flow (Smith, 2005), a simplified version of Darcy's Law is depicted in figure 6-1 below.

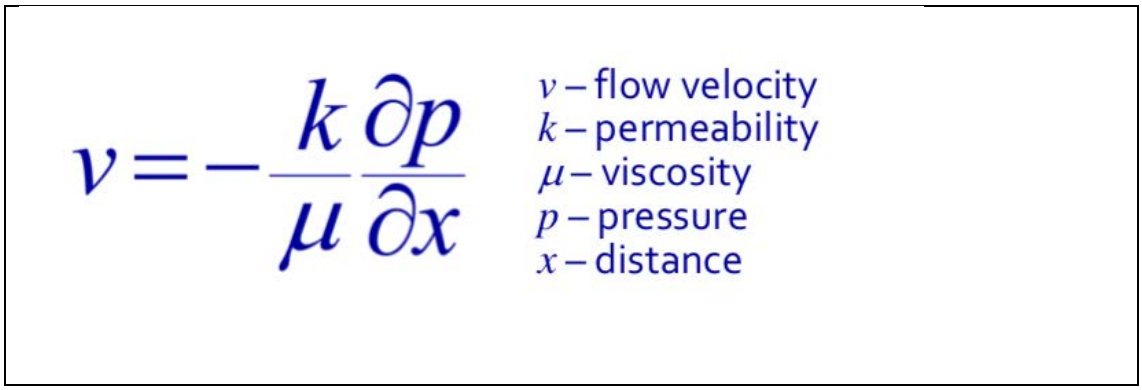

Figure 6-1 Simplified version of Darcy's law in linking to knowledge flow (Stouffer & Smith, 2011)

As described by Smith, in petroleum industry terms, ***v*** is the velocity of the fluid flow, **μ** is the viscosity (stickiness) of the fluid, **∂p/∂x** is the local pressure gradient, and **k** is a

[34] Darcy's Law – A mathematical relationship discovered (1856) by the French engineer Henri Darcy that governs the flow of groundwater through granular media or the flow of other fluids through permeable material ("Darcy's Law," n.d.)

proportionality constant called the permeability of the rock. Smith corroborates Darcy's mathematical formulation linking to his personal experience with fluid flow, as:

- Fluid flows faster through a more permeable structure than a less permeable structure, i.e. the more viscous a fluid is, the less easily it flows.
- Fluid flow is improved by applying pressure (either positive or negative pressure).

Smith further relates O'Dell's observations about knowledge being 'sticky' as consistent with Darcy's description of fluid flow in that:

- Knowledge flows faster through a more permeable organization than it does through a less permeable organization.
- Tacit knowledge is stickier than explicit knowledge.
- Knowledge flow through an organization is improved by applying pressure (e.g., competitive pressure, availability of new technology, managerial pressure).

Stouffer and Smith described how Marathon Oil had utilized these concepts to develop a holistic KM Program (Stouffer & Smith, 2011) and provided further analogies to Darcy's Law and knowledge flow:

- Increase "Permeability" by improving access to knowledge and building knowledge connections
- Increase "Pressure" via management leadership and metrics to measure KM
- Decrease "Viscosity" by turning tacit knowledge into explicit, actionable knowledge
- Decrease "Distance" by bringing people, knowledge and communities closer together

Building on the concepts provided by Smith, the researcher proposes that while an efficient way of moving fluid is via pipes, however simply providing pipes does not guarantee flow. In this analogy, one could compare the pipes to KM supporting processes and one could envision knowledge (tacit or explicit) as the fluid. Simply installing a KM process will not guarantee knowledge flow. Pressure must also be applied, either negative or positive (e.g. a push or a pull) to enable the transfer. To conclude this comparison, just as the case of transfers of larger or regular volumes of fluid would prove to be haphazard and inefficient if there were no pipe; so too for knowledge flow in the absence of systematic KM processes.

Chapter Five introduced the first *Pharma KM Blueprint* element with the **principle** of the need to value and maintain *knowledge assets* in the same way as physical assets. In the next three chapters, the researcher will bridge the gap from the theoretical field of knowledge management to the practical, to solve the common problems identified via the industry consultation and the researcher's own experience throughout this research, as follows:

- Chapter Six – **The Pharmaceutical Product Knowledge Lifecycle (PPKL) Model** - Will address the challenge of enabling knowledge flow to increase visibility, access and use of the product and process knowledge assets 'end-to-end' (E2E) across the product lifecycle
- Chapter Seven - **The House of Knowledge Excellence (HoKE) Framework** – Will demonstrate the necessity of implementing a systematic KM program,

incorporating KM practices, pillars, and enablers to support the effective management and flow of knowledge assets.

- Chapter Eight – A **Knowledge Management Effectiveness Evaluation (KMEE) Tool** - Provides a practical KM diagnostic tool that may be used to identify and evaluate areas of opportunity and track progress on closing these knowledge gaps.

The Pharma KM Blueprint is represented in Figure 6-2.

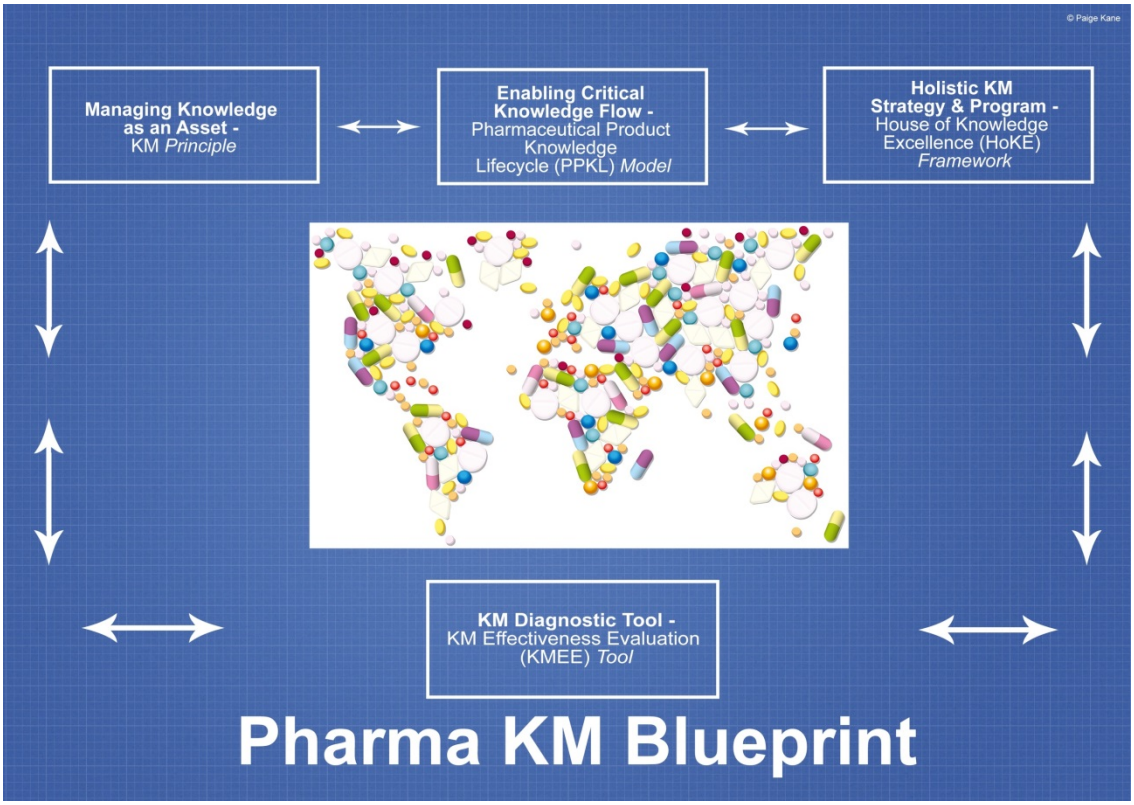

Figure 6-2 Pharma KM Blueprint - Kane 2018

6.1 Development of the Pharmaceutical Product Knowledge Lifecycle (PPKL) Model

This chapter proposes a *Pharmaceutical Product Knowledge Lifecycle (PPKL)* model, adapted from the product lifecycle presented in ICH Q10. The motivations to develop this *knowledge* lifecycle are twofold. First, the terms, *knowledge* and *knowledge management* (KM) are referenced across ICH guidance documents Q8 -Q11 and in the ICH Q12 draft in over 200 instances. Yet more specific regulatory guidance setting out the expectations for knowledge does not exist. Without a focused discussion on the product lifecycle it is difficult to understand how such knowledge is created, connected and utilized across the lifecycle. Industry consultation undertaken as part of this research surfaced a specific request to better define the relationship between the product lifecycle and KM (Kane, Lipa, & Hubert, 2015).

Second, in the context of making product knowledge visible, enabling knowledge flow and increasing availability, the researcher believes the lifecycle phases as depicted in ICH Q10[35] mis-represent actual practice in the *context of knowledge management and knowledge flow*. The researcher therefore offers a re-imagined model to enhance the understanding of the critical role that knowledge plays in the product lifecycle. It is the opinion of the researcher, that the very absence of knowledge from the product lifecycle model, depicting how the product and process knowledge assets are created and derived into other organizational knowledge outputs, directly contributes to the

[35] The product lifecycle is depicted in ICH Q10 Annex 2 page 17 (International Conference on Harmonisation, 2008a)

ambiguity and compartmentalization of lifecycle knowledge, and greatly inhibits the intended benefits sought by the ICH suite of Quality documents (Q8-Q12).

6.2 Product Knowledge – the Regulatory Landscape

As examined in previous chapters, ICH Quality guidance issued during the span of 2005-2012 created awareness of risk-based science approaches. The ICH Quality guidance documents share common expectations of leveraging product and process knowledge as an enabler to effective risk-based science. However, as noted in the literature review the ICH Implementation Working Group (IWG) recognized that there were several issues which warranted further clarification and subsequently published a Q&A for Q8/Q9/Q10 (International Conference on Harmonisation, 2010). This document provided additional interpretation for forty-six questions in total, five of which were directly related to knowledge management:

1. *Does Q10 suggest an ideal way to manage knowledge?*
2. *Is a specific dedicated computerised information management system required for the implementation of knowledge management with respect to ICH Q8, Q9 and Q10?*
3. *Will regulatory agencies expect to see a formal knowledge management approach during inspections?*
4. *How has the implementation of ICH Q8, Q9, and Q10 changed the significance and use of knowledge management?*
5. *What are potential sources of information for Knowledge management?*

The ICH Quality Implementation Working Group response to the knowledge management questions provides limited but extremely valuable guidance and insight. The short answer to the first three questions was “no”. The response to question four confirmed that knowledge management was not considered as a ‘system’, rather, it was seen as an enabler to the concepts described in ICH Q8, Q9 and Q10. The last question related to sources of information for knowledge management. Listed below are the examples provided in that ICH Q&A document (International Conference on Harmonisation, 2010):

- *Prior based on experience obtained from similar processes (internal industry scientific and technical publications) and published information (external literature and peer-reviewed publications);*
- *Pharmaceutical development studies;*
- *Mechanism of action;*
- *Structure/function relationships;*
- *Technology transfer activities;*
- *Process validation studies;*
- *Manufacturing experience e.g. Internal and Vendor audits, Raw material testing data;*
- *Innovation;*
- *Continual improvement;*
- *Change management activities;*
- *Stability reports;*
- *Product Quality Reviews/Annual Product Reviews;*
- *Complaint Reports;*
- *Adverse event reports (Patient safety);*
- *Deviation Reports, Recall Information;*
- *Technical investigations and/or CAPA reports;*
- *Suppliers and Contractors;*
- *Product history and /or manufacturing history;*

- *Ongoing manufacturing processes information (e.g., trends).*

The list, intended as an example of the scope but not limited to, underlines the breadth of the knowledge assets that may be created right across the lifecycle. Without a systematic business practice, or a collection of practices, processes and tools, supporting KM these assets may not even be captured or appropriately curated within the organizations. Furthermore, depending on a person's role or location in the organization, much of this knowledge may not even be visible or accessible to them. These challenges link directly to several comments in the industry consultation sessions conducted as part of this research, which highlighted the need for greater visibility and access to knowledge. More specifically, it also resonates with a question that came from the PDA 2014 KM Workshop asking, "How to overcome boundaries in hierarchy and function that generate islands of information?"(Gorsky, Smalley, Neway, Reifsndyer, & Ross-montgomery, 2014). This question speaks to the fact that, for many organizations, knowledge may be captured in the first instance but is then stored in a functional or hierarchical silo, aka a "knowledge island". These knowledge islands contribute to a form of institutional "locked-in syndrome".

In addressing the need to process post-approval changes in a more predictable and efficient manner, the ICH Q12 concept paper was issued in 2014 entitled, *Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management* (International Conference on Harmonisation, 2014). The ICH Q12 concept paper identified gaps in realization of intended benefits.

> *"There is currently a lack of a harmonised approach on technical and regulatory considerations for lifecycle management. While the concepts in ICH Q8, Q9, Q10 and Q11 provide opportunities for a more science and risk-based approach for assessing changes across the lifecycle, several gaps exist which limit full realisation of intended benefits*."

The concept paper also shared the aim of ICH Q12 as being: 'To enhance the management of post-approval changes, and transparency between industry and regulatory authorities, leading to innovation and continual improvement.', (ibid.).

Two clarification issues relating to ICH Q10 aspects were also highlighted in the ICH Q12 concept paper:

> *Establish criteria for a harmonised risk-based change management system based on product, process and/or clinical knowledge that effectively evaluates the impact of change on quality, and, as applicable to safety and efficacy.*

And,

> *Clarify expectations and reinforce the need to maintain a knowledge management system that ensure continuity of product and process information over the product lifecycle*.

During the Q12 drafting process, members of the ICH Q12 Expert Working Group attended KM Dublin 2015, to gain insights about ongoing KM activities within the sector and to capture feedback on any KM guidance needs (Kishioka, Cook, & Kruse, 2015). This draft of ICH Q12 was greatly anticipated by KM practitioners, with the hope that concepts for the Q10 enabler of KM would be further discussed and the references related to product and process knowledge found across Q8 - Q11 would be

consolidated to provide a more holistic understanding of the characteristics of product and process knowledge.

November 2017 brought the publication of the ICH Q12 draft, focusing on established conditions and post approval changes with modest additional KM guidance (International Conference on Harmonisation, 2017). The draft highlighted:

a) The need to ensure that firms had agreements for knowledge sharing related to product and process robustness or informed changes.

b) In addition to the individual sources of information, there should be a holistic view of quality performance for a product or product family.

The draft firmly positioned knowledge at the center of the change management process, and although a holistic view of quality performance was discussed, there was no mention of an actual holistic view of the product and process knowledge. Figure 6-3 depicts the diagram from the Q12 draft which places knowledge between *Knowledge Management* and *Change Management*.

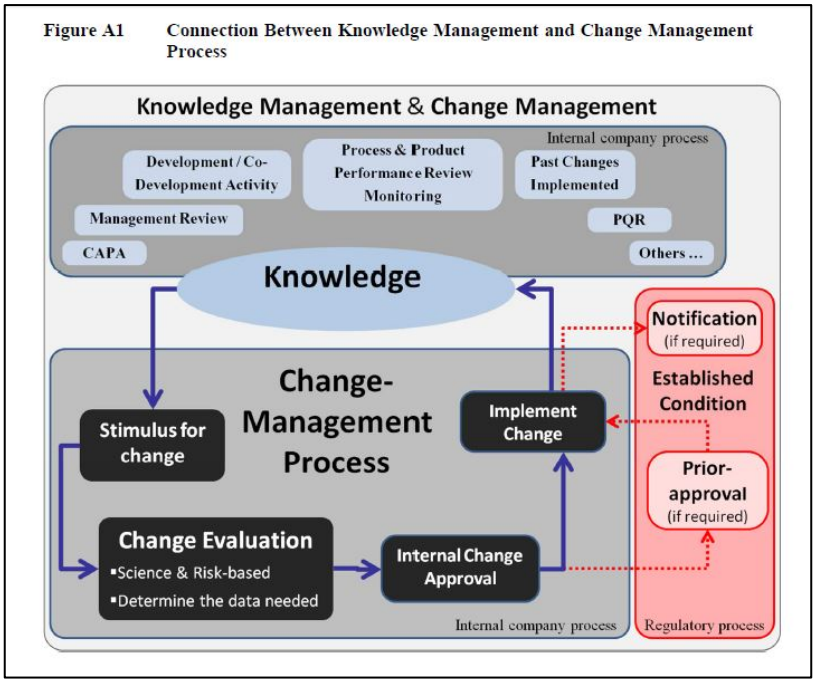

Figure 6-3 ICH Q12 Draft - Putting Knowledge at the Center of Knowledge Management and Change Management (International Conference on Harmonisation, 2017)

In response to the industry consultation feedback as discussed in Chapter Four, the researcher suggests that organizations could greatly benefit from further guidance to assist in forming a holistic end-to-end (E2E)[36] view of product knowledge assets, similar to the Q12 recommendation for a holistic view for quality performance. One path towards further guidance could be achieved If regulatory guidance for KM[37] was approached in the same way as ICH Q9 was developed for QRM. However, while this route could reduce the current levels of ambiguity, the researcher concludes that expectations from a regulatory perspective could in fact be over-burdensome, and therefore not welcomed by the sector as a whole.

[36] E2E refers to the product lifecycle from product development through product discontinuation

[37] The researcher is not specifically advocating for regulatory guidance for KM – as evidenced in the industry consultation events, any guidance, either by industry or regulators would be beneficial

6.3 The ICH Q10 Product Lifecycle

Turning attention back to ICH Q10, the product lifecycle provides a foundation of shared understanding for the lifecycle phases of a medicinal product as shown in, Figure 6- 4 below.

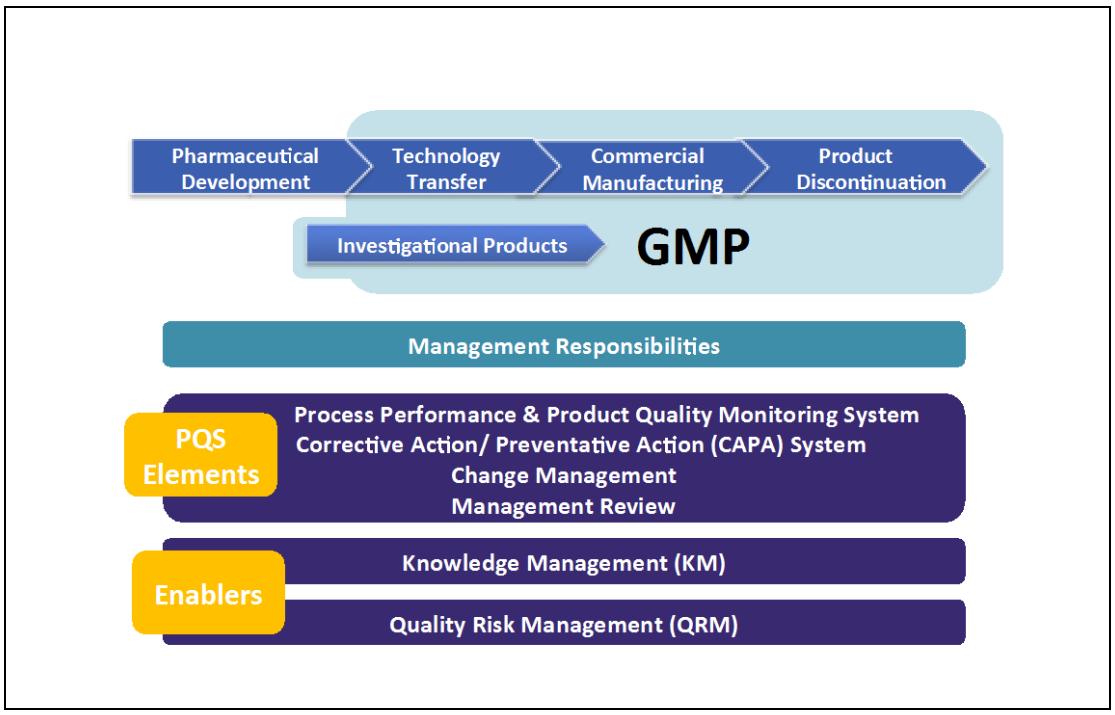

Figure 6-4 ICH Q10 PQS Diagram inclusive of a product lifecycle (updated to enhance graphic quality)- ICH Q10 Annex 2

The researcher suggests that not only is KM an enabler of the PQS as depicted in the ICH Q10 model, but it is in fact fundamental to how the sector creates value for patients and stakeholders, as it enables end-to-end visibility, flow and availability of *what* is known about the products.

Although, the suite of ICH guidance highlights the importance of capturing and building on product and process knowledge, recommendations on how this might be achieved are not included. Understanding the flow between the product lifecycle phases, the

range of supporting business processes and the needs of the myriad of groups involved in capturing knowledge assets can leave organizations in a quandary as to how to enhance visibility and utilization of the behemoth of product and process knowledge gathered over the lifecycle. A lifecycle approach to KM provides a unique value proposition to help an organization look end-to-end at the flow of its knowledge assets, transcending organizational structure, geographies and other boundaries. In practice, enabling knowledge flow across the multiple phases of the product lifecycle can be very difficult.

Figure 6-5 offers a *Vison for Knowledge*, presented by Martin Lipa, Merck Manufacturing Division KM Leader, at the 2018 CASSS CMC Forum (M. J. Lipa, 2018). This vision correlates directly to the researchers position, that: *[KM's] chief role may be in the enablement of end to end (E2E) product knowledge flow, visibility, and availability.*

Figure 6-5 Vision for (Prior) Knowledge – CASSS CMC Forum (M. J. Lipa, 2018)

In summary, Lipa's vision for linking knowledge to the product lifecycle is as follows:

1. ***We know what we know*** – The organization knows who has the knowledge, knowledge can be found across lifecycle phases and across organizational boundaries, i.e. "knowledge flows".

2. ***We know what we should know*** – The organization comprehensively understands what it should know about a product, critical knowledge is identified (tacit and explicit) and retained.

3. ***We use what we know*** – The organization is using knowledge (as expected in Q8-12) for activities (not inclusive) such as: product development, risk assessments, definition of established conditions, change management, continual improvement, and Product Quality Reports/Annual Product Review.

Reflecting on the challenges identified in the industry consultations, such as 'lack of awareness of knowledge and system existence' (KM Dublin 2015), and the need for a 'burning platform to better connect the dots' or the need to 'overcome boundaries in hierarchy, function that generate islands of information' (PDA 2014), the stage is now set to look that the product lifecycle through the lens of KM.

6.4 Connecting Product and Process Knowledge

Product and process knowledge is created constantly through a variety of business processes, dialogs and other interactions between colleagues. This knowledge is stored across many different locations (i.e. formal and informal repositories and other IT systems) as well as in the heads of subject matter experts. Linking back to the opening quote from O'Dell that "knowledge is sticky', two challenges stand out for the researcher, the first of which being the visibility of lifecycle knowledge assets and the

second is the flow of those knowledge assets. This was echoed in the BPOG KM Technical Roadmap (BioPhroum Operations Group, 2017) where the team noted:

> *The biopharmaceutical community (the industry and its stakeholders) can advance IT tools and systems by* ***articulating what knowledge and knowledge flow is, defining organizational knowledge flow challenges****, developing best practices and biopharmaceutical use cases … and creating real-time, networked knowledge management systems throughout the biopharmaceutical industry*

Figure 6-6 provides a graphic representation of typical business processes involved in knowledge creation across the product lifecycle. It should be noted that many of these processes occur offline from the main plant floor manufacturing process. The diagram provides an illustration of the variety of business processes and the diverse range of knowledge repositories which often exist. The researcher presented this along with the *Pharmaceutical Product Knowledge Lifecycle (PPKL)* model at the PDA Europe Symposia June 2018. Attendee feedback[38] confirmed the complexities of business processes, repositories and the tacit knowledge of subject matter experts was indeed reflective of industry knowledge visibility and availability challenges.

[38] The attendee list for this symposium was unavailable due to EU General Data Protection Regulation (GDPR) effective May 2018

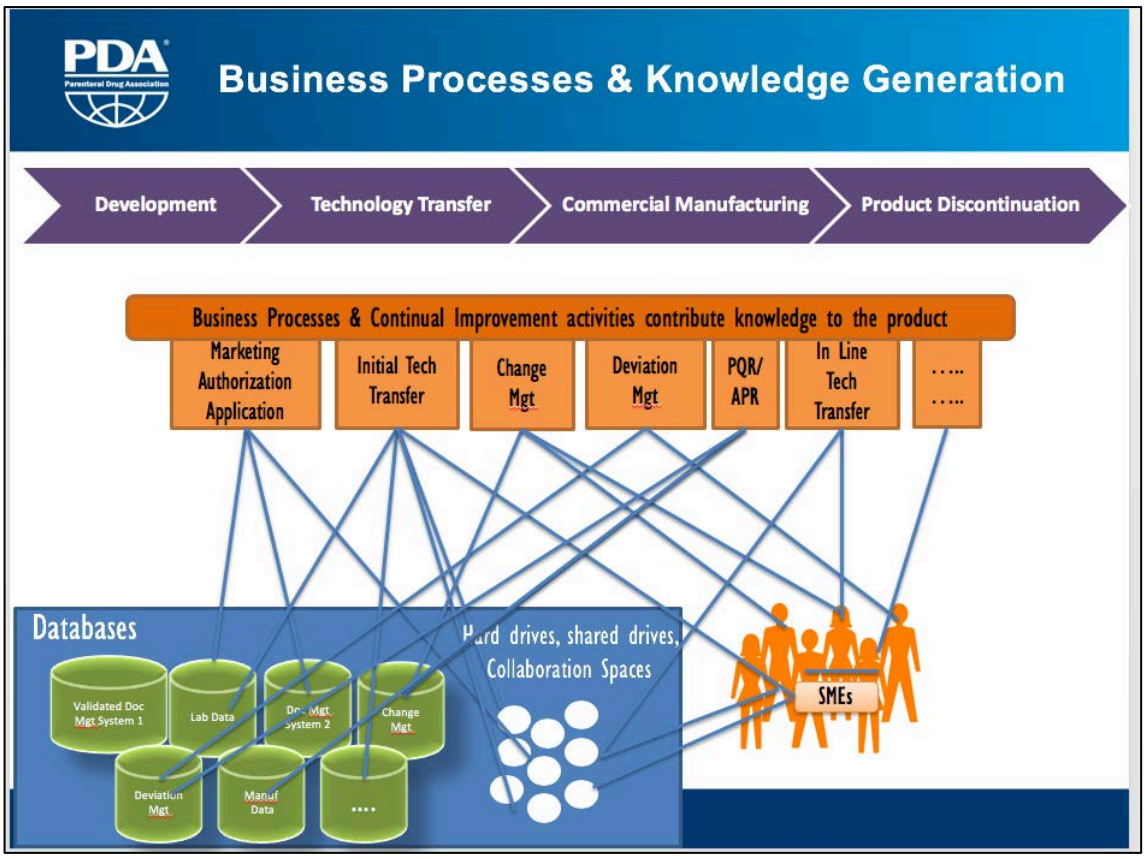

Figure 6-6 Knowledge generating business processes/ knowledge repository examples – P. Kane PDA EU Meeting June 2018

Concurring once again with one of the themes gleaned from the KM Dublin 2015 break-out sessions which identified "pain points" as the 'existence of multiple IT systems/repositories and a lack of awareness of knowledge and systems existence'. This also resonates with the earlier issue of lack of connection between the many "islands of knowledge" (PDA 2014).

Developing and manufacturing medicinal products, is complex. A vast amount of knowledge is generated, and as identified in ICH Q8, Q10 and Q12, the industry has opportunities to apply this knowledge to accelerate product realization and continual improvement.

The researcher, reflecting on the insights gain from the industry consultations and direct experience, summarizes as follows:

- Guidance is lacking on product lifecycle knowledge lifecycle and the knowledge generated within the lifecycle phases and activities
- The industry recognizes there is a problem, but it is difficult to articulate
- More effectively managing product and process knowledge is a broad issue, and with a clear benefit to patients and to the business (reliable supply, access to medicines and lower costs with process improvements)

6.5 Reimagining the ICH Q10 Product Lifecycle Model

Every day that the product is manufactured, more knowledge is created, and more is learned about the process and the product. Lipa also shared an interesting graphical representation, developed in collaboration with Dr. Rob Guenard, at the CASSS Regulatory CMC Forum in January of 2018 (M. J. Lipa, 2018). Figure 6-7 provides a visual representation of the growth and risk categorization of different types of explicit knowledge assets (GMP and uncontrolled assets), created throughout the lifecycle of a product. What is not identified in the diagram are tacit knowledge assets, which also continues to grow over the product lifecycle.

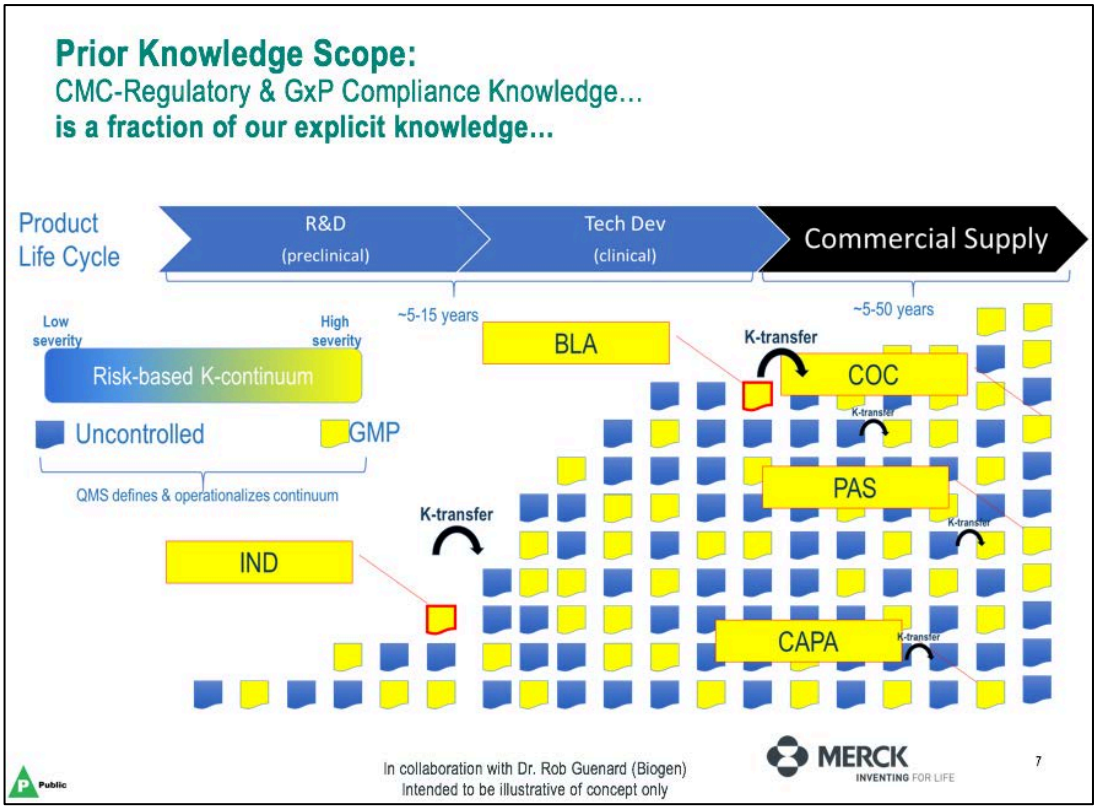

Figure 6-7 Visualization of product lifecycle knowledge growth (M. J. Lipa, 2018)

Taking in account the tremendous amount of knowledge that is generated across the organization (internal and potentially external to the Marketing Authorization Holder) across the lifecycle of a product, the researcher asserts that:

- If a primary goal of ICH Q10 is *product realization*, which requires that an organization applies the best of what it knows (it's collective knowledge and experience) in its decision-making for that product

And,

- If every product interaction – whether formal or informal – is viewed as an opportunity to deepen the knowledge of the product, then

This requires a re-imagination of the ICH Q10 depiction of the product lifecycle. The researcher believes a new articulation of the lifecycle better aligns with the non-linear nature of product development, manufacture and knowledge transfer throughout the life of the product.

The researcher proposes four areas of opportunity to enhance the ICH Q10 model.

a) Technology Transfer would be better considered as a Technology **AND** Knowledge transfer *activity* that occurs several times during the lifecycle of a product. (therefore, remove Technology Transfer as a lifecycle phase and represent it is an activity across the lifecycle).
b) Addition of a new lifecycle phase of *New Product Introduction (NPI)* to replace the Technology Transfer lifecycle phase to cover the initial commercialization of the product, which is a highly "knowledge rich" activity.
c) Introduce a new *activity* for *Technical Product Support and Continual Improvement across* the lifecycle.
d) Introduce a *vision* for end to end (E2E) product visibility and availability, and a methodology for transparency of product knowledge throughout the lifecycle.

Based on these enhancements the researcher proposes the following *Pharmaceutical Product Knowledge Lifecycle (PPKL) Model*, that incorporates key knowledge generating activities and sets the stage for improved articulation, visibility and availability of product and process knowledge. This new model is shared in Figure 6-8.

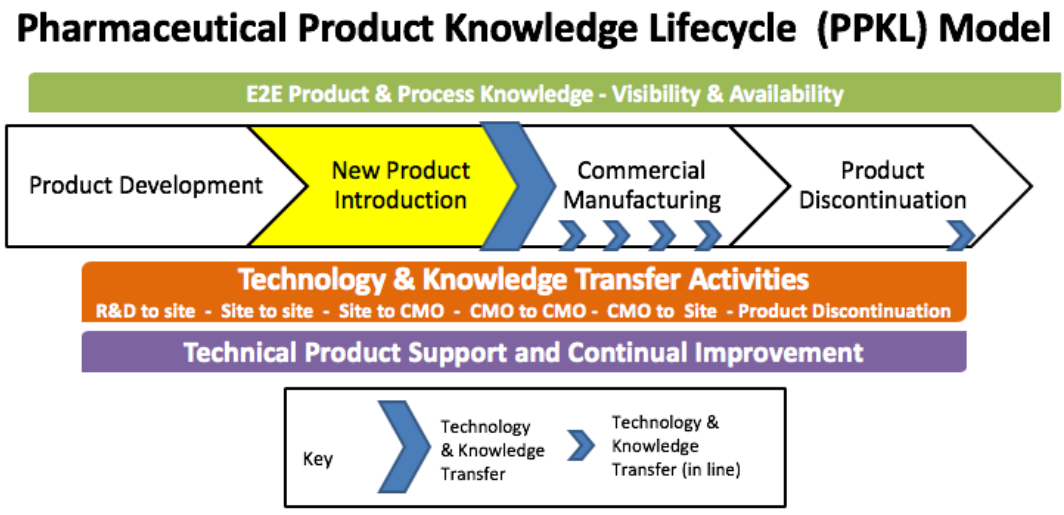

Figure 6-8 Pharmaceutical Product Knowledge Lifecycle Model (PPKL) – research output Kane 2018

6.5.1 Reimagining the ICH Q10 Product lifecycle Model - Technology Transfer

The Technology Transfer (TT) phase of the product lifecycle is of particular importance when managing product and process knowledge. ICH Q10 emphasizes goal of technology transfer is to:

> *Transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation.*

ICH Q10 goes on to further explain 'This [technology transfer] knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement'. With that description shared, the researcher suggests a more accurate description of this critical activity would actually be of **Technology and Knowledge Transfer**. This is because, the tacit knowledge transfer is frequently undervalued and underestimated by the technical teams managing the technology transfer project and, in the experience of the researcher, a frequent cause of failure and ongoing process related problems post transfer.

On the specific topic of *Technology Transfer*, there are multiple sector guidance documents, as listed below:

- ISPE: Good Practice Guide: Technology Transfer (ISPE, 2014)
- PDA: Technical Report No. 65: Technology Transfer (PDA, 2014)
- NIHS Japan: Guideline for Technology Transfer (NIHS, 2005)
- WHO: WHO Guidelines on Transfer of Technology in Pharmaceutical Manufacturing (World Health Organization, 2011)

These guidance documents share best practice and recommendations regarding technology transfer (TT) activities. However, there is little reference to or guidance provided relating to the tacit knowledge required for the success of the transfer. Although guidelines outline recommended documents and explicit knowledge assets that should be considered in the transfer process, the *tacit* knowledge about the process, which is critical and difficult to characterize and capture, receives little focus. Typically, a small number of technical experts are sent from the sending site to the receiving site to teach, guide, troubleshoot for a short transitional period of time in order to share their knowledge of the product and process and aid a successful transfer. Given the time and budget pressures that are often present during this initial start-up phase for a new product introduction at the receiving site, the co-ordination of these expert resources and the quality of the contact they have with the final commercial operations team is often less than optimal. In many cases their time is spent assisting in the set-up of the equipment and/or process to assist the project team to meet key project milestone, such as qualification and validation activities, and little time is left for training and coaching the new team responsible for commercial production of the product(s) post-handover.

The researcher proposes Technology Transfer is one particular area that could benefit from a formal set of KM practices and tools to systematically capture the critical tacit knowledge necessary to support successful technology transfers, with very real potential to benefit the organization by reducing operational costs and resources post transfer. One such KM tool that the researcher has developed and used effectively to

support TT Projects includes a formal *Knowledge Mapping Tool.* An example of such as tool is provided in Appendix III.

Another misnomer that the researcher has sought to address with the adaptation of the product lifecycle model is the belief that "Technology Transfer" is a discrete phase over the life of a typical product. In fact, throughout the life of any given product there most likely will be multiple technical transfers. Informal benchmarking[39] within the expert focus groups and KM Task Teams that the researcher is involved with has noted that, for small molecule products one could expect four or more TT events as the company continues to optimize production and costs over the product lifecycle. Indeed, technology transfers may be ongoing throughout the manufacturing phase and product discontinuation phases as products move to other nodes in the manufacturing network, are outsourced to third party partners, or the manufacturing site is acquired by a new organization (CPhI Pharma Insights, 2016a). This has been illustrated on the adapted lifecycle model by showing multiple TT chevrons occurring throughout the product lifecycle.

Moving medicinal products to a new facility can present a tremendous "knowledge flow" challenge. This knowledge flow challenge was highlighted in KM Dublin 2015 referring to 'Knowledge islands across geographies, across functions, at handoff points and across projects' and in the direct experience of the researcher, technology transfer projects often experience, and suffer from, these challenges. At the 2014 PDA KM

[39] Formal benchmarking of number of Technical/Knowledge transfers in relation to capture of tacit knowledge could be an opportunity for future research.

Workshop, knowledge flow for technology transfer was listed as a "critical and high priority" and informally, the 25 respondents to the 2017 *ISPE Biopharmaceutical KM Benchmarking Survey* also listed technology transfer as a key topic that could benefit from additional KM Focus.

Furthermore, the technology transfer (TT) for a medicinal product typically involves multiple activities: transfer of the active pharmaceutical ingredient (API) or drug substance (DS), transfer to the drug product (DP) or fill/finish (FF) facility as well as the transfer of the analytical methods to the respective testing facilities. The last TT activity is the final transfer of all product knowledge to an archive facility when the product is scheduled to be discontinued, this is highlighted on the PPKL Model, shown in Figure 6-8 with a final chevron, acknowledging this transfer in the product discontinuation lifecycle phase. Figure 6-9 provides a diagrammatic representation of the complexities involved in a typical TT activity for a medicinal product.

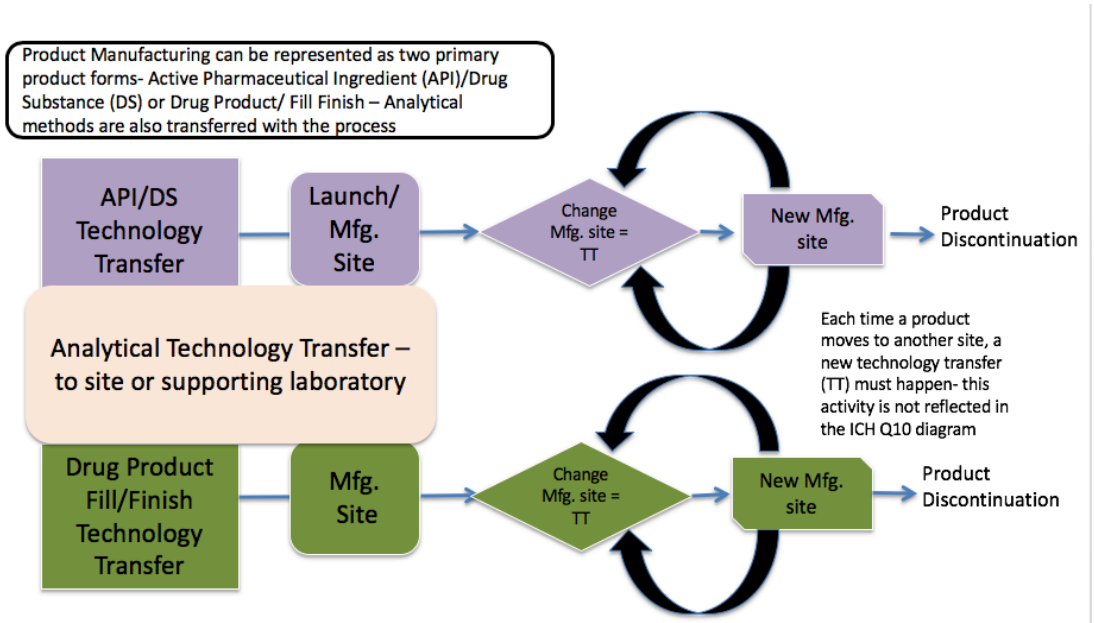

Figure 6-9 Technology Transfer (TT) Commercial Manufacturing through Product Discontinuation lifecycle phases - Kane 2017

Adding to complexity, multiple TT activities that transpire over the lifecycle of the product due to technical or business reasons can result in a "hostile" transfer. Business decisions to move manufacturing could be a result of company "right sizing", product portfolio balancing or outsourcing the product to a contract manufacturing organization (CMO). This can lead, in the experience of the researcher, to less than optimal knowledge sharing environments due to loss of jobs or other human costs arising from the economic penalties at the "sending" site.

Biopharmaceutical sector technology transfer guidance documents refer to the *sending unit* and the *receiving unit*, and Table 6-1 lists examples of the array of sending and receiving units that may be involved in a technology transfer over the product lifecycle.

Table 6-1 Technology Transfer sending/ receiving unit examples

Sending Unit (SU)	Receiving Unit (RU)
MAH Development Organization	MAH Manufacturing Site
MAH Manufacturing Site	CMO Site
CMO Site	CMO Site
MAH Development Organization	CMO Site
CMO Site	MAH Manufacturing Site
Product discontinuation (any type of site)	Explicit Knowledge to Archive facility

The biopharmaceutical sector is not alone in addressing the challenges to transfer critical knowledge across organizational boundaries. In 2012 APQC, at the request of 15 organization across multiple industries, conducted research to seek out best practices of improving the flow of knowledge during process development (APQC, 2012a).

Table 6-2 shares the four high level knowledge flow best practices and associated sub-activities, identified by this APQC research, for organizations to consider.

Table 6-2 APQC best practices of improving the flow of knowledge during process development (APQC, 2012a)

1. Create a strategy for capturing and transferring knowledge	a) Align process development knowledge capture efforts with key business drivers. b) Link process development knowledge capture and transfer efforts to existing improvement methodologies or principles. c) Embed knowledge capture and transfer activities into the process development stage-gate process. d) Communicate in the language of your "customers."
2. Develop an effective process to capture and transfer process development knowledge	a) Integrate a robust lesson learned process into process development. b) Leverage existing groups to guide and vet knowledge. c) Accelerate process development knowledge capture and transfer with targeted events. d) Distinguish among types of process development knowledge to capture and transfer.
3. Create organizational support for capturing and transferring process development knowledge	a) Establish explicit governance and accountability for process development knowledge capture and transfer. b) Capture internal customer insights by partnering with business units. c) Create opportunities for leaders to learn from each other. d) Adopt change management principles and engage people to foster organizational support. e) Use trained change agents. f) Build and maintain a centralized, searchable repository for critical process development knowledge.
4. Continually review and improve the process development knowledge capture and transfer process	a) Enlist and engage process development stakeholders to continuously enhance knowledge capture and transfer efforts. b) Use leading and lagging indicators to monitor the program's impact over time.

The learnings identified by APQC would benefit the biopharmaceutical sector when used to complement the industry specific guidelines that address pharmaceutical products such as, control strategy, facility fit, process qualification and analytical methods, to name but a few. In the experience of the researcher, in particular, the

concepts identified above such as, ‘embed knowledge capture and transfer activities into the process development stage-gate process’ and ‘build and maintain a centralized, searchable repository for critical process development knowledge’, would be particularly beneficial to the success of the overall transfer process.

Linking back to the APQC recommendations for improving the flow of knowledge in the *Product Development* phase, and acknowledging the impact of the diversity of sites, systems and culture, the specific recommendation of ‘Communicate in the language of your customers’, is crucial when crossing internal or external organization boundaries. In addition the ICH Q12 draft consensus guideline suggests that knowledge sharing agreements be built into quality agreements and contracts (International Conference on Harmonisation, 2017, p. 28). However, this assumes that effective and efficient business processes for knowledge capture and curation related to the product and process already exist at the sending site; and that the receiving site has established, effective KM processes which stand ready to receive this knowledge as part of the transfer.

While the researcher has dedicated substantial time and thought on the topic of effective technology and knowledge transfers, a proposed area of future detailed research includes further examination related to the tacit knowledge elements of technology and knowledge transfers.

Finally, to close the loop on this element of the lifecycle, the reimagination of the ICH Q10 product lifecycle offers an adapted *Product Knowledge Lifecycle (PPKL) Model*,

which replaces the phase formerly entitled *Technology Transfer* with a phase entitled *New Product Introduction* (See Figure 6-10). This phase is intended to depict the initial and finite activities specifically related to the first instance of commercializing a given product and is considered a special case of Technology Transfer. The first transition from *Product Development* into *Commercial Manufacturing*, with the introduction of a new approved product, presents both challenges and opportunities for an organization, the success of which hinges on the ability of that organization to create, capture, communicate and curate new knowledge about that product. The *Knowledge Mapping Tool* included in Appendix III is intended to be flexible for use in cases of new product introductions or later stage lifecycle transfer, whether the knowledge assets mapped are indicated as "under development" (NPI cases) or existing assets requiring "update" to reflect current conditions.

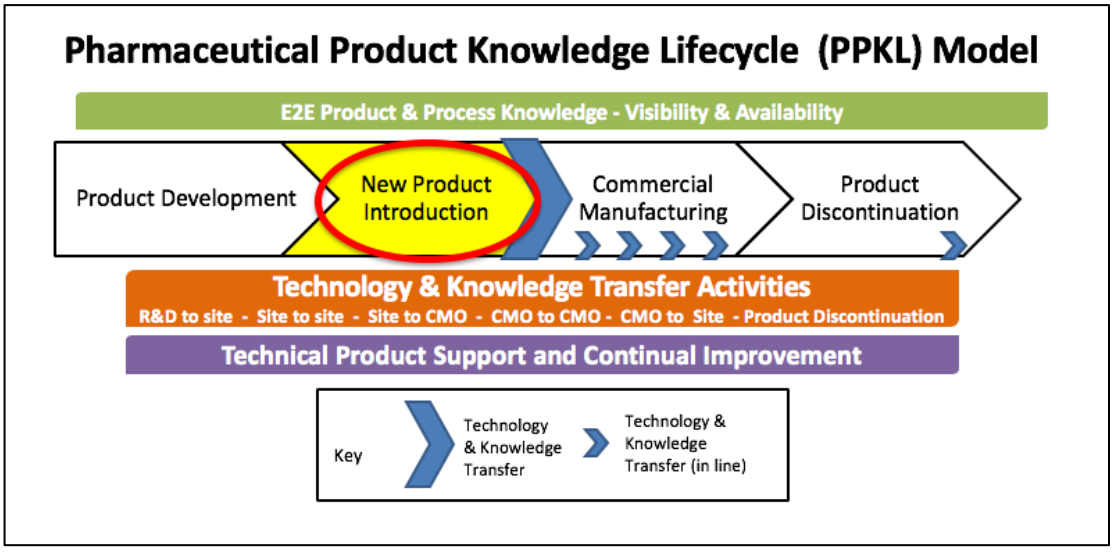

Figure 6-10 Product lifecycle recommendation – Technology Transfer to New Product Introduction – Kane 2018

6.5.2 Reimagining the ICH Q10 Product lifecycle Model - Technical Product Support and Continual Improvement

The next element of the adapted lifecycle model that the researcher would like to draw particular attention is to the introduction within the model of an end-to-end (E2E) workstream entitled, *Technical Product Support and Continual Improvement.*

During the lifecycle of a product, the organization will continue to learn and build knowledge about the respective product. This can occur during *New Product Introduction*, ongoing *Commercial Manufacturing*, through a variety of *Technology Transfer* activities. In addition to this, learnings may arise as a result of planned and unplanned activities such as:

- enterprise resource planning techniques established or updated to plan the shop floor workflow necessary to execute a batch,
- learnings from deviation resolution or product/ customer complaints,
- additional studies for process improvement and optimization.

The researcher suggests an E2E workstream of *Technical Product Support and Continual Improvement* begins at the New Product Introduction phase when the manufacturing process is locked in order to perform technology transfer to the initial receiving site. This support and improvement activity continue across the product lifecycle until the product is discontinued. It should be noted that although the product may no longer be manufactured, expertise and knowledge regarding the product and process may still be needed for activities such as product complaints and to inform next generation product development. The activity of continual improvement and technical product support is represented in Figure 6-11 below.

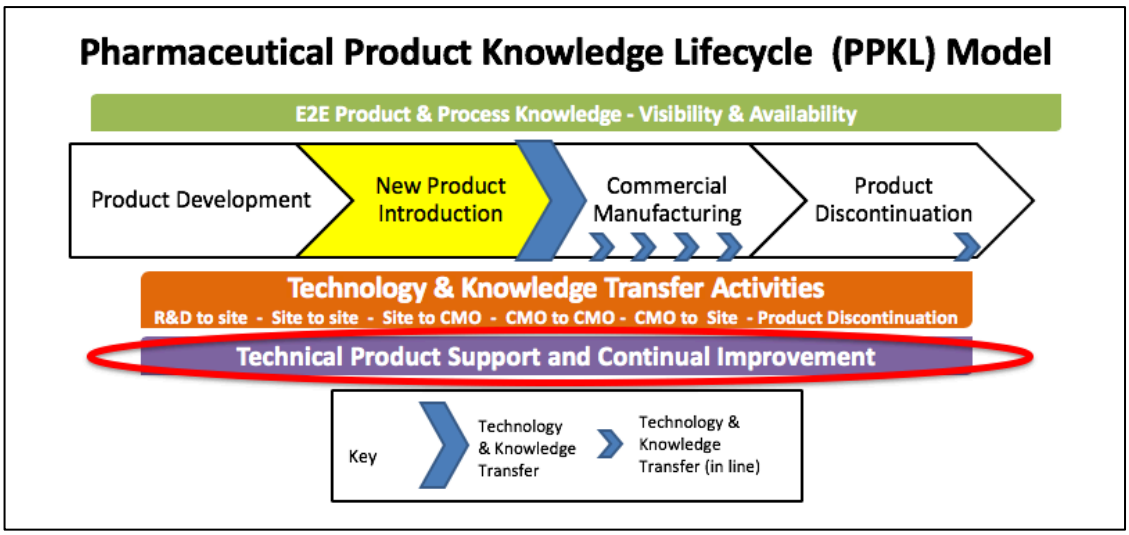

Figure 6-11 Product lifecycle recommendation – Technical Support and Continual Improvement (Kane 2018)

If a formal process is used to capture, collate and curate the critical aspects of product and process knowledge gained from the ongoing process verification activities, such as process trending or SPC activities, CAPAs, annual product quality reviews (APQRs) and change management oversight, the knowledge will most likely reside in an array of different business process systems, IT repositories and even the personal computers belonging to subject matter experts (refer back to Figure 6-6 for other sources). Further contributing to the "knowledge island" or "silos" issue raised during the industry consultation research activities.

This *Technical Product Support and Continual Improvement* element of the adapted lifecycle is purposefully included to provide greater E2E *knowledge transparency* in order to enable enhanced E2E *knowledge flow.*

Without knowledge transparency (or visibility of the knowledge assets), there can be no knowledge flow; without knowledge flow there can be no *use* of that knowledge.

The consequence for the organization of ineffective transparency and visibility of the knowledge assets is an ineffective Pharmaceutical Quality System (PQS). This can result in grave consequences for the patient and the business.

The acknowledgment of the rich product and knowledge generated across the product lifecycle is highlighted in ICH Q8- Q12, however as previously noted, the specific knowledge 'types' are not easy to identify in a concise way. The detailed list provided in the response from the ICH Quality Implementation Working Group in the Q&A document (International Conference on Harmonisation, 2010), as described in section 6.2, is a positive step in assisting organization to recognize and compile their critical lifecycle knowledge assets.

The literature review in Chapter Two noted two specific examples of organizations seeking to make their product knowledge visible across the product lifecycle, not by using a complex information technology solution, but by introducing a standard business processes that catalogues or indexes product knowledge assets as the knowledge is created. Genentech Roche's (Reifsynder, Waters, & Guceli, 2018) product knowledge KM practice is outlined as the *Product History File* (PHF) and Pfizer (Kane & Brennan, 2014) describe a formal business process called the *Process Understanding Plan* or PUP. The PUP is a business process that the researcher was involved in developing, in conjunction with other colleagues, while in her role at Pfizer. One key element of these business processes includes roles and responsibilities for creation and maintenance of the product and process knowledge assets. The researcher suggests that dedicated roles for E2E preservation and curation of product

and process knowledge are not be well defined across the industry (based on industry consultation feedback and the experience of the researcher) and is significant area of opportunity for the sector. To labor the point, when something is considered everyone's responsibility, it is actually no one's responsibility. Returning to the key principle arising from this research that knowledge for the biopharmaceutical sector must be valued and managed in the same way that physical assets are managed in the sector, development of these dedicated KM roles, to enable stewardship of the knowledge assets, is crucial.

Benefits of E2E product knowledge availability and the rationale for implementing KM processes extend beyond the articulation of KM in ICH Q10. As discussed in Chapter Four, improvement of operational effectiveness was one of the top drivers for implementing KM – within and outside of the biopharmaceutical sector (Knoco, 2014, 2017). It should be noted, that the business need for product and process knowledge may extend beyond the lifecycle phase of product discontinuation, as knowledge of the product may have value beyond any regulated record retention requirements to inform learnings of future and existing marketed products.

A future topic of research that this researcher recommends involves the development of a practical KM practice or methodology to deliver greater transparency of product knowledge across the product lifecycle. The researcher conceptually calls this future methodology a *Product Roadmap* that will live with the product across the lifecycle, as a map of existing and necessary knowledge assets, enabling greater transparency and therefore flow to those responsible for the product from development to discontinuation. The researcher will highlight this as a topic of a future research in

Chapter Nine, as the development and implementation of this element is considered to be expansive and worthy of a thesis in its own right.

6.6 The Pharmaceutical Product Knowledge Lifecycle (PPKL) Conclusions

In summary, the researcher has presented a novel *Pharmaceutical Product Knowledge Lifecycle (PPKL) Model* as the second element of the *Pharma KM Blueprint*. The model is offered to encourage those responsible for the development, manufacture and distribution of biopharmaceutical therapies to think differently about the knowledge that is created during the lifecycle of a product. The PPKL Model proposed is an adaptation or reimagination of the ICH Q10 Product Lifecycle published in 2008 and incorporates the following novel features:

- The model highlights the *vision* for end-to-end (E2E) product and process knowledge asset visibility, transparency and availability in order to enable knowledge flow of critical knowledge to those that need it throughout the product lifecycle.
- The model includes the addition of a new lifecycle phase of *New Product Introduction (NPI)* to replace the Technology Transfer lifecycle phase.
- The model highlights that *Technology Transfer* is an *activity* that may occur multiple times across the product lifecycle.
- The model includes the addition of a new E2E process to capture the *Technical Product Support and Continual Improvement* activities that occur across the product lifecycle.

To further develop the *Pharma KM Blueprint*, Chapter Seven will next introduce the *House of Knowledge Excellence (HoKE) Framework*, as a strategic and a programmatic approach to managing knowledge in organizations.

Chapter Seven

Pharma KM Blueprint Part Three: Pharmaceutical Knowledge Excellence Framework – The House of Knowledge Excellence (HoKE)

> *[The] House of Knowledge Excellence Framework depicts the foundations for successful KM by outlining the relationships between knowledge enablers, pillars, practices, and the strategic objectives of the business. The four pillars— people, process, technology, and governance— provide the strength of the framework. Kane and Lipa … assert that the power of this framework lies not only in explaining the function and role of each element of the "house," but in the top-to-bottom integration that clearly links the KM program to the overall business strategy. (Calnan, Lipa, Kane, Menezes, 2018, Introduction, p. xix)*

7 House of Knowledge Excellence (HoKE)

Chapter Five introduced the Pharma KM Blueprint with the principle of the need for the biopharmaceutical sector to manage and value knowledge as a critical asset. Chapter Six illustrated the second element of the *Pharma KM Blueprint*, with the presentation of the Pharmaceutical Product Knowledge Lifecycle (PPKL) Model. Here, the third element of the blueprint is introduced in the form of, the *House of Knowledge Excellence (HoKE) Framework*.

The HoKE framework provides an opportunity to define what we mean by *Knowledge Excellence* and how it exceeds the mere *management* of knowledge. "Knowledge Excellence" is not simply the application of a series of discrete knowledge solutions or

the provision of sets of tools but rather about enabling and sustaining knowledge-focused business capabilities. The essence of the *House of Knowledge Excellence Framework* offers a holistic, programmatic approach to implementing KM founded on the four pillars of *People, Process, Governance* and *Technology*, in order to enable practical approaches to get knowledge to flow. HoKE requires a deep understanding about "how" work gets done on a day-to-day basis and how best to influence the behaviors of the employees or knowledge workers within the organization. Employees must be encouraged and enabled to think and act differently in how they seek and share knowledge.

The researcher proposes that the rationale for pursing capabilities in knowledge management should not be to merely satisfy regulatory expectations, as highlighted in ICH Q10, but to deliver value to the business and ultimately the patient.

The genesis of the *House of Knowledge Excellence (HoKE) Framework* stems from the industry consultation sessions in which biopharmaceutical sector KM practitioners highlighted the need to further define and visualize KM Strategy and KM Program design, as well as to define practical KM approaches. As informed by the literature review, very few biopharmaceutical organizations have implemented a programmatic approach to knowledge management, to date. Where organizations are pursuing KM, it often starts out as a discrete KM project to address a specific knowledge gap or business driver.

The House of Knowledge Excellence (HoKE), is a practical approach that organization may use to assist in either the development of a KM strategy, the roll out of a holistic KM program or in the identification of KM approaches that may benefit biopharmaceutical companies (Kane & Lipa, 2018). The title of the HoKE was specifically chosen to reflect the need to move beyond the compliance expectations of managing knowledge to realize the true business benefits of being excellent in the capture, curation and use of our knowledge.

The framework was developed by the researcher, in conjunction with one other colleague M.J. Lipa, and published in 2017 as a book chapter entitled, *The House of Knowledge Excellence – A Framework for Success* (Kane & Lipa, 2018). The published work is presented herein in full, as the researcher believes that summarizing would do the HoKE framework an injustice. [Please note the footer page numbering reflects the contiguous thesis page numbers.] The 13 case studies analyzed via the HoKE framework are listed in Tables 4-8 and 4-9 on pages 94 and 95 of this thesis.

It is important in this point to acknowledge the contribution of my colleague M.J. Lipa to development of the HoKE Framework. The main development of the HoKE framework was based on experience and work of the researcher. The model was validated by Lipa, as an experienced KM practitioner himself. The model was enriched by the addition of KM practice of taxonomy and additional enhancements to the lessons learned KM practice. Lipa also helped bring the HoKE visuals to life.

The following pages comprise of the published book chapter.

12

The House of Knowledge Excellence—A Framework for Success

Paige E. Kane and Martin J. Lipa

CONTENTS

In this chapter, the authors present a new model, *The House of Knowledge Excellence*, as a comprehensive framework for KM programs, which is based on benchmarking and experience of the biopharmaceutical industry and beyond. This model can be used to educate and build awareness of the benefits of a holistic approach, and also leveraged as a gap analysis tool for current KM programs to enable them to deliver additional value.

Editorial Team

Introduction

The case studies shared in Section IV attest to the great progress being made with knowledge management initiatives that are underway throughout several organizations, the most common pitfall for many KM programs (across multiple industries) remains the failure to consistently deliver on their intended outcomes. In the author's opinion, this comes about as a result of a lack of fundamental understanding about what organizations are really trying to accomplish with a knowledge management program.

Often, KM programs seek to deliver the outcomes of improved collaboration, or vibrant communities of practice, or the establishment of integrated knowledge repositories, or related goals. Although these aspirations may be valid *leading* indicators of KM success, we question are these really the meaningful outcomes that will garner sustained senior management support and ongoing investment?

Organizations are often tempted to pursue the *silver bullet* promised by software vendors (e.g., the next generation software tool that will solve all of the collaboration and connectivity problems faced by civilization) as their route to success. Although acknowledging these tools may well prove indispensable when utilized in the right context; deploying a collaboration, community, or connectivity tool risks being disconnected from what is most important to the business.

Even *ICH Q10 Pharmaceutical Quality System* (ICH Harmonised Tripartite Guideline 2008), which insightfully positioned KM front and center as a key enabler across the entire product lifecycle, has challenges from industry members and claim it is too vague or high level to establish any meaningful, sustainable focus for KM.

This lack of focus was highlighted in Knoco's 2014 Global Survey of Knowledge Management (Knoco 2014), which uncovered a huge diversity in organizational reporting lines for KM programs, is a marker that industry—including the biopharmaceutical industry—has not yet normalized on the

delivery of KM and how value is derived. As discussed in the survey, the KM solid line was reported most frequently as being in to one of HR, operations, IT, strategy, learning and development, R&D, projects, or business improvement. However, the research shows more than 30 different areas of the business were cited as being responsible for KM programs, including a large percentage of KM programs that report directly to the senior management team. The authors do not suggest there is a single *right* answer, but this diversity is a clear signal there is some normalizing yet to occur on the *what* and the *how* of KM, and further it is the author's opinion that the *principal pitfall for KM lies in not inherently linking it to the Business Strategy.*

Without an effective KM program, organizations risk not achieving the objectives established by their overall business strategy, which is of course uppermost in the minds of most senior executives. Indeed, establishing that KM plays an active role in accelerating products to market, improving stability of supply, helping to identify risks to product quality, or reducing the threat of recalls—emphasizes to senior management the true potential for KM. Unveiling this line of sight to the business strategy is even more critical in the current environment of the biopharmaceutical industry as it continues to transform due to a variety of trends and drivers.

A *second common pitfall is from implementing that KM is not understanding how to establish successful, sustainable knowledge management solutions*.

Like the old parable about the blind men and an elephant (Sato 1927), each believing they know what it is they have discovered, some involved in KM solution roll out claim too quickly and too easily that a KM program or solution has been achieved without stepping back to understand the big picture and all associated interconnections.

It is crucial to understand this big picture, and create the right foundation on which to establish KM success. A holistic and comprehensive approach includes focus on people and process, in addition to technology and governance. Many have attempted KM, suggesting "if we build it [KM], they will come." However, experience across multiple industry sectors has clearly illustrated this is not the case.

A 2014 study by APQC (2014) on managing content and knowledge explored the link between content management and knowledge management. Content management (CM) is a close cousin of KM is sometimes even treated as a KM solution yet more often than not it is implemented as an IT solution without a larger understanding of KM principles and practices. The APQC study found that organizations who have incorporated content management as part of a formal KM strategy are *seven times more likely to report their overall content management is effective* than when content management is deployed on its own. This is just one example of how an effective KM strategy helps establish a solid foundation for business processes.

The purpose of this chapter is to present a new framework that describes how these key KM foundational elements of *practices, pillars and enablers* and overall *business strategy* relate to each other.

A Framework for Knowledge Excellence

Research has proven that knowledge management programs that are focused on delivering targeted business results or *outcomes* are more likely to be both successful and sustainable (Prusak 1999; Chua and Lam 2005). It is critically important to select KM outcomes that will help the organization deliver on its strategic objectives as these are more likely to sustain the business investment in the KM program, elicit sponsor commitment, and enhance employee engagement. Aligning the KM program with the strategic business objectives increases the chances that the KM initiative will withstand the inevitable transitions in leadership, portfolio prioritizations, and other unforeseen challenges likely to present over time. Thus, conveying the best possible chance that the KM program will remain relevant, and continue to build on successes for the long haul.

It is imperative to think about knowledge management not simply as a *solution*, or as a *tool*—these both have narrow, restrictive connotations—but rather as a knowledge-focused business *capability*. A capability is defined as *the ability to do something* and in this case that *something* is to manage knowledge. In this chapter, we will henceforth refer to these *knowledge-focused business capabilities* as KM *practices*, which encompass the holistic application of the concepts to be presented in the upcoming framework.

Before the framework is introduced one final key concept must be addressed. KM is generally understood to encompass caring for, curating, directing, and making decisions about organizational knowledge assets. More importantly, KM is about enabling *knowledge to flow* in order to achieve the desired business outcomes (higher quality, more stable supply, faster problem solving, increased employee engagement, etc.), which in turn, will help the business achieve its long-term strategic objectives.

Figure 12.1 introduces the *House of Knowledge Excellence*, which provides a framework to clearly link the KM program to the business strategy. By maintaining a clear line of sight from the business strategy to the supporting KM objectives, a thoughtful and relevant KM strategy and supporting KM program can be established. This alignment is critical to the KM program providing value in the eyes of senior leadership and other stakeholders within and outside the company.

The following sections will help to illustrate how the individual elements of the *house* relate to each other and will provide more insight and examples for each element.

Challenges Shaping the Face of KM in the Biopharmaceutical Industry

When considering KM, in particular as a key enabler in delivering an ICH Q10-based Pharmaceutical Quality System, there are several questions that arise regarding the impact of recent external trends and drivers (Figure 12.2):

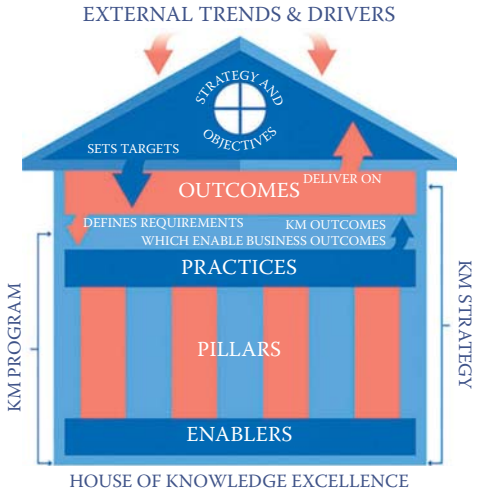

FIGURE 12.1
House of Knowledge Excellence.

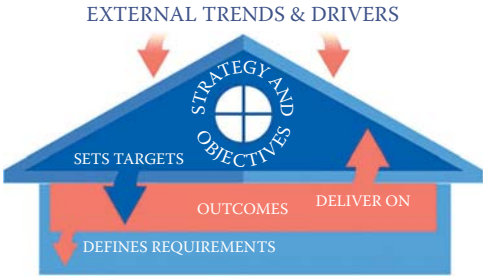

FIGURE 12.2
Understanding the impact of external trends and drivers.

- What are the opportunities for KM to have a meaningful impact in the biopharmaceutical industry?
- How can KM help biopharmaceutical companies deliver medicines and other therapies to patients more rapidly?
- How could an effective KM program support operational efficiencies for the company, improve employee engagement, and help address many of the other challenges that face the industry?

As discussed elsewhere in this book, in an environment of mergers and acquisitions, increasing regulatory expectations and baby boomers retiring (to name but a few), taking a fresh KM perspective of these challenges may be helpful.

Table 12.1 lists a subset of common challenges, trends, and drivers facing the industry today, coupled with elements of business strategies (and

TABLE 12.1

Challenges, Trends, and Drivers Facing the Biopharmaceutical Industry

(a) Challenge, Trend, or Driver	(b) Strategy or Objective to Address	(c) Illustrative Barriers/ Challenges to Knowledge Flow
Regulatory Driver(s)		
Regulatory expectation that knowledge is applied to improve patient outcome (e.g., ICH Q10)	More efficient postapproval changes product innovations	Difficult to surface prior knowledge from legacy products Difficult to understand rationale from past changes SMEs have left the company—losing knowledge of legacy products Design space not adequately defined
Regulatory expectation for improved understanding of risk	Improved risk assessment process and outcomes (standard process, routine frequency, etc.)	Difficult to understand rationale and decisions from prior assessments Lack of uniform assessment of risk across products, time, etc.
Business Environment Driver(s)		
Global competitiveness (pricing pressures, generic competition)	Operational Excellence (process capability, cost savings, etc.)	Inability to find historical knowledge to support process improvements Knowledge not flowing with the product throughout the lifecycle Past knowledge not easy to find/not findable Not knowing who the experts are Silo learning within groups, facilities, regions, etc.
Increased therapeutic area competition	Shorten time to market/ accelerate development timelines	Culture of not sharing Lack of processes to share Limited leverage/use of knowledge from prior products, modalities, etc. Inability to find knowledge efficiently to support development

(*Continued*)

TABLE 12.1 (*Continued*)

Challenges, Trends, and Drivers Facing the Biopharmaceutical Industry

(a) Challenge, Trend, or Driver	(b) Strategy or Objective to Address	(c) Illustrative Barriers/ Challenges to Knowledge Flow
Mergers and acquisitions	Increase technical capabilities, optimizing portfolio	Challenge to integrate new teams and capabilities Potential reduction in force Employees hording knowledge Often results in moving products from site-to-site—need for tacit knowledge that can be scarce (labor intensive and expensive) KM considerations not included up front—SMEs leave the company, knowledge transfer not planned proactively
Pressures to innovate to sustain growth	Operational Excellence (process capability, cost savings, etc.)	Inability to find historical knowledge for process improvements Past knowledge not easy to find/not findable Silo learning within groups, facilities, regions, etc.
Shift to outsourcing in multiple stages of the product lifecycle (e.g., clinical studies, product collaborations, contract manufacturing, and supply)	Leveraging external collaborations and third parties for competitive advantage	Contracts focus on regulatory needs not necessarily knowledge needs Culture of collaborators (third party or pharma organization) may not be conducive to sharing knowledge Concerns regarding intellectual property—reduction in learning Collaboration technology limitations
Emerging markets	Effectively and efficiently supplying products to emerging markets while satisfying evolving requirements in those markets	Location not conducive to collaboration Lack of resources Lack of internal capabilities in the markets Need to provide market specific products/packaging and labeling introduces great complexity to managing product knowledge

(*Continued*)

TABLE 12.1 (*Continued*)

Challenges, Trends, and Drivers Facing the Biopharmaceutical Industry

(a) Challenge, Trend, or Driver	(b) Strategy or Objective to Address	(c) Illustrative Barriers/ Challenges to Knowledge Flow
People/Talent Driver(s)		
Baby Boomer retirement	Business continuity	Retirees not replaced when they leave Lack of time/business process to transfer knowledge to colleagues prior to leaving Replacement is not in place/ knowledge transfer cannot happen Retirees not willing to share knowledge
Evolving workforce, (Millennials entering the workforce)	Innovation, attracting new and diverse talent	Technology platforms do not meet the expectations of the new workforce Different styles of working (discussion with peers vs. research alone, where content is stored, etc.) Notion that millennial will work at multiple employers over their career—more turnover and potential knowledge loss than in previous generations
Virtual/remote workers	Reduction of facility footprint	Reduction in people-to-people interaction—the *water cooler* and *coffee station* do not exist Risk of colleagues not developing an internal network—less connectedness and awareness of other peers in the organization

associated business objectives) that are typically invoked to address these challenges, with the potential barriers to knowledge flow identified that put that strategy or objectives at risk.

When examining challenges, trends, and drivers within the industry, it is important to emphasize there is no *one-size-fits-all* KM approach is available to address them. However, when challenges are described in terms of knowledge flow barriers, common themes begin to emerge. *Understanding*

these knowledge flow barriers is the first step in defining which KM practices will be required to achieve success.

Furthermore, it is not just the KM practices themselves that will help to address the business drivers. In practice, a key factor lies in influencing *how* the work gets done. Successfully embedding KM practices within an organization to ensure knowledge flow requires changes in the behavior of the people doing the *day job*. This is especially the case in large, well-established organizations that can be slower to adopt newer, more agile ways of working in response to changes in technology and the incoming workforce.

In another recent study conducted by Knoco (2014) the top reason cited for *not doing KM* was that the culture was not yet ready for KM. For KM to truly succeed, employees must think and act differently in how they seek and share knowledge, and recognize the value and importance of knowledge *flow* rather than knowledge *hoarding*.

To address this *People* challenge, KM teams may opt to build skills and capabilities by leveraging tools from well-established change management methodologies. These methods can help to target the desired behaviors for knowledge seeking and sharing while identifying and addressing any risks to the successful realization of the KM program. Standardized processes and practices should be developed that embed knowledge seeking and sharing capabilities in the flow of the day-to-day work. These processes and practices should actively encourage employees to ask for help when solving a problem instead of using excessive time and resources to solve it through heroics.

It is also important to understand that as the millennial generation ascends to make up the majority of the workforce following the retirement of the *baby boomers*, work styles, norms, and company culture will begin to reflect this new generation of workers. Inevitably, the mechanisms and behaviors for sharing knowledge will also change and it is therefore imperative for the company to acknowledge and address this in their KM strategy if it is to succeed.

A good example of this change is evidenced in a recent internal focus group undertaken by Merck. The focus group discovered that millennials have a preference for *self-service* or the use of a trusted network for finding information. When asked how they gather information to solve a problem outside of work, their response typically was *Google and YouTube*, somewhat tellingly followed by *asking mom and dad*. This begs the question, is the biopharmaceutical industry ready for the expectations of this *new way of working*, or will companies quickly feel archaic for their bright new hires and become less attractive places to work?

An additional challenge worthy of note is the perception that the biopharmaceutical industry is somehow unique. Acknowledging that this largely appears to be an internal industry perception associated with concerns of protection of intellectual property and patents, the *first-to-market* race, the value of investment in new and novel drug development, and the extraordinary long regulatory approval timelines. However, this perception seems to overlook other industries (e.g., aerospace, nuclear, oil and gas, aviation) that face similar business and

regulatory challenges as the biopharmaceutical sector that have successfully leveraged their knowledge to bring additional value to their business.

Learnings from publications, and knowledge networks such as APQC, indicate that strong leadership support is required to embrace and embed knowledge management within their organization and proactively build a culture that enables knowledge sharing. This will be discussed further later in this chapter.

MYTH BUSTING KM IN THE BIOPHARMACEUTICAL INDUSTRY (PHARMA)

MYTH: *As Pharma is regulated it makes KM more complicated than for other industries.*

FACT: Many other industries and organizations are highly regulated. It should be noted that all U.S. government agencies are highly regulated by multiple internal agencies. Many other industries also face regulatory oversight but have been successful in KM, including those in aerospace (FAA regulations).

MYTH: *As Pharma is a regulated environment and we already spend a lot of time maintaining our records so KM is not needed.*

FACT: Identifying and managing regulated records is only one component of a KM program and strategy. NASA (www.NASA.gov, similar to Pharma, has long product lifecycles—their missions may last 60 years or more. Business drivers such as an aging workforce, employees need for resources, and long product lifecycles can be addressed with a systematic approach to KM (Hoffman 2014).

MYTH: *KM in Pharma is about managing "regulated content."*

FACT: Regulated content is important, however process improvements, exploratory studies in the commercial manufacturing space as well as the transfer of technical and business processes are key in building new talent, transferring knowledge when employees leave, etc.

MYTH: *KM is new in Pharma.*

FACT: KM has been going on in Pharma for years, formally in small pockets of the industry but mostly on an informal basis. A formal approach requires a more holistic understanding of the knowledge flow challenges and ability and willingness to learn from others, whereas an informal approach can greatly reduce effectiveness.

MYTH: KM in Pharma requires unique solutions.

FACT: APQC has found that many industries share the same knowledge flow issues (see Chapter 4). Leveraging solutions such as expertise location, knowledge mapping, and after-action reviews can be applied regardless of industry.

Knowledge Management Strategy

If you don't know where you are going, any road will get you there

Louis Richardson,

KM World 2015.

How can you hope to deliver a meaningful, impactful KM program without a plan that defines what you are trying to accomplish? (Figure 12.3).

A *strategy* is defined as "a careful plan or method for achieving a particular goal usually over a long period of time" (Anon 2016). In the author's opinion, a strategy should also guide an organization to explore the potential risks that may threaten the realization of the proposed plan. This subject of strategy raises more questions to consider:

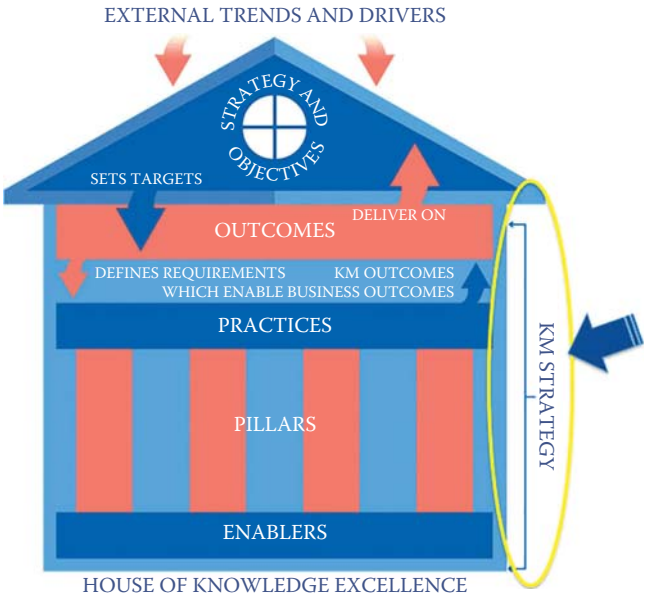

FIGURE 12.3
Examining the Knowledge Management strategy.

- Do you have a strategy for codifying and socializing the objectives for your KM program?
- Have you have defined what success looks like for your KM program, and how you will get there?
- Does your strategy *vertically integrate* the elements in the *House of Knowledge Excellence*, by establishing the key business outcomes KM will seek to enable, which KM practices will be required, and which associated foundational elements are currently in place?

Indeed, one could say that there are no knowledge management *projects*, per se. Rather, KM projects are really *business* projects that aim to address a business problem by *improving knowledge flow* (or inversely, by *eliminating waste associated with barriers to knowledge flow*) so that the business can achieve a desired outcome.

Therefore, a good KM strategy should begin with a clear understanding of the overarching business strategy it is supporting and which objectives will drive the achievement of the desired outcomes. The KM strategy should then work to achieve or enhance these outcomes. It is important to describe the benefits of the KM program *in the same language that senior leadership describes other business outcomes*.

A case in point—while it is highly unlikely that your overall business strategy has an outcome of *increased collaboration*, this remains a commonly referenced goal for many KM programs. Although enhancing employee collaboration may be a good installation (or *leading*) measure of progress, it is a step short of describing how KM can help achieve the broader business strategy. In other words, *the goal of the KM strategy should be to enable the business outcomes,* for example, shorter product development cycles, which is a realization (or *lagging*) measure, and increased collaboration is a lever to achieve this.

There are many ways to develop a strategy, but the most important feature is to *have* a strategy. One technique is to use a *Design for Six Sigma* methodology, which starts by understanding the customer needs. In the case of building a holistic KM program, this means understanding the internal customer or business needs and how the elements of KM strategy link to the desired outcomes (Lipa et al. 2014).

Other important attributes of your KM strategy should:

- Capture the current state of how knowledge is managed.
- Discuss why a change in the way the organization manages knowledge is necessary.
- Define the desired future state of KM for your organization.
- Set the direction to get there, including where the strategy will initially be targeted (e.g., pilot opportunities).
- Establish meaningful, reportable metrics or measures of progress toward realization.

- Define the known risks (and mitigation options).
- Define the guiding principles for KM at the organization.
- Align and concentrate resources for KM roll-out and support.
- Explore interdependencies with other work, groups, initiatives, etc.
- Define what you will not do (e.g., areas that are not a priority).

A note of caution when creating your strategy; avoid it being a set of glossy slides that sit in a binder on the shelf. Instead, focus on creating a strategy that you can use as a contract with those members of senior management sponsoring the effort and also to provide a tangible, practical guide for strategy execution.

To support the creation of a KM strategy, multiple KM maturity models exist that can be used to evaluate the current state of KM at your organization in a semiquantitative manner. For example, the APQC KM Capability Assessment Tool (APQC 2010) assesses KM maturity in terms of *Strategy*, *People*, *Process*, and *Technology*. By performing such an assessment, one can understand the current level of KM capability and identify what is required to achieve higher levels of KM maturity. This type of assessment will also highlight where peer benchmarking may add value. These steps can inform the focus of your strategy and identify the steps necessary to achieve it. By performing a maturity assessment on a periodic basis (e.g., annually), one can also measure progress toward realization of the strategy in an objective manner.

Knowledge Management Practices

When considering what it is that a KM program and the people that support it actually *deliver* to the broader business, it is helpful to think about the KM program as providing the *capability to enable knowledge flow*. This capability is enabled through one or more KM *practices* (sometimes referred to as *approaches*, *solutions*, *tools*, and *methodologies*) and includes the products and services provided by KM practitioners within the organization (Figure 12.4).

As an analogy, think about a Swiss Army Knife (O'Dell 2015). A Swiss Army Knife is a multipurpose pocket knife of individual tools, which when coupled with the right need and right enablers, give the user the *capability* to do something they could not easily do without the tool. For example, to cut a rope, open a bottle, or tighten a screw.

One can think about KM practices in a similar way. The right KM practice applied in the right manner at the right time *can enable the capability of the organization to do something they could not easily do otherwise*. The practice itself will typically promote knowledge flow, such as improved connectivity, access to experts, and sharing of lessons. This in turn, will enable specific business objectives such as speed to product launch, solving problems faster, and increased employee engagement. The premise being without, for example, a systematic *Lessons Learned* KM practice, the knowledge from a past

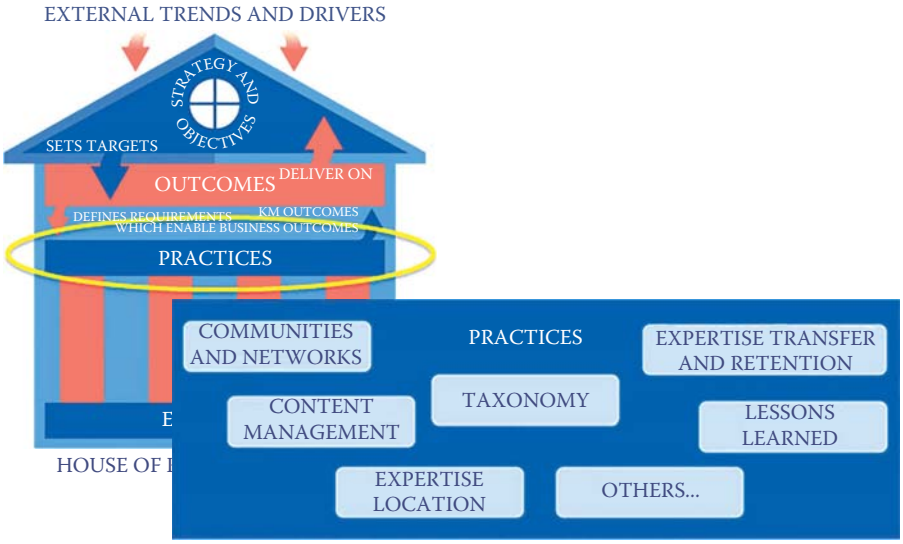

FIGURE 12.4
Common KM practices.

project might not have been shared, and the current product launch could take longer (or experience some other indication of decreased effectiveness).

Critical to the success of any KM program is that the right KM practices are selected. As per the theme already established in this chapter, this requires a clear understanding of the knowledge flow problems one is trying to solve. There are a variety of techniques to do this, from simple VOC (voice of the customer) and anecdotal stories from colleagues of past issues, to more structured and robust (and arguably more accurate) means such as *knowledge mapping*. It is important to understand the need to select the right practice to solve a given problem as opposed to just deploying a practice because *it is a good idea* or available.

The good news is the number of KM practices has grown substantially because KM emerged as a mainstream concept in the 1990s. There is now a rich array of KM practices to tackle the many knowledge flow problems. Several commonly used KM practices to improve knowledge flow include the following:

- Communities and networks
- Content management
- Taxonomies
- Lessons learned
- Expertise location

- Expertise transfer and retention
- Other practices, including transfer of best practices

In reality, these may be better described as groupings, or families of KM capabilities as there are many variants within each practice listed above and each addresses a different type of knowledge flow problem. More detail is provided below on these common KM practices.

However it is worth noting that currently, there are no clear trends or standard configurations across KM programs and essentially no two KM programs look exactly alike. This is demonstrated by the variety of case studies and other published KM literature that outline the different drivers prompting KM deployment, the influence of different functions *owning* KM, the impact of the culture of the organization, and indeed the size, spread, and complexity of the organization.

APQC has established a model to relate many of these KM practices titled, *Blended KM Approaches for Enabling Knowledge Flow* (see Figure 12.5), based on the following two criteria:

1. The level of explicit versus tacit knowledge being transferred
2. The degree of human interaction required

This is a useful reference model that organizes practices by these criteria and establishes a continuum for practices from the most basic self-service options (explicit knowledge requiring little human interaction) to the

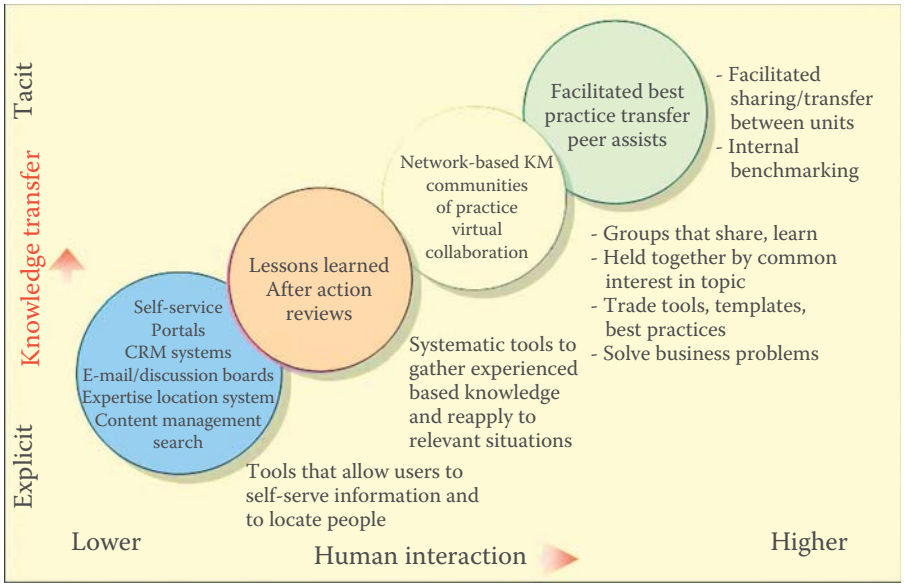

FIGURE 12.5
KM tools and processes. (Reference: APQC 2008).

most involved instances (high tacit knowledge requiring a high degree of human interaction to flow).

There follows a more detailed description of each of the common KM capability presented above, including a description and relevant considerations for each.

Communities and Networks

KM Practice	Communities and Networks
Description	Communities and networks (henceforth *communities*) are collections of people who share some level of interest and/or expertise on topic. A Community of Practice (CoP) is the most common type of community and can be defined as *Groups of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly* (Wenger and Trayner-Wenger 2015). Communities may take many different forms (in-person, virtual, mobile, …) and may exist for a variety of purposes, including best practice sharing, knowledge sharing, problem solving, and others. Communities are helpful to enable tacit knowledge flow, as the interaction between members is typically dynamic and context-sensitive. Communities may also be used to help codify tacit knowledge into explicit knowledge (e.g., capture of best practices) as well as to aggregate explicit knowledge around a topic via hosting a home page or work space, whether public or private. Communities can greatly vary in size and the types of interactions they have as being in person or virtual.
Considerations	Although communities have proven to be one of the most powerful practices to connect people and access the tacit knowledge that exists in the heads of people in the organization, the success rate for communities is relatively low. Proven practices for setting up a community for success include ensuring a value proposition for the individuals in the community as well as for the organization, having a community leader and/or steward, understanding that different communities exist for different reasons, and recognizing the motivations and participation of the individuals that make up the community. Communities may be informal or more formal. Informal communities tend to rely on the energy of a motivated few. Although more formal communities also rely on this energy to get started, the enabling structure (e.g., link to business outcomes) will help sustain them over time, especially as CoP leaders change.

Content Management

KM Practice	Content Management
Description	Content management is traditionally an IT-focused capability—a close cousin of document management—and generally describes the administration of digital content through its lifecycle, from creation through consumption, including editing, access administration, and publication. Additional features may include workflows, version tracking, coauthoring, and more.

(*Continued*)

KM Practice	Content Management
	Content management is a starting point for many KM programs, as the most visible, tangible issue many companies face is *not knowing* what content they have or where it all is. In the biopharmaceutical industry, *pain points* that illustrate this may include: the ability to quickly and confidently locate all relevant content for a technology transfer, research a problem. Given the long timeline and distributed resources often associated with product discovery and development locating content can often be challenging. Yet *SharePoint sprawl* has caused a proliferation of team collaboration sites, where in larger companies, on average, more than 100 new sites are created per month, typically with very little governance or stewardship associated, often with no standards behind them. This makes it exceptionally difficult for users to know how to store and more importantly, how to find content (Greenfield 2009).
Considerations	The success and relevance of content management can be greatly enhanced with application of the KM principles, pillars, and enablers, which is how content management becomes viewed as a KM capability. In addition to a holistic approach, creating an intuitive, user-centric taxonomy is a key success factor in people being able to find what they want, when and how they want to. Taxonomy also greatly enhances the effectiveness of searching the underlying content. There are many mature content management technology solutions in the marketplace, although be aware these typically focus only on the pillar of technology and perhaps some focus on process. A recent APQC study suggests that KM provides support and structure for content management, and that organizations that have content management as part of a formal KM strategy are seven times more likely to report their overall content management is effective (APQC 2014).

Taxonomy

KM Practice	Taxonomy
Description	*Taxonomy* is simply a way to group things together, typically by various characteristics associated with each entity. Taxonomies are often associated with IT systems, such as with content management and search but have much broader application. Taxonomies can enable standardization across areas of an organization, where different groups may use different terms to describe similar things. For example, it is likely that your organization has many virtual collaboration spaces across many different teams. But are they consistent and standardized in terms of what is stored there, how the folder structure is defined, and what the file names are? The answer is likely *no*, and this is normal. In reality, people are describing the content, for example, through the folder path and file name. However they are likely doing this at an individual or at best team or department level. Their view is limited to the work they do and how they describe it. Taxonomy can bring standardization and consistency across individuals, teams, functions, and even organizations, through defining a structure and common set of terminology to describe all relevant content.

(*Continued*)

KM Practice	Taxonomy
	Having a common taxonomy is a powerful enabler to search engines. Search engines help surface content, often unstructured, however, the content may still be lacking context. And when you search, you never know *what you do not find*. Taxonomies bring structure and this content can be very reliability surfaced through a search and be weighted with higher relevance. See Chapter 27 for more detail on key taxonomy terms and concepts.
Considerations	The business case for taxonomy may be more elusive than other KM practices but the anecdotal evidence is often a powerful motivator. Taxonomies must be designed with adequate input from the user base as they are—after all—to benefit the users and if they are not intuitive, they will not be as effective. Taxonomy must also adapt with changing needs of the business and evolution on how the content is viewed, so governance and a change control process are key considerations.

Lessons Learned

KM Practice	Lessons Learned
Description	Lessons learned refers to a collection of practices, including *lessons learned*, *after action review*, *postmortem*, and others that are typically associated with a reactive analysis or critique of a task or event. This analysis is intended to surface and describe the key *lessons* by the person or team involved in the task or event. The concept of lessons learned is often associated with things that did not go well, for example, *not repeating the same mistake over and over*, but is intended to capture all learning and insights, both *bad* (what did not go well to avoid doing again) as well as *good* (what went well to leverage in the future). Lessons learned is a key concept associated with learning organizations, which are able to be adaptive, and continually improve their work.
Considerations	The concept of lessons learned has been around for some time and is commonly practiced with varying levels of effectiveness in project management, most often after completion of a large and/or complex project. A common challenge associated with lessons learned include when to do them. For example, a *lessons learned* session after a three year capital project may not be ideal as early lessons may have faded from memory, and there will be a significant lag to extracting lessons to apply elsewhere. Embedding lessons learned into stage gates or other more routine checkpoints is a good practice to address this. It is often a challenge to ensure the lesson is *actually learned* by implementing the insight into work processes and practices, such that future work can benefit. It is great that the lesson may be identified, but the real value is ensuring it impacts future work through driving improvements to how work is done. Another consideration is the transparency with which lessons are surfaced, in particular *negative* lessons. It is common with the stress and pressure in the business environment to judge on what went wrong and to assign blame. These are barriers to effective lesson sharing. A *safe to speak up* culture must be nurtured to gain rich insights to how work is actually done and drive improvements.

Expertise Location

KM Practice	Expertise Location
Description	Expertise location is a general term that refers to a process or system to find a specific person with a specific skill or capability or a specific combination of skills and capabilities. Technology systems are typically referred to in a general sense as *ELS* or expertise location systems. Social tools (e.g., internal tools like Yammer or discussion boards) can also be used to locate experts to help, however, ELS have specific traits as described by an industry benchmarking study (APQC 2008) are • Formal • Brokered • Centrally managed • Expertise areas predefined In addition, some companies predefine *experts*, whereas others aggregate information from various sources and let the *seeker* determine if the person identified has the skills and experience to help. When experts are predefined, care must be taken to ensure there is a rigor in the selection process, whether it is testing or managerial decision point. When information is aggregated, it could be from the Human Resources database, training information, documents developed, self-declared skills and capabilities, or a combination thereof.
Considerations	Expertise location can be a very powerful KM practice; however, there should be a methodology to ensure that skills and capabilities are still relevant if the organization changes or employees have job changes. Regarding relevance: Skills—are they really specific to your company or is it a *Biopharmaceutical* skill? Organization names—with internal reorganizations, this could be a potential invalidating link, or causing a high amount of system mitigation. It is recommended to consider designing such systems in relation to the *work streams* within the organization rather than the organizational construct. Considerations should also be given to the change management activities associated with leveraging expertise location, as these types of systems only work if they expertise is maintained (update to date, high quality, relevant, etc.) and people leverage the process or system to seek out expertise.

Expertise transfer and retention

KM Practice	Expertise Transfer and Retention
Description	Expertise transfer and retention refers to a broad collection of practices that involve transferring tacit knowledge from one person to another. Perhaps the simplest example is on-boarding, whether an employee new to a company or new to a job functions. Arguably the most effective on-boarding occurs when the person leaving the position is involved so they can *show them the ropes* and explain how things really get done (tacit knowledge—hence the need to explain). On-boarding is typically not regarded as a KM activity but looking at on-boarding through a KM lens has the opportunity to greatly improve its effectiveness.

(*Continued*)

KM Practice	Expertise Transfer and Retention
	Other practices exist, such as knowledge retention interviews that seek to determine business critical areas of expertise by a certain individual and subsequently focus interviews on these topics. These interviews are often conducted per standard work to assess risk, determine topics, and capture results, and often by trained interviewers.
Considerations	This grouping covers a wide variety of practices. In business, expertise transfer is going on every single day when people interact and the vast majority of this transfer happens through the course of work. However, it is common for major issues to arise when the normal course of work does not ensure continuity of insights and expertise—for example, when a highly tenured expert leaves the company. These events may cause disruptions to business and as such require special attention—enter knowledge management. These practices vary greatly in effort and need to be tailored to the needs of the business. A very common type of expertise transfer in biopharmaceutical is a *technology transfer*. There is no specific practice associated with this per se, yet an established KM program will greatly support the success of doing technology transfers (e.g., existence of taxonomy for product knowledge).

Other KM practices

KM Practice	Other
Description	As presented previously, there are many different KM practices and variants of each to address many types of knowledge flow problems. Many other practices exist to solve niche issues or emerge as technology evolves. Examples of other often cited practices not explored here include, transfer of best practices, peer assists, before action reviews, knowledge mapping (see Chapter 26), and other practices in use and development across multiple industries.

How to Learn More

It was not the author's intent to fully define the KM practices listed above and there is no definitive answer for what might be considered a *best practice*. These and other practices are well documented in other KM sources not specific to the biopharmaceutical industry, often in the form of case studies. The case studies that follow in this book will highlight the use of many of these practices, so the reader may gain insight into the context in which they are applied. In addition, Section 4 contains a matrix to highlight which *practices* are evidenced in the respective case studies. Other selected sources of best practices and case studies on KM that the

authors have found useful include *APQC*, *Knoco*, and *Straits Knowledge*, among others. In addition, several entities recognize leading KM practices through awards and industry recognition, including *KM World* and the *MAKE* (Most Admired Knowledge Enterprise) awards and worth a review for any prospective KM practitioner.

Pillars

Often overlooked in the design of KM practices is a comprehensive supporting framework. A sound framework is critical to ensure that the practices move beyond a selection of optional tools or well-intentioned *good ideas*. Many experienced knowledge management practitioners have learned of the trilogy of knowledge management as *people, process,* and *technology.* Collison and Parcell included in their book *Learning to Fly* (Collison and Parcell 2004), that a successful KM program must have the right balance of these three elements. More recently, some knowledge management thought leaders have also included *governance*, as a key component of a successful KM program. Nick Milton, a prolific KM author, devotes considerable time and effort writing about the importance of governance. Based on the authors experiential learning in building KM programs, and witnessing both challenges and successes, governance had been selected as the fourth pillar supporting the *House of Knowledge Excellence* given its importance to successful realization and sustainability.

The pillars, as depicted in the *House of Knowledge Excellence* shown in Figure 12.6, are key structural aspects within the framework; it should be recognized that applying KM practices alone would not guarantee a successful outcome. In fact, in a review of KM project failures two of the four main observations noted in *Why KM Projects Fail* (Chua and Lam 2005), relate directly to the pillars of *People* and *Technology*. The remaining two observations are closely related to the other pillars of *Process* and *Governance,* and therefore help to validate their criticality. The top four observations for KM project failures include the following:

1. Cultural factors are multilevel (related to people)
2. Technology issues are nontrivial (related to technology)
3. No content, No KM (related to process)
4. A KM project is nothing short of a project (related to governance)

The sections below will further discuss the four pillars and address how they provide a framework for the *House of Knowledge Excellence* (See Figure 12.6).

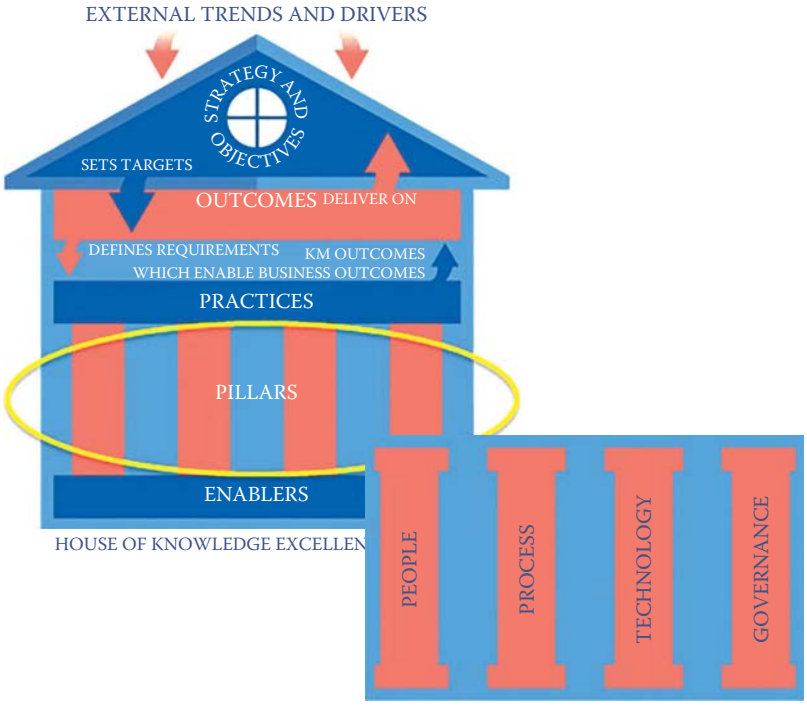

FIGURE 12.6
Pillars supporting successful KM.

People

People are at the center of knowledge creation and knowledge sharing. For each KM practice under development considerations should be given as to how people will engage and benefit from its implementation. When exploring the pillar of *People*, there are two primary components:

1. *People and culture* in regards to the creation, use, and value of knowledge and as leadership's role in developing and supporting a knowledge sharing culture.
2. *Dedicated KM roles* to design, deliver, and sustain a KM program (e.g., people that are needed to build and design the knowledge flow frameworks). Specific roles will be discussed further in this chapter.

People are at the center of knowledge creation and sharing. For any KM practice developed or implemented, considerations should be given how people will engage and benefit from implementation. The culture of the organization is an important influencer of norms and behaviors in how people create, share, value, and reuse knowledge. Ideally, the organizational culture should

encourage and support investing the necessary time and resources to capture the available information, knowledge, and learning as a part of the day job—or in the flow of the work. Acknowledging, that with the current pace of the business, it can be a challenge to balance the *need to get the work done* with a longer-term view of conducting the work in such a way that the information and knowledge can be reused and leveraged. Listed below are some common challenges and barriers to capturing, seeking, and sharing knowledge *in the flow* of daily work and related opportunities:

Challenge	Opportunity
Lack of *clear expectation* from management or leadership to capture information/knowledge/learnings for future use	With senior leader sponsorship, expectations can be set that specifically relate to capturing and reusing information/knowledge/learnings—and associated accountability; consequences must apply, both positive to reinforce good behavior, or negative if expectations are not met
Lack of *defined business processes* to capture information/knowledge/learnings	Dedicated KM roles can enhance business processes to capitalize on knowledge capture and reuse, may need to design new processes to enable capture and reuse
Lack of *technical solutions* to aid in the capture of information/knowledge/learning	Senior leader sponsorship can help in attaining funding for technical solutions
Lack of *incentives—WIIFM* (what is in it for me)	A change management plan could be developed outlining incentives to engage colleagues in knowledge sharing and endorsed by senior leadership/KM sponsor

A combination of senior leader sponsorship and provision of dedicated KM roles can go a long way in addressing barriers that can be found relating to the impact of people and culture on the KM program. Additional information on KM roles will be further discussed in this chapter.

In Support of Dedicated KM Roles

To further enable the *people* pillar in the *House of Knowledge Excellence*, dedicated KM roles are key to addressing, not only the cultural challenges but also the business process challenges. When we consider the biopharmaceutical industry, it is safe to assume that every company has a dedicated quality unit. Yet, having a quality mindset is the job of each and every colleague every day. No one would challenge the expectation that everyone is responsible for quality; nevertheless there is still a dedicated group, whose primary role may be to release the product that has the responsibility to define, implement, and maintain the Pharmaceutical Quality System (PQS). Given the regulatory expectation in ICH Q10 that prior knowledge will be used and knowledge management is an enabler of an effective PQS, one could draw a corollary that dedicated roles are necessary to provide focus and expertise to develop the framework for a knowledge management program. Size and scope of a knowledge management team responsible for a dedicated

knowledge management role is, of course, very specific to the business. It is, however, not uncommon in large oil and gas industry organizations to see a knowledge management team ranging from 10 to 25 people. Whereas, in the biopharmaceutical industry we tend to see slower adoption and smaller, less formal, less dedicated, and sometimes less integrated teams.

Three of the challenges identified above can be better addressed through the allocation of dedicated KM roles that provides a central/programmatic support to ensure a consistent approach and understanding:

Challenge	Opportunity
Lack of *defined business processes* to capture information/ knowledge/learning	KM role enhances business processes to capitalize on knowledge capture and reuse, may need to design new processes to enable capture and reuse
Lack of *technical solutions* to aid in the capture of information/ knowledge/learning	KM role collaborates with the IT functions—new IT technologies or approaches may be needed to enable knowledge flow (e.g., expertise location, search, discussion boards, and collaboration spaces)
Lack of *incentives*—WIIFM (what is in it for me)	KM role develops change management plan including incentives to engage colleagues knowledge sharing—to be endorsed by senior leadership/KM sponsor

Recognizing that dedicated roles are critical for KM success—having the *right roles* in the *right mix* is a key enabler that will enhance realization of the potential KM benefits. Further description of roles will be discussed in the *enablers* section later in this chapter.

Process

When considering the pillar of *process* in the KM space, there are two major components:

- *Business Processes* (e.g., new product introduction, technology transfer, and new employee orientation).
- *KM Processes* that enable knowledge flow (such as standardized processes for lessons learned, or communities of practice).

Business processes are a critical vehicle for KM program realization, as it is through these processes that the business actually operates. As discussed elsewhere in this chapter, a core tenant of KM is to improve the performance of key business processes. This can be achieved through analyzing the business process under review using knowledge mapping and other techniques in order to identify knowledge flow opportunities and the current pain points. Notably, it is in these very same places where the resulting KM practices can be embedded into the business process, or *operationalized*, as the new way of working. For example, during technology transfer (tech transfer), utilization of a document repository may be left to the discretion of the worker.

When KM is embedded into existing processes, such as the tech transfer example—use of a document repository may become a part of *standard work* for knowledge capture during tech transfer and as a result builds KM into the business process.

KM processes are also a major driver in the need for standard work in how KM is delivered in order to maximize its impact. For example, a standard work package should exist for how *lessons learned* are conducted—variable processes will only confuse the target audience and cause the practice to fail over time. Likewise, KM processes for community design and operations, taxonomy change management, metrics reporting, and others should be similarly standardized.

Technology

In this age of big data, information highways and social media, technology is an absolute necessity to support effective knowledge sharing and efficient knowledge flow. There is a multitude of articles and books written on how to successfully apply technology to business processes. One such success factor is a strong partnership with the information technology (IT) organization, which typically has long experience in helping their customers implement business solutions. However, a KM practitioner may look at technology through a different *lens*, hence the benefit for a strong partnership. When applying a *KM Lens* to a technology solution, the following items may want to be considered:

- Who is the target audience for this solution?
- Are there *secondary* customers that may only consume but not contribute? (Note: a knowledge mapping exercise of the business process may help to identify any secondary customers of the content proposed for the system).
- What type of metrics will the system generate to help inform the system steward or curator of progress and uptake?
- Who is using the system (from what region, department, etc.)? Details such as region and department can help determine where additional change management work could be applied. In addition, the ability to discern *content creators* and *content users* are helpful.
- What type of content or system functionality are users accessing the most (this would allow a steward to possibly encourage similar content to be added as it has high value).
- Can usage spikes be correlated to change management/user engagement activities?
- What other systems are out there that captures similar content? Can they be leveraged?

- Would this system benefit from any type of gamification* or providing visual acknowledgments or recognition for high volume contributors, etc.?
- Is there an easy to find *suggestion* box for users to provide feedback?
- Are success stories sought after via the system and are they visible from the system?

Many organizations start KM technology solutions with a pilot and build in learnings prior to expanding. Pilots can provide a cost-effective approach to test, and then rapidly embed key learnings, into the overall system design and roll out. In addition, leveraging cost effective COTS (commercial off the shelf software) may also be an option with a creative IT team.

Governance

There are two key aspects when considering *Governance* in the context of KM:

- Governance at the KM *program* level
- Governance at the KM *practice* level

It is important to take a holistic view, as implementing governance at program and practice will provide complementary and synergistic outcomes.

KM Program Governance

At the *KM program* level, governance requires that careful consideration have been given to establishing responsibility and accountability for the KM program, as well as for setting direction and program targets. It is recommended that program governance is formal, and sponsored by senior leadership such as through a sponsor or steering committee, with well-defined processes and procedures for approving business cases, changes to scope, funding, etc. As identified earlier, KM strategies should be linked to the business strategy. Leveraging formal KM governance is one way to help create such a link, and validates the importance of KM and helps to earn KM a *seat at the table*.

KM can also be effectively deployed through other business decision and direction setting processes such as *Hoshin Kanri* or IT portfolio prioritization, which help offer visibility as to where applying KM practices can provide additional business value. Effective governance at the program

* Gamification: 1. The application of typical elements of game playing (e.g., point scoring, competition with others, and rules of play) to other areas of activity, typically as an online marketing technique to encourage engagement with a product or service (Oxford Dictionaries).

level establishes a strong foundation for governance at the practice level (that could be less formal).

KM Practice Governance

At the *KM practice* level, governance refers to how KM practices are deployed, monitored, and sustained within a KM program. The intent of this governance is to set priorities for the practice (e.g., where it is deployed, who is trained, and key enhancements) and to monitor performance (e.g., metrics and success stories). In addition, governance is required to establish and operate the standard processes mentioned in the *process* pillar. One example could be a change management process, which requires that new skills must be input into an expertise location system. The level of formality may depend on the scope and complexity of the actual KM practice if one were to add skills or master data to an IT system, or modify a taxonomy, a more formal process of a steering committee may be utilized to ensure that all considerations are taken on board prior to making changes to standards.

NOTIONS ABOUT PEOPLE, PROCESS, TECHNOLOGY, AND GOVERNANCE

People: People are at the center of knowledge creation and sharing. For each KM practice developed or implemented, considerations should be given how people will engage and benefit from implementation. The success of changing business practices via KM practices to further enable knowledge flow is dependent on people accepting and embracing new practices.

Process: When thinking about process in the KM space, there are two major components: (1) business processes (e.g., new product introduction, technology transfer, and new employee orientation) and (2) the KM processes that enable knowledge flow (such as standard processes for lessons learned, or communities of practice).

Technology: Technology is an enabler to many KM practices; however, if technology is the primary focus, the technology tool could result in being the next *new thing* and not actually solve the underlying business process issue. Technology should be used to *enable* people and processes and thus be user friendly and attractive and accessible.

Governance: Governance is needed on two levels, first at the KM program level and second at the individual KM practice level. At the

program level, governance means that thought has put into establishing responsibility and accountability, as well as for setting direction and establishing targets. Governance may be formal, such as through a sponsor or steering committee with well-defined processes and procedures for approving business cases, changes to scope, etc. At the KM practice level, it refers to how KM practices are monitored and curated within a KM program (e.g., a community steward is providing a type of governance through managing the community on a day-to-day basis).

Pillar Summary

The importance of embracing all four pillars cannot be understated. Their individual and combined roles have been demonstrated through the work of many KM programs, and are supported first hand by the experience of the authors. Table 12.2 attempts to illustrate the impact of omitting a pillar from a well-intentioned KM program.

TABLE 12.2

Impact Assessment of Omitted Pillars

People	Process	Technology	Governance	Impact
	✓	✓	✓	NO consideration for PEOPLE (culture or roles): KM FAILS. If knowledge seeking and sharing is not an expected and valued behavior, if people do not have the capability to engage in KM solutions, or if people are not motivated (by positive and negative consequences), then people will not engage in using KM practices, and knowledge will revert back to the old ways of working.
✓		✓	✓	NO consideration for PROCESS (business or KM processes): KM FAILS. Knowledge gets *"stuck."* Without a process, it does not flow (O'Dell 2011). If knowledge flow is not embedded into the business processes through which work gets done every day by every employee, it will forever be something extra to get done and not viewed as the same as core work. Further, there will be no structure to how KM practices are executed, leading to confusion and eventually abandonment of the change.

(*Continued*)

TABLE 12.2 (*Continued*)

Impact Assessment of Omitted Pillars

People	Process	Technology	Governance	Impact
✓	✓		✓	NO consideration for TECHNOLOGY: KM FAILS. Our work is intertwined with technology, and while some KM practices may have limited success independent of technology solution, the reality is that everyone uses technology every day to do their work—whether through e-mail, content management, search, etc. Leveraging technology helps embed KM where people are already working and it is through technology as a catalyst that KM can scale and enable virtual collaboration and knowledge flow on a global scale, as well as provide analytics and other technologies that can unlock new potential for KM.
✓	✓	✓		NO consideration for GOVERNANCE: KM FAILS. Without governance, there is no leadership, no control, no oversight, and perhaps no link to business priorities. Therefore, KM becomes disconnected from the core work and priorities of the business and in time, is likely to become irrelevant.

Enablers

All too often, organizations set off on a well-intentioned knowledge management effort but fail to recognize the importance of some key *enablers* and their role in delivering successful outcomes (Figure 12.7). Before we continue please consider these definitions of *enable* and *enabler*:

- *Enable*: To make (something) possible, practical, or easy
- *Enabler*: *One that enables another to achieve an end*

Key KM enablers include the following:

- Change management
- Change leadership
- Dedicated KM roles and skill sets
- Ownership and stewardship
- Partnerships

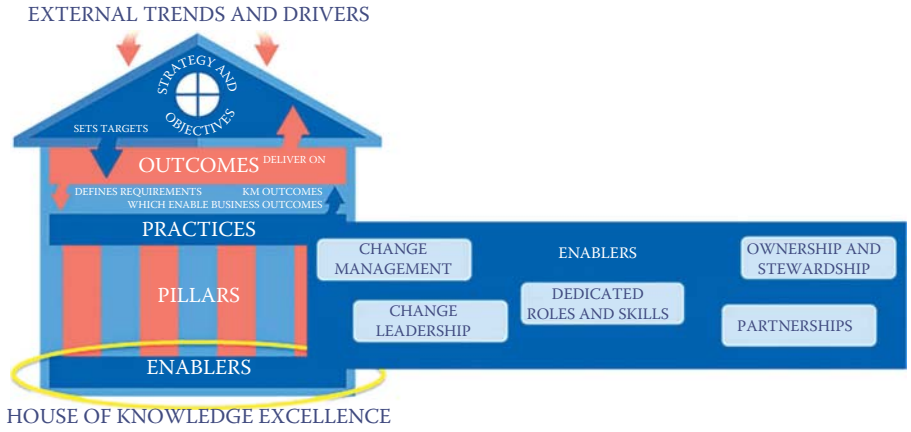

FIGURE 12.7
Enablers for successful KM.

In fact, it is claimed that up to 70% of KM initiatives fail to meet their stated goals and objectives (Chua and Lam 2005; Knoco 2014). A variety of underlying reasons have been identified, which include lack of support and commitment, organizational culture, knowledge hoarding behaviors, change resistance, and others (Knoco 2014). Many of these failures can be traced to the exclusion, disregard, or superficial understanding of the key KM enablers explained in this section:

- Change management
- Change leadership
- Dedicated KM roles and skill sets
- Ownership and stewardship
- Partnerships

It is important to think about these enablers as critical to facilitating knowledge flow in a *practical*, *possible*, and *easy* manner. They are the foundations on which knowledge flow can be successfully established and sustained. The following sections will further discuss these key enablers and explore linkages as to why they are critical to KM success.

Change Management

Perhaps the enabler that has the most impact of all is effective *change management*. A word of caution, this is not to be confused with *change control*, which is a familiar compliance process. Rather, change management is about organizational change—sometimes called transformational change—and

focuses on a structured methodology for leading an organization, and the individuals that make up that organization, through a specific change.

In the case of implementing knowledge management, there are often multiple changes in play, including changes to how people think and behave about sharing knowledge (e.g., fighting *knowledge is power*), changes to how people do their work on a daily basis (e.g., starting problem solving by understanding if similar problems have been successfully resolved), to changes in how people are incented and rewarded for seeking and leveraging the knowledge of others (e.g., fighting the *not invented here* syndrome).

Why Is Organizational Change Important?

Recognizing that organizational change is necessary and is absolutely essential to any successful KM program. If this is not recognized, then it is likely that your KM program is at high risk of not delivering on desired outcomes as essentially all KM practices require some change in the mindsets, behaviors, or actions of the target population. Change management provides methodologies to dissect a given desired change, so that it can be analyzed in a very fundamental manner.

For example, one popular change management methodology, illustrated below, helps to describe the change and the associated risks to successful realization in terms of:

- People (e.g., capacity and resistance)
- Intent (e.g., clarity and alignment)
- Delivery (e.g., resources and partnership)

This methodology also provides tools to analyze sponsorship continuity and techniques to secure leadership and sponsor support (Kotter International 2007). Other models for leading change exist, such as the *Kotter 8-Step Process for Leading Change* (Kotter International 2015).

Although these change methodologies and models are typically directed at large-scale transformational change within an organization they offer powerful approaches to better understand the changes required to ensure success of the KM program and therefore greatly increase the probability of success. It is recommended that all KM programs employ some skills in the art of change management, while adapting these methodologies to make them fit for purpose for your need.

Organizational culture change is closely related to change management. Some level of *culture change* will be required for the success of your KM program. However, it is better to understand this up front and address it in your KM strategy to ensure the appropriate level of sponsorship support from senior leaders. It is imperative to understand, at least at a high level, the culture of the organization going through such a change and the barriers that exist. If business leaders and KM leaders fail

to recognize or understand what is changing and establish conditions for this to happen, how can they hope to be successful?

Change Leadership

Change leadership refers to the behaviors and actions of leaders in the organization that drive successful, sustainable change throughout the organization. *Change leadership* differs from *change management* in that it is an engine for change, not a methodology or set of tools and structures to keep a change effort under control (Kotter 2011).

Change management methodologies will often help to define which elements of change leadership will be required, typically described in the category of *sponsorship*. However, the concept of sponsorship in many places feels overused and underrealized. Leaders are typically responsible for sponsoring many change initiatives simultaneously—and may believe they are sponsoring them effectively—this is often not the case. Reasons for this might include the following:

- Sponsorship of too many simultaneous changes.
- Lack of commitment to or understanding of the change itself.
- Sponsors not modeling the desired behavior.
- Sponsors not holding people accountable for the new way of working.
- In many cases, sponsorship has become diluted and has lost some effectiveness (and often, they probably do not even recognize it).

Why Is Change Leadership Important?

One of the most common causes of failure cited for a KM effort is the lack of senior leader buy-in. Successfully engaging leaders in the organization—at all levels, starting with the leader who has the authority to initiate and legitimize a change—and leveraging these leaders to provide sponsorship for the change is a critical element of successful change. Ask yourself if you would rally behind a leader who says *do as I say but not as I do* (or who *talks the talk* but who does not *walk the walk*)? Leaders who are engaged, visible, modeling the change, and holding people accountable for the new way of working will bring more people through the change with them. Providing change leadership requires effort at all levels of the organization—it is not a spectator sport. According to Thien (2015), this includes taking time to learn, being committed to the change, creating the right environment, setting expectations, and remaining resolved. Other elements of change leadership may include the following:

- Effective, consistent communication.
- Adequate, regular attention to the change and how it is proceeding.
- Deployment of resources, including of people resources *and* financial resources.
- Support development of new skills.

Dedicated KM Roles and Skillsets

Roles, and associated defined responsibilities, are a *subset of the People pillar*. Having the right roles in the right mix is a key enabler that will enhance realization of KM benefits. This section presents further discussion on KM roles.

With many competing priorities, if a KM program is pursued it is important to maintain a focus to ensure tangible progress, whether the focus is defining a strategy, designing and deploying KM practices, or stewarding and sustaining a KM program. What roles are required and what skills and capabilities make up these roles?

There are a variety of well-documented KM roles, for example, by APQC (2015) list many KM roles including the KM leader, KM design team members, IT specialist, facilitator and supporting KM advisory group. These roles are central to getting a KM program off the ground. As a KM program matures and expands, other common roles may arise, such as:

- KM Champion (or KM team lead, or Chief Knowledge Officer [CKO])
- KM Specialists (or KM Analysts)
- KM domain specialists (e.g., deep expertise in lessons learned)
- Change Management and Communication specialists
- Taxonomists
- Program Manager and/or Project Manager

In addition, there are often other support roles required that may be akin to traditional IT roles such as:

- Business Analyst
- Business Architect
- User experience expert

Over time, other roles may emerge, for example, that of *knowledge stewards* who are responsible for the ongoing support of KM practices and processes.

Although some of the roles may be more clearly defined (e.g., taxonomist), many KM roles such as the KM Champion and KM Analyst are best realized through a combination of diverse skills. KM often sits at the intersection between disciplines—in many ways KM fills a gap between the functional areas it serves and information technology, human resources, learning and development, and operational excellence. Therefore, these diverse skills and competencies reflect the understanding and fluency in leading and facilitating a diverse team *while also* understanding the business context *and* having competency in knowledge management.

A recent KM survey across industries reported that KM team make-up varies across industries, but five core skills are common, including:

- facilitation
- change management
- organizational skills
- information technology
- information management

(Knoco 2014). Additional skills and attributes of KM leaders include the following (Leistner 2010):

- Service mentality
- Diverse experience across multiple fields
- Ability to inspire passion
- Multicultural experience

Why Are Dedicated Roles Important?

Committing resources to a KM effort is paramount. Understanding what roles and associated skills are necessary is fundamental in establishing a KM program for long-term success. This may require leveraging extensive benchmarking, outside help, or time to up-skill internal staff to catalyze the start of the KM effort.

Ownership and Stewardship

Ownership means ensuring someone is responsible and accountable for the various elements of a KM program. There must be a responsible party that *owns* the KM program, its definition and evolution, but is also responsible for the deployment and realization of KM into the business. This role is often referred to as the *KM Champion*. There needs to be clarity between the roles of KM Champion and the business sponsors on these expectations. A common model, linked to the broader culture change and associated change management topics discussed previously, is to think about the KM Champion as owning the KM program, the KM practices, and everything required to operate and support the program, whereas the business sponsor is ultimately responsible for driving the change into the business operations and realizing the benefits.

Another way of thinking about ownership is to ask—*who is responsible for knowledge management*, and a likely response is the *KM Champion* and then asks *who is responsible for managing knowledge* and this may prompt a much broader response. Ultimately, it is the staff of the organization who must manage their knowledge—for example, the scientists and engineers and others—who are *knowledge workers*, (Drucker 1999), that is, those doing the work every day where knowledge is created, synthesized, and is hopefully (by design) flowing.

This can be further illustrated by an analog to safety. Who is responsible in your organization for being safe? Is it the safety department? Clearly not—the safety department deploys the processes, builds capabilities, defines goals, and metrics to monitor progress, and keeps abreast of current best practice, legislative commitments, and requirements. But safety is the responsibility of every employee in how they approach and execute their work on a daily basis to ensure it is done in a safe manner and that everyone goes home safe at the end of their day.

Let us consider the role of stewardship next. Stewardship of a KM program is associated with the ongoing *care and feeding* of the operational aspects of the program. Stewardship can be considered conducting, supervising, or managing of something; the careful and responsible management of something entrusted to one's care.

For example, you may be familiar with stewards who are responsible for facilitating a KM community, or a lessons learned process. Think about these stewards as KM practice subject matter experts (SMEs) who are responsible for executing these processes on a repeatable and consistent basis while also helping to facilitate continual improvement. Furthermore, stewards allow a KM program to scale more easily into other areas of the business and have a stake in how a given KM practice is improving their *day job* on the shop floor.

Why Are Stewards Important?

Committing resources that have the right skills, competencies, and enthusiasm to support the KM effort is crucial. It is therefore important to clearly define the expectations and time commitments for these key ownership and stewardship roles. Unstated assumptions as to what each party does should be avoided.

Likewise, it is important to commit to stewarding to help ensure that KM processes do not fade from use as priorities change. Having stewards also helps to promote a community of practitioners as a KM program is more broadly deployed within an organization. This cohort can assist with new implementations, learning from each other, and helping to drive further improvements. Conversely, not having these stewards can cause processes to drift apart, eventually risking the intent of the KM program.

Partnership

There are many functions and disciplines that KM may need to interact with in order to establish a successful KM program. KM has the opportunity to build linkages to many *sister* functions that typically exist in organizations, including Learning and Development, Human Resources (HR), information technology (IT), and Operational Excellence (OpEx), sometimes also known as Lean Six

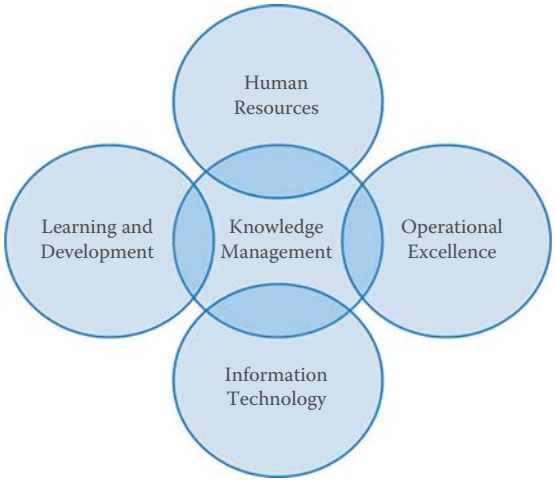

FIGURE 12.8
Linkages between KM and partners.

Sigma (LSS), as shown in Figure 12.8. Initially, KM practices may feel independent from these other disciplines, yet these disciplines are similar in many ways to KM in that they are also enabling *the business* to drive improvements and are often situated in some tier of a central organization and serve a broad user base.

Why Is Promoting Partnerships Important?

In many instances, what these sister organizations are trying to achieve is tightly linked to what KM is trying to achieve—and often their outcomes depend on improvements in knowledge flow. Furthermore, like KM, each of these functions is typically speaking to the business leaders, exploring what problems the leaders are trying to solve, and each, to some varying level of maturity and sophistication, has a strategy and plan to help the core business improve their outcomes.

One must recognize that business leaders may perceive these as a set of disconnected plans and strategies. Yet, there are synergies to be gained when understanding and partnering with these sister functions, for the mutual benefit of all. If the maturity—or desire—does not exist to ensure alignment, it is critically important to ensure there is not *misalignment*—as this will cause disruption to core work and may well render KM efforts ineffective.

In terms of partnerships, another interesting way to think about KM, is that KM often fills a gap between established functions and the business. KM programs can work in the *white space* between functions to address issues. As per the famous marketing slogan by BASF (Deutsch 2004) "We do not make a lot of the products you buy. We make a lot of the products you buy better." Likewise, KM can enable additional value from processes and tools that already exist in the organization. Table 12.3 lists some of the interdependency between these functions.

TABLE 12.3

KM Partnership Opportunities

Sister Function to KM	KM Partnership Opportunity
Learning and Development	At the core, learning and development is about building capability through competency development. In many ways, so is knowledge management. Knowledge management builds capability through the flow of knowledge, leveraging expertise to solve problems, learning from experts, collaborating as a community, and more. In fact, many learning models such as the 70:20:10 model (Lombardo and Eichinger 1996) of learning, depend on this. In this model, the *10* refers to the 10% of learning that occurs from structured courses and programs, the *20* refers to the 20% of learning that occurs by learning from others, and the *70* refers to the 70% of learning that occurs on the job. For many KM programs, the *20* and the *70* are squarely in the same space where KM is centered in trying to enable access to expertise, collaboration via communities, effective lessons learned, etc. So understanding and aligning with a learning strategy has clear benefit for both functions and can make the *learners* experience much more seamless and integrated (Lombardo and Eichinger 1996).
Human Resources	Human Resources, like L&D, also builds organizational capability through talent development programs, rotations, and other means, often including on-boarding processes. Also similar to the L&D relationship, KM can support capability development through improved access to experts and other tacit knowledge. There is also an opportunity to surface and set expectations for use of KM practices and knowledge sharing behaviors during the on-boarding process, and establishing a KM competency model for the organization. A common set of KM practices involving knowledge retention and transfer can be leveraged to create or enhance off-boarding processes in partnership with HR.
Information Technology	Perhaps the most common partnership with KM is with IT. This appears to be due to the many software tools that exist and the marketing that comes with them for how these tools solve the problems of sharing and collaboration. Many tools are directly marketed as KM solutions. Whereas many software solutions are key enablers to KM approaches, for example, collaboration spaces, search engines, social platforms, etc. Reality is that these are very rarely successful when deployed as an IT system without the benefit of many of the enablers and holistic approaches presented in this book. Therefore, the opportunity to partner with IT is one of great synergy where IT can bring tools that form the primary user experience to many of the KM practices, yet how these user experiences support knowledge sharing, and how the IT system is configured and established as part of the workflow can help IT realize benefit of an IT investment while enabling the broader goals of the KM strategy.
Operational Excellence	Opportunity for partnership should also be sought with OpEx functions in the organization, with a key opportunity being OpEx's quest for elimination of waste through the creation, deployment, and continuous improvement of standard work. KM's challenges is similar in many ways—to identify knowledge *waste* in a process through knowledge mapping or related means, and deploy practices to standardize this knowledge flow. Even more powerful is when KM practices can become fully embedded in robust standard work deployed by OpEx efforts.

TABLE 12.4

Key Barriers to KM Success and Enablers to Address

Barrier to KM Success (Knoco 2014)	Enabler(s) to Address
Lack of prioritization and support from leadership	Change leadership, KM strategy
Cultural issues	Change management
Lack of KM roles and accountabilities	Dedicated KM roles and skillsets Ownership and stewardship
Lack of KM incentives	Change management, change leadership
Lack of a defined KM approach	KM strategy
Incentives for the wrong behaviors	Change management, change leadership
Lack of support from departments such as IT, HR, etc.	Partnerships
Insufficient technology	Partnerships, change leadership

Enablers Summary

There are several enablers that can help drive success for your KM program. These enablers are intended to go beneath what lies on the surface when deploying KM practices (e.g., communities, taxonomies, and expertise location) in order to ensure proper organizational alignment and support, roles and skills, partnerships, and a deep understanding of what you are trying to accomplish. These are based not only on the experiences and observations of the authors, but are also broadly recognized by KM practitioners, as barriers to successful KM implementation. Table 12.4 reports the top eight barriers to KM, and contrasts these barriers to the KM enablers listed in this section.

Scale your efforts as appropriate but keep these enablers in mind as you design your KM approach and it will yield a more successful and sustainable KM program.

Putting It All Together

This chapter has presented a framework, entitled the *House of Knowledge Excellence* as a holistic model to reference when designing and delivering KM capabilities as summarized in Figure 12.9.

The power of this model lies not only in listing each element of the house, but also in the composite framework this creates, which is integrated from

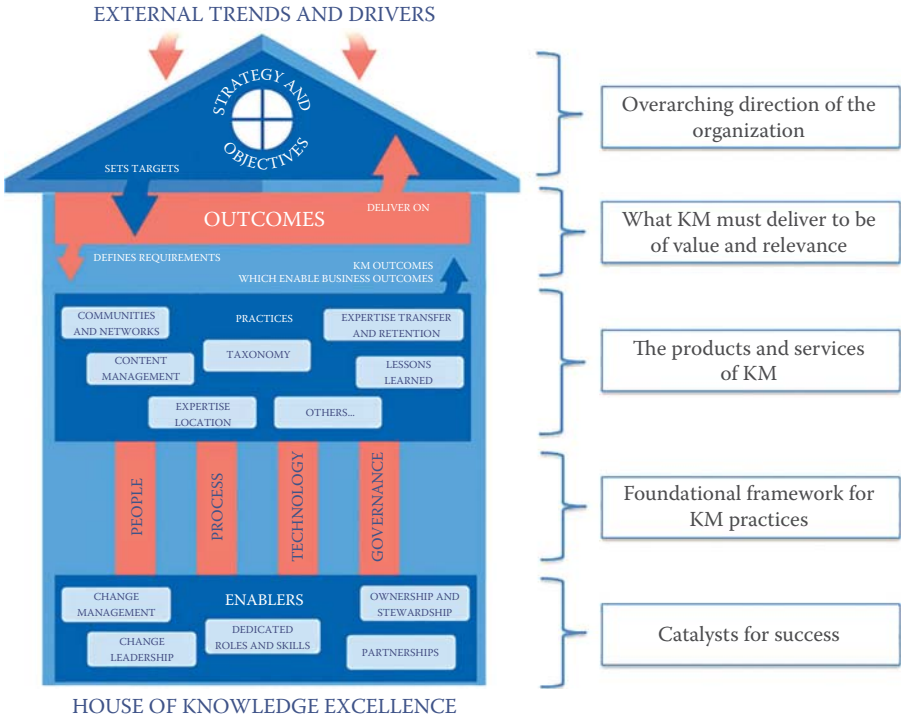

FIGURE 12.9
The House of Knowledge Excellence explained.

top to bottom. Often, organizations will jump into KM with good intentions but only focus on selected KM practices without fully appreciating the drivers that flow from above, and the foundations (pillars and enablers) on which those practices must sit. Based on the experience and beliefs of the full editorial team involved in this book, the best possible outcome can be achieved through an integrated approach.

In closing, as global regulatory health authorities continue to develop their understanding and concepts related to the ICH Q10 PQS-based enabler of *knowledge management*, there is a tremendous opportunity to continue to build industry maturity and share case studies in the knowledge management space.

To summarize, Table 12.5, which follows, presents some recommended *KM practices* to address the various barriers to knowledge flow identified previously in Table 12.1.

TABLE 12.5

Common Challenges, Trends, and Drivers Facing the Industry and Example KM Practices to Address

(a) Challenge, Trend, or Driver	(b) Strategy or Objective to Address	(c) Illustrative Barriers/Challenges to Knowledge Flow	(d) Example KM Practices to Address Barriers/ Challenges
Regulatory Driver(s)			
Regulatory expectation that knowledge is applied to improve patient outcome (e.g., ICH Q10)	More efficient postapproval changes product innovations	Difficult to surface prior knowledge from legacy products Difficult to understand rationale from past changes SMEs have left the company—losing knowledge of legacy products Design space not adequately defined	Knowledge mapping Content management Communities and networks Knowledge capture and retention program Taxonomy
Regulatory expectation for improved understanding of risk	Improved risk assessment process and outcomes (standard process, routine frequency, etc.)	Difficult to understand rationale and decisions from prior assessments Lack of uniform assessment of risk across products, time, etc..	Knowledge mapping Expertise location Communities and networks
Business Environment Driver(s)			
Global competitiveness (pricing pressures, generic competition)	Operational excellence (process capability, cost savings, etc.)	Inability to find historical knowledge to support process improvements Past knowledge not easy to find/not findable Not knowing who the experts are Siloed learning within groups, facilities, regions, etc..	Communities and networks Expertise location Content management Transfer of best practices Taxonomy
Increased therapeutic area competition	Shorten time to market/ accelerate development timelines	Culture of not sharing Lack of processes to share Limited leverage/use of knowledge from prior products, modalities, etc. Inability to find knowledge efficiently to support development	Communities and networks Expertise location Lessons learned Content management Taxonomy

(Continued)

TABLE 12.5 (*Continued*)

Common Challenges, Trends, and Drivers Facing the Industry and Example KM Practices to Address

(a) Challenge, Trend, or Driver	(b) Strategy or Objective to Address	(c) Illustrative Barriers/Challenges to Knowledge Flow	(d) Example KM Practices to Address Barriers/ Challenges
Mergers and acquisitions	Increase technical capabilities, optimizing portfolio	Challenge to integrate new teams and capabilities Potential reduction in force Employees hording knowledge Often results in moving products from site-to-site—need for tacit knowledge that can be scarce (labor intensive and expensive) KM considerations not included up front—SMEs leave the company, knowledge transfer not planned proactively	Communities and networks Knowledge mapping Expertise location Expertise transfer and retention Transfer of best practices
Pressures to innovate to sustain growth	Operational excellence (process capability, cost savings, etc.)	Inability to find historical knowledge for process improvements Past knowledge not easy to find/not findable Siloed learning within groups, facilities, regions, etc.	Communities and networks Expertise location Content management Transfer of best practices Taxonomy
Shift to outsourcing in multiple stages of the product lifecycle (e.g., clinical studies, product collaborations, contract manufacturing and supply)	Leveraging external collaborations and third parties for competitive advantage	Contracts focus on regulatory needs not necessarily knowledge needs Culture of collaborators (third party or pharma organization) may not be conducive to sharing knowledge Concerns regarding intellectual property—reduction in learning Collaboration technology limitations	Collaboration spaces Communities and networks After action reviews Tacit knowledge transfer sessions
Emerging markets	Effectively and efficiently supplying products to emerging markets while satisfying evolving requirements in those markets	Location not conducive to collaboration Lack of resources Lack of internal capabilities in the markets Need to provide market specific products/packaging and labeling introduces great complexity to managing product knowledge	Communities and networks Expertise location Knowledge mapping

(Continued)

TABLE 12.5 (*Continued*)

Common Challenges, Trends, and Drivers Facing the Industry and Example KM Practices to Address

(a) Challenge, Trend, or Driver	(b) Strategy or Objective to Address	(c) Illustrative Barriers/Challenges to Knowledge Flow	(d) Example KM Practices to Address Barriers/ Challenges
People/Talent Driver(s)			
Baby Boomer retirement	Business continuity	Retirees not replaced when they leave Lack of time/business process to transfer knowledge to colleagues prior to leaving Replacement is not in place/knowledge transfer cannot happen Retirees not willing to share knowledge	Expertise retention Transfer of best practices Communities and networks
Evolving workforce (millennials entering the workforce)	Innovation, attracting new and diverse talent	Technology platforms do not meet the expectations of the new workforce Different styles of working (discussion with peers vs. research alone, where content is stored, etc.) Notion that millennials will work at multiple employers over their career (site reference)—more turnover and potential knowledge loss than in previous generations	Gamification Internal social media Communities and networks
Virtual/remote workers	Reduction of facility footprint	Reduction in people-to-people interaction—the *water cooler* and *coffee station* do not exist Risk of colleagues not developing an internal network—less connectedness and awareness of other peers in the organization	Communities and networks Internal social media Expertise location

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Chapter Eight

Pharma KM Blueprint Part Four: Knowledge management Effectiveness Evaluation (KMEE)

8 Knowledge Management Effectiveness Evaluation (KMEE)

8.1 Introduction

This chapter will introduce the fourth and final element of the *Pharma KM Blueprint,* namely the *Knowledge Management Effectiveness Evaluation (KMEE).* The KMEE is an innovative diagnostic tool, developed by the researcher, to facilitate a structured evaluation of the effectiveness of how an organization uses its knowledge. The KMEE was designed to help identify *actionable* items that functional groups could undertake to improve the management of their knowledge and to identify potential opportunities (i.e. gaps) for improving the availability, access, visibility, flow and use of the knowledge assets required by the members of their group in order to be able to conduct their day-to-day work efficiently. The development of this diagnostic tool was inspired by analysis of data received from a KM maturity evaluation exercise executed using the *APQC KM CAT™ – KM Capability Assessment Tool* within the researcher's own organization. Following the completion of the *APQC KM CAT™* evaluation, the researcher recognized that while the APQC KM Capability Assessment Tool worked well at a business level, it did not provide enough granularity to evaluate the needs at a front line team or shop-floor level.

While a “one size fits all” evaluation methodology might be considered optimal, in application, customizing the scoring tool has proved important to create the practical linkages between KM theory and practice. Evaluating organizational KM maturity scored using the KM-CAT tool for a large organization provides valuable business level information, and when coupled with the KMEE tool executed at a functional group level, deep insights into the overall effectiveness of the organization’s KM capability right down to the front line team members are captured. This chapter provides a real-world example of the application of the KMEE evaluation tool within the researcher’s own organization.

8.2 Evaluating Knowledge Management Maturity, Knowledge Flow, and Improvement

Measuring KM maturity is an important element of assessing the success of any effort to improve KM practices. Learning from a core business performance principle, ‘If you are not measuring, you’re not competing’ (Snee, 2006), this is also true when evaluating use of knowledge assets. However, measurement alone is not enough to drive improvement, measuring the *right things* is critical to the success of any organizational change effort.

Available KM maturity measurement methods range from academic-backed models to practitioner-led models (Kruger & Snyman, 2007; Lin et al., 2012; Trees, 2016) . Research has demonstrated that organizations that systematically track their KM maturity are significantly more likely to achieve other higher-level KM capabilities related to standardization, alignment, enhancement, and KM program expansion

(Trees, 2016). As discussed in the literature review in Chapter Two, understanding KM maturity by benchmarking knowledge management programs can also be helpful to identify opportunities to improve knowledge flow.

It is worth re-visiting an observation linked to KM Maturity from Kruger and Snyman.

> *It is clear that the inability to bridge the gap between theoretical propositions and practical usability is not only hindering knowledge management practitioners from successfully assessing the level of knowledge management maturity reached within organizations but, more importantly, is making managers lose faith in knowledge management as a strategic enabler.* (Kruger & Snyman, 2007)

The researcher has direct experience of using the *APQC KM CAT™ – KM Capability Assessment Tool* in multiple instances (within two large biopharmaceutical companies and one biotechnology industry collaboration group). The researcher found that in practice, the KM CAT™ tool was informative to assess *KM Program* and high-level organizational maturity. A key benefit of using the KM CAT™ is the ability to benchmark the maturity value for a given organization against the extensive APQC data set (both sector centric indices and industry agnostic indices). However, when executed at the divisional level, the KM CAT™ proved difficult to translate the findings from the maturity assessment into specific actions for individual teams. A helpful analogy to consider is how a global stock market index can be used to describe the overall performance of a sector but provides little insight in the performance of individual businesses included in the index average. This reflection and the need to close the 'knowing – doing gap' provided a thought-provoking linkage for the

researcher back to the Kruger and Snyman observation shared above. Diving deeper into the maturity assessment, the challenge with the KM CAT™ was multifaceted and evaluation of the feedback from participants revealed the following:

1. The structure and taxonomy used within the KM-CAT™ question set required deep experience with the tool to "translate" the questions for participants. Participants were unfamiliar with much of the KM specific terminology, for example when questioned about access to a *Expertise Locator* KM Tool (a searchable tool to help them find an expert in a subject area within their organization) participants not aware that a staff contact database system available on their internal company intranet was in fact an *Expertise Locator* tool.
2. Participants felt many of the standard benchmarking questions were not relevant to them as individuals or to their teams (e.g. details related to overall budget for KM, leadership sponsorship for KM etc.), and therefore could not answer those questions with confidence.
3. Participants felt that many capabilities which they actually demonstrated were not recognized or reported through the KM-CAT™ tool due to the scoring methodology i.e., groups felt they were acknowledged for progress or unless all the capabilities within a given maturity level were met.
4. Benchmarking results were not presented at a level that the individual teams felt they could meaningfully action
5. KM Advocates[40] within some teams were frustrated that the level of assessment didn't clearly identify practical examples of how individual groups could improve (as related to item 4 above).
6. The full assessment took multiple hours to complete; it was too time consuming with limited "relevance", in the view of participants at lower level teams.

[40] KM Advocates were employees within a functional team passionate about KM approaches who helped their team avail of enterprise KM tools and approaches.

Upon consideration of the feedback, the researcher considered one simple solution would be to take the KM-CAT™ deeper in to the organization, however the researcher did not believe the sentiments shared around relevance, terminology, and reporting detail would be addressed. Based directly on this feedback, the researcher sought to develop a KM maturity evaluation tool that was:

- Relevant to smaller teams/ functional groups, focusing on items within their control
- Could be used as a base line to further measure specific team capability
- Was capable of articulating gaps within the teams
- Included a scoring template that could recognize the achievement of individual capabilities
- Included a scoring template that enabled prioritizing and closing identified gaps
- Could be administered by a local KM advocate, and did not require an SME from the KM Program Team to "translate"

Before sharing the details of the resulting KMEE Diagnostic tool developed by the researcher it is first useful to understand the key features and scoring mechanisms embedded within the APQC KM-CAT™ tool.

8.3 APQC's Knowledge Management Capability Assessment Tool™ (KM-CAT™)

According to APQC the *APQC's Knowledge Management Capability Assessment Tool*™ (KM-CAT™) helps an organization assess its capabilities and maturity in knowledge management (KM) and focus its KM investments to produce the highest return on value. This assessment maps the current as-is state of KM and the knowledge flow processes within an organization in order to:

- Measure the current maturity of the enablers and infrastructures employed,

- Evaluate the current status of knowledge flow processes and supporting approaches,
- Set an objective for the improvement of business processes through the flow of knowledge,
- Guide the evolution of organizational change, and
- Compare or benchmark with similar efforts of other internal units or external organizations.

The KM-CAT™ is divided into four major sections with subcategories.

Table 8-1 APQC KM-CATTM - Four major sections with subcategories

Sections	Subcategories – or focus areas
Strategy	• Objectives • Business case • Budgets
People	• Resources • Governance structure and roles • Change management • Communication
Process	• Knowledge flow process • KM approaches • Measurement
Content and Information Technology	• Content management • IT processes and tools

Within each section capabilities are described ranging in maturity levels 1-5. APQC describes the levels of Maturity (APQC, 2010) as:

- Level 1, an organization is aware that it has a problem retaining and sharing knowledge.
- Level 2, initial knowledge approaches are in place. The focus is on helping localized knowledge flow and adding value.
- Level 3, the knowledge flow processes are standardized, and the focus is on meeting business requirements, achieving results, and developing a supporting infrastructure.

- Level 4, the KM efforts align with the organization's business objectives and the focus is on leveraging core knowledge assets across the enterprise.
- Level 5, KM practices are embedded in key business processes and the focus is on the competency of the business.

Scoring of the KM-CAT™ requires that all capabilities within that level must be demonstrated in order to achieve a score in the level (e.g. level 1, 2, 3 etc.). In addition, all capabilities associated with any given level below the current maturity level must also be demonstrated within the organization in order to be considered benchmarked to that level. To further explain the scoring, an excerpt of the KM-CAT™ KM Approaches & Tools section is shown below:

Level	Achieved Y/N	Capability
3		Standard methods are used to capture and retain valuable knowledge.
		The organization uses replicable knowledge flow processes and KM approaches.
		Enablers and infrastructure support knowledge flow process.
		KM methods and tools are available to knowledge workers on demand.
		KM maturity and capabilities are assessed.
		A KM "resource center" is established, including KM reading materials, case studies, and presentations.
2		Some KM approaches to support knowledge flow (e.g., communities of practice, knowledge capture, lessons learned, and expertise location) are implemented in parts of the organization.
		Knowledge maps for each initial KM focus area identify content and knowledge needs/gaps.
		Core business processes that require enhanced knowledge flow are identified.
1		Story-telling and one-to-one exchanges are the primary approaches used for knowledge transfer.

Table 8-2Example of APQC KM CAT data collection sheet for a given capability

For example, three capabilities are required to be in place in order to meet the criteria for Level 2 for this KM Capability assessment, all three capabilities within Level 2 must

be met, in addition to the single capability required at Level 1. If the Level 1 capability is not demonstrated, even if all Level 2 capabilities were achieved, the organization would not score KM maturity at level 2.

There are many positives with the KM-CAT™ however, the scoring methodology and process is particularly challenging when trying to evaluate and engage functional teams. While the researcher agrees with the overall rationale for scoring [41], the results as presented by the APQC methodology, are not particularly insightful at the function level. Table 8-3 describes challenges and potential solutions to consider for an updated tool.

Table 8-3 Opportunities for KM-CAT™ Tool

KM-CAT™ Challenge	Potential Solution
Administration of KM-CAT™ questions required deep experience with the tool to "translate" for participants	Develop a set of customized questions maintaining intent of the KM-CAT™ to retain the ability to benchmark with APQC
Questions around strategy and resources and were not relevant to most participants	Identify questions relevant to individual teams working in the business (not the KM Team)
All capability in a level must be met to get credit for them	Devise a methodology score progress within a maturity level to credit each capability met
Scope of KM-CAT™ was too high level to enable local teams to understand where they fit	Design the tool that it is relevant for individual teams yet still maintains integrity, to enable rolled up to the KM-CAT™
Assessment too long	Identify relevant/applicable capabilities for functional teams (items within their control) in order to simplify

8.4 Need for a supplemental tool for localized functional KM Assessments

The researcher acknowledges that the KM-CAT™ is suitable for measuring overall organization and KM program maturity /capability, however, due to feedback and

[41] Scoring methodology is similar to that of Malcolm Baldrich Quality Award, in which APQC was also involved in the development

challenges previously discussed, the researcher endeavored to create a focused capability diagnostic tool aimed at smaller groups/teams that:

1) Is customized to reflect specific KM tools and processes within the organization – drives engagement at the individual or team level, and not at the KM Program level. In addition, the customization aids in developing specific action plans.
2) Is scored to clearly acknowledge all capabilities met within levels, with "credit given" even if not all capabilities within a given level have been achieved. Participant feedback found this very frustrating .
3) Provides visual results of specific scoring to enable future progress tracking.
4) Provides a mechanism to prioritize gaps identified.
5) Provides templates for reporting and action planning. i.e. Pre-populated templates with specific recommendations, outlining the benefit to the organization for closing the gap.

8.5 Development of the Knowledge Management Effectiveness Evaluation (KMEE) Tool:

The development of the KMEE tool included the following steps.

1) Each capability within the APQC KM-CAT™ tool was first reviewed for relevance for each individual group – e.g. a smaller part of the organization whose primary responsibly was supporting product realization and continual improvement and did not have a responsibility for developing the overall Divisional KM program.
2) Capabilities deemed relevant from the APQC KM-CAT™ tool were then supplemented with specific organizational "translations" of the capability to clarify the requirements and relevance.
3) Capabilities were organized via the sections and sub-sections of the original APQC KM-CAT™ tool and each of the criteria for the maturity level was also included.

Note, the version of the APQC KM-CAT™ tool that was leveraged for further development contained 4 Sections and 12 sub sections and 151 individual capabilities.

After review and evaluation of the full APQC KM-CAT™ assessment tool, the researcher determined that 28 individual capabilities arranged into 3 sub categories/focus areas would be most suited to individual groups within the biopharmaceutical organization seeking to improve its KM maturity and knowledge flow. Table 8-4 shows:

Table 8-4 APQC KM CAT areas to be used in the KMEE

Sections	Subcategories	Capabilities Identified
Process	(PR1) Knowledge flow process (PR2) KM approaches (PR3) Measurement	12
People	(PP3) Change management (PP4) Communication	11
Content and Information Technology	(IT1) Content management/ Information Technology processes and tools	5

Each of the sections have subcategories, which have been labeled as in the APQC Tool (PP3, PP4, PR1, PR2, PR3, IT1. Note, that in the full APQC assessment there are additional subcategories not represented in the KMEE. Within each of the KMEE levels of maturity (levels 1-5) the number of associated capabilities are identified, are shown in Table 8-5:

Table 8-5 Capability description within maturity levels depicted

Level	Description of Maturity Level	Number of Capabilities
1	Initiate	4
2	Develop	7
3	Standardize	9
4	Optimize	5
5	Innovate	3

The modified KMEE evaluation tool is now shown in the next three tables. Table 8-6 related to *Content and IT* capabilities, Table 8-7 evaluates *People* capabilities, Table 8-8 evaluates Process and Knowledge Flow capabilities.

Table 8-6 KMEE Content and Information Technology (IT)

Level	Category	APQC Capability Description	KMEE Function Specific Description of Capability
1	Content and IT (IT1) Content Management Processes	General document management processes are in place.	General document management processes are in place. What are they?
1	Content and IT (IT1) Content Management Processes	Existing information technologies (IT) and tools are leveraged and used where possible.	Existing KM information technologies (IT) and tools are leveraged and used where possible (i.e. expertise locator, XX discussion boards, XXX product knowledge system XXX, Enterprise Search)
2	Content and IT (IT1) Content Management Processes	Content is identified and organized at business unit or domain.	Knowledge/Content is identified and organized at a group level or workflow level (may be sporadic)- list the methodology
3	Content and IT (IT1) Content Management Processes	Standardized taxonomies for classifying core knowledge assets exist.	Your group uses a standard naming convention for storing content - what is the methodology?
3	Content and IT (IT1) Content Management Processes	Content management workflows are standardized.	Content management workflows are standardized. All colleagues know where to store their content on shared spaces with supporting document management practices - list the practices

Table 8-7 KMEE People Capabilities

Level	Category	APQC Capability Description	KMEE Function Specific Description of Capability
1	People: (PP3) Change Management	Current state assessment of successes and problems in knowledge sharing include the identification of potential barriers and competing issues impacting knowledge flow required for business results.	Have you done an assessment to gauge KM issues in your group/site? If so do you know the issues and barriers?
2	People: (PP3) Change Management	Education and training plans are in place to support initial KM projects.	All colleagues in your group have been trained on the core KM approaches for all GTO - i.e. expertise locator, XX discussion boards, Enterprise Search, Lessons learned portal, enterprise search. And if part of colleagues roles- the product knowledge system XXX, Technology Transfer system (if relevant).
3	People: (PP3) Change Management	Barriers to sharing and using knowledge are identified and addressed.	Your group has identified barriers to sharing and using knowledge and have addressed them (with help from the KM team if needed) - list the barriers and solutions
3	People: (PP3) Change Management	Accountability is expanded for knowledge flow processes and approaches.	Groups outside of the official KM group are working to ensure that knowledge flows across the site/business (e.g. collaborative development process XXX, etc.) - list how your team is leveraging
3	People: (PP3) Change Management	KM advocates are in place across the enterprise.	Colleagues who are responsible for advocating for KM projects / approaches are in place in your organization (site for sites and center groups for center)
4	People: (PP3) Change Management	Formal recognition is given for KM efforts, success, and lessons learned.	Formal recognition is given for KM efforts, success, and lessons learned within your group and across other groups -give examples
4	People: (PP3) Change Management	KM training is provided to new-hires to help make KM a part of the culture.	Overview of the division/group specific KM approaches are provided to new hires or colleagues that have joined the organization from another part of the business
4	People: (PP3) Change Management	KM advocates have accountability for KM results.	Colleagues responsible for advocating for KM projects / approaches (site for sites and center groups for center) have accountability/ success for group KM approaches in their performance objectives
5	People: (PP3) Change Management	KM is aligned with talent management and leadership development.	Talent management processes leverage KM approaches/ processes (e.g. current online profiles, expertise locator) to ensure that talent & experience is visible to all colleagues- also leaders leverage the expertise locator/profiles to ID potential diverse candidates for new development opportunities/ roles
2	People: (PP4) Communication	KM advocates discuss the value of KM to the business with senior leaders and key stakeholders.	KM advocates (site or program colleagues) have been identified for your group and engage with leaders and managers to discuss the KM approaches/ projects and value to the group
3	People: (PP4) Communication	Success stories from initial KM projects are broadly communicated.	Has your site or group communicated any success stories levering KM, if so what or what are the opportunities?

Table 8-8 KMEE Process and Knowledge Flow Processes

Level	Category	APQC Capability Description	KMEE Function Specific Description of Capability
2	Process: (PR1) Knowledge Flow Process	**Stabilized** knowledge flow processes are embedded in KM approaches e.g., Communities of Practice, Lessons Learned, After Action Review, etc.	List the processes that enable knowledge to flow across groups, projects, etc. Examples could be Lessons Learned, CoPs, discussion boards
3	Process: (PR1) Knowledge Flow Process	**Standardized** knowledge flow processes are used across multiple instances or situations.	What are the **standardized** processes to enable the flow of knowledge across multiple groups in the organization
4	Process: (PR1) Knowledge Flow Process	Knowledge flow processes are embedded in core business processes and domains.	Your group us leveraging KM concepts of knowledge flow and capture into the design of "systems", business processes (e.g. collaborative development process XXX, Investigations using KM techniques. Etc.)
2	Process: (PR2) KM Approaches	Knowledge maps for each initial KM focus areas identify content and knowledge needs/gaps.	Your group has participated in a Knowledge mapping exercise and gaps have been identified. List the date of the exercise
2	Process: (PR2) KM Approaches	Core business processes that require enhanced knowledge flow identified.	Your group understand what core business processes would benefit from applying the "KM" lens to help with knowledge flow- list them
3	Process: (PR2) KM Approaches	Standard methods are used to capture and retain valuable individual knowledge	We have methodologies (plural) for capturing the knowledge of individuals.
3	Process: (PR2) KM Approaches	KM maturity and capabilities are assessed.	KM maturity and capabilities are assessed using the Knowledge management Effectiveness Evaluation (KMEE) Tool – list date
4	Process: (PR2) KM Approaches	KM competency maps exist for individual roles and/or jobs.	Individual roles / jobs within the group clearly state what knowledge is needed and generated in the specific role
5	Process: (PR2) KM Approaches	KM approaches, methodologies and tools are integrated with process improvement, organizational development, and learning approaches.	List the KM approaches, methodologies and tools you use that are integrated with process improvement, organizational development, and learning approaches e.g. when we do an OpEx project, innovation project, troubleshooting, etc., are we also using the KM tools/processes?
5	Process: (PR2) KM Approaches	KM becomes a "core competency" of the organization.	What is the evidence that KM is a "core competency" and competitive advantage of your group
1	Process: (PR3) Measurement	An assessment of critical knowledge in current business processes / domains is conducted.	Has your group participated in a Knowledge Mapping exercise? If so have you implemented the remediation plan?
2	Process: (PR3) Measurement	Local KM activity measures are in place and used.	KM Advocate or group leader measuring/ monitoring the use of KM activity within the group e.g. the participation in discussion boards 'X', the updating of online profiles, etc. - list the examples

8.5.1 Scoring Methodology:

The researcher evaluated each focus group's assessment determining if each capability criteria (using the customized questions) were met. A scoring mechanism was designed to reflect capability attainment which was visually represented in a heat map. The collection of responses was conducted in a spreadsheet – see Appendix IV. The three main categories of Content and IT, People, and Process and Knowledge Flow are represented in the header colors, blue, orange and pink. Sub categories are listed under each respective category and the number of capabilities in each sub category is denoted in brackets in the table header. Depending on the format of the collection method and number of participants, the data sets ranged from 150- 360 responses to evaluate per assessment. Examples of focus groups heat maps in are presented for a team with low KM maturity versus a team demonstrating higher KM maturity in Tables 8-9 and 8-10 respectively below:

Table 8-9 Focus group demonstrating low KM Capability: Green cells indicate achieved, Grey indicate N/A

People (9)	People (2)	Process (3)	Process (7)	Process (2)	Content & IT (5)
PP3 Change Management	PP4 Communication	PR1 Knowledge Flow	PR2 KM Approaches	PR3 Measurement	IT1 Management Processes
L1	L2	L2	L2	L1	L1
L2	L3	L3	L2	L2	L1
L3		L4	L3		L2
L3			L3		L3
L3			L4		L3
L4			L5		
L4			L5		
L4					
L5					

In contrast, results from the second focus group that demonstrated a more mature KM capability is shown below:

Table 8-10 Focus group demonstrating higher KM Capability. Green cells indicate achieved, Grey indicate N/A

People (9)	People (2)	Process (3)	Process (7)	Process (2)	Content & IT (5)
PP3 Change Management	PP4 Communication	PR1 Knowledge Flow	PR2 KM Approaches	PR3 Measurement	IT1 Management Processes
L1	L2	L2	L2	L1	L1
L2	L3	L3	L2	L2	L1
L3		L4	L3		L2
L3			L3		L3
L3			L4		L3
L4			L5		
L4			L5		
L4					
L5					

Reviewing the contrasting results of the two teams, who it must be reminded all belong to the same organization, one can recognize the level of detail reported is invaluable for each team to understand their specific KM capabilities and learn which approaches can be used to improve the KM capabilities and knowledge flow within their team. Helping them to work more effectively and purposefully in the future.

A business decision by the leadership of the respective groups was agreed that all teams should aim to reach a level 3 maturity as the initial maturity performance improvement target. As such, the researcher provided a report to show the gaps (if any) to reach capability both the internal goal of level 3 maturity, as well as what would be required to strive towards a level 5 maturity, the highest level of maturity on the model. Figure 8-1 is an example of how these results were visualized for the team leadership to aid their comprehension and ownership of the organizational changes required.

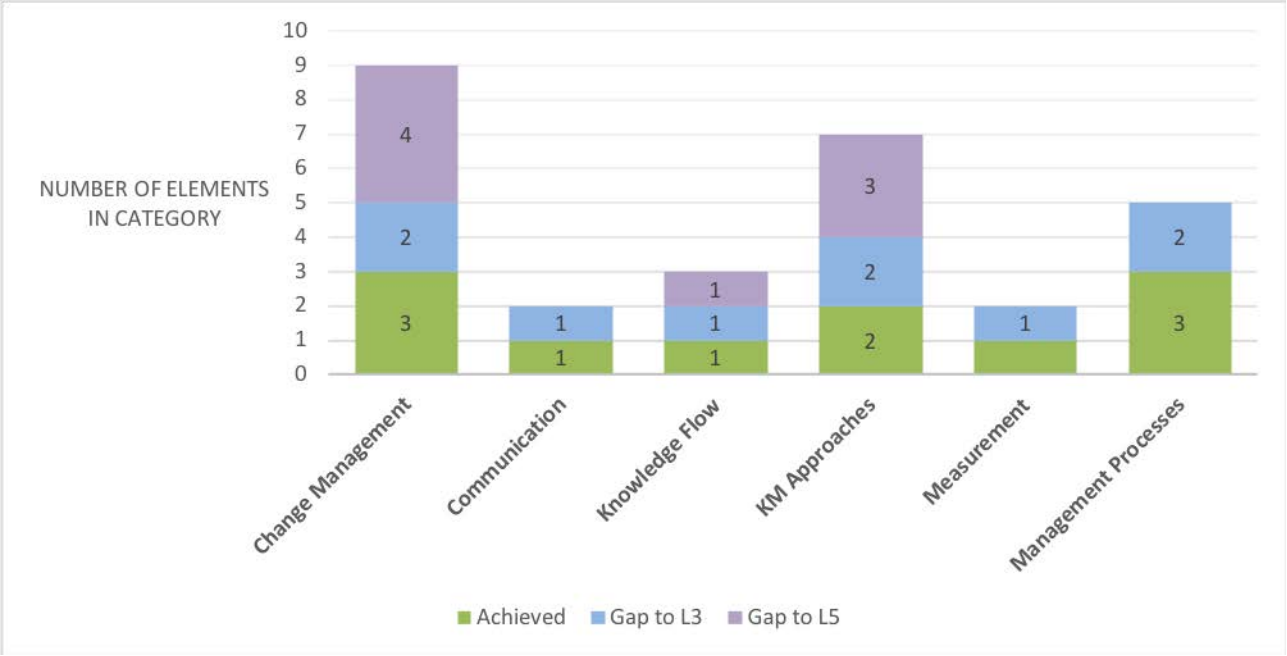

Figure 8-1 Blue indicates the number of capabilities required to fill the gap to achieve level 3 maturity, Green is the gap of capabilities to reach level 5 maturity.

8.5.2 KMEE Reporting and KM Plan – A Roadmap to KM Capability Improvement

To assist each functional area, the researcher developed a KM plan template to suggest opportunities and methodologies to close the gaps, as well as articulate business benefits to build KM capability. The full report provided to each team was shared as a power point presentation and included:

- The rationale for the KM Maturity Assessment
- The date of focus group/assessment
- Focus group participants and facilitators
- What was working well
- Discussion Insights
- For each Category (People, Process, Content & IT) the following were provided
    - A listing of gaps noted to level 3 (L3)[42]
    - Recommendation for closing the gap
- Prioritization map that was developed based on the perceived ease to implement the gap closure and the value of closing the gap

Each team was also provided their detailed KMEE evaluation spreadsheet with assessment notes and scoring so that individual groups could manage their implementation plan and track progress.

The case study below describes an actual business challenge with knowledge flow and how the Knowledge Management Effectiveness Evaluation (KMEE) assessment tool was used to establish practical actions to address this challenge.

[42] As the business focus was to have all groups achieve a level 3 (L3) capability, focus was on closing the gaps for L3 for this fiscal year.

8.6 Case Study: The KMEE in Application – Evaluation of a Technical Services Organization

A large global biopharmaceutical organization sought to optimize knowledge flow within their global technical services organization (TSO)[43]. The TSO generates key product and process knowledge as shown in Table 8-11, and was unsure as to:

1) What could the organization do to better enable knowledge to flow to those that needed it and

2) how well it was doing leveraging the KM tools and approaches that already existed in the organization.

Table 8-11 Example product and process knowledge generated by a Technical Services Organization

Example product and process knowledge generated by a Technical Services Organization	
Studies to investigate product or raw material failures, including forensics	Technology Transfer methodologies and reports
Pilots and reports for technologies for testing and manufacturing	Platform knowledge e.g. specific "playbooks" for technical processes
Technical problem resolution	Training materials for new technologies
Product Risk Assessments	Studies to optimize product production
Process Validation Studies/Reports	Cleaning Studies

KM became a key focus as some recent examples of "not knowing" had come to light, including:

- Inability to find reports after key individuals left the company.
- No standard processes in place to ensure key critical knowledge (e.g. reports, presentations) transferred off of hard drives when someone leaves the group.
- Employees based at another site were unaware of a specific study in support of continual improvement that had been run for a product (manufactured in multiple facilities). Study information was stored locally and not in a shared

[43] In many pharmaceutical companies, a (global) technical services organization is key in driving product realization and continual improvement.

area. Similar studies were undertaken by another group costing a significant amount of money.

- Sites required extensive technical support as self-service materials in the technical topic were not easy to find.

These examples, highlighted opportunities to become more efficient in the flow of knowledge, internally (within the TSO organization), and externally to the respective sites that manufactured products in the network.

Not only was the organization interested in how it could establish a baseline on how it was doing with managing its knowledge, it was interested in also articulating a *KM optimization* plan to improve knowledge flow. The first challenge was in determining how to create a baseline for the "as is" state of the 13 functional areas within the organization.

The second challenge was to provide the organization meaningful results that could then be actioned to improve the maturity and knowledge flow within each team. The APQC KM-CAT™ had previously been used to measure the divisional KM Program Maturity. As previously discussed, this technical services organization did not feel that the APQC KM-CAT™ results accounted for capabilities that had been achieved within the TSO because of the scoring and reporting methodology. With these challenges recognized, there was desire from the KM team and sponsors to not negate the APQC

KM-CAT™ assessment and link to the overall KM Maturity that had been previously benchmarked[44].

The 13 technical services organizations identified participants, a representation of the respective groups, to participate in a KMEE evaluation. The KMEE was administered to each of the 13 groups over a time span of several weeks.

Afterwards, each of the 13 groups received an individual report to clearly identify capabilities that had been met, capabilities that had been partially met and capabilities that had not been met. Each team were also provided an action plan to help them close the gaps necessary to reach up to a level three – or standardized KM Maturity as described by the APQC KM Maturity Model. In the opinion of the participants, the pilot was successful as it provided a baseline and a specific action plan to address knowledge process deficiencies. Further administration of the KMEE included the addition of a workshop format and additional tools to assist KMEE facilitators (found in Appendix IV).

8.7 Research Outputs related to the Development of the KMEE:

The following list catalogues the range of research outputs created during the development of the *Knowledge Management Effectiveness Evaluation (KMEE)* diagnostic tool:

A. Assessment Methodology & Tool / Overview and Sponsor Alignment and Gap Closure Prioritization & KM Plan Template Presentation (PowerPoint)

[44] APQC KM-CAT™ results are benchmarked not only in the biopharmaceutical industry but also across multiple industries

B. KMEE Workshop Preparation Methodology & Checklist (Word)
C. KMEE Capture and Scoring Template that includes gap closure options (Excel)

All materials developed in support of the KMEE can be found in Appendix IV.

8.8 Conclusion

The KMEE tool was developed to provide a practical link between the KM theoretical proposition and the practical business application that Kruger and Snyman indicated is so critical for the success of KM programs. This KMEE tool, with the help of a KM practitioner, translates KM terminology into local business nomenclature, thus enabling meaningful engagement with knowledge workers and ensuring an efficient and effective evaluation of the knowledge flow process within organizations, right down to front line team member level.

It could be argued that the model is too closely linked to the APQC KM-CAT™. However, feedback from the management teams involved in the pilots discussed in the case study indicated a strong preference to maintain a link back to a "proven" benchmarking tool, hence building a positive case for the strong linkage to the APQC Maturity tool. In addition, the action plans arising from the completion of the KMEE tool provided teams with recommendations that were in the direct control of the team to enable them to improve the management and sharing of their knowledge.

The researcher presented the case study pilot KMEE process and observations to APQC and was subsequently invited to submit this research for consideration at the 2019 APQC KM Annual Meeting. There is further potential to collaboratively work with

APQC to determine if any additional streamlining or improvements might be considered.

In summary, it is the opinion of the researcher that this tool could easily be leveraged in other teams within organizations that would like to evaluate their knowledge management capability and knowledge flow effectiveness.

Chapter Nine

Implications of Research and Future Work

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9 Implications of Research

This thesis has examined the current state of knowledge management (KM) in the biopharmaceutical sector. The research ambition was to evaluate the available theory and move it into practice by identifying and developing KM practices and tools that can be utilized across the biopharmaceutical sector to better enable the flow of knowledge.

Through this exploration, the researcher established a founding principle that, knowledge must be valued and managed as a critical asset within an organization, in the same manner as physical assets. In addition, the research identified that in order to realize the ambitions of ICH Q10, stated as, 'enhance the quality and availability of medicines around the world in the interest of public health', (ICH Q10, 2008), there is a crucial need to enhance the effective and efficient flow of knowledge across the product lifecycle.

The next key finding states that in order to extract value from this organizational knowledge there must be practical, integrated and systematic approaches implemented for the identification, capture, curation and visibility of the critical knowledge assets before the matter of enhancing the flow of knowledge can be addressed. While these concepts are important to any business within the traditional

biopharmaceutical sector planning on remaining competitive, they represent a "game changer" (or "game over") opportunity for any organization planning to develop, manufacture or market advanced therapeutic products, personalized medicines or next generation products.

Models and frameworks developed by the researcher were designed specifically for the biopharmaceutical sector and offer innovative ways to reconsider biopharmaceutical knowledge, facilitate knowledge flow and enhance utilization in order to reduce the risk of failures (e.g., reliable supply of medicines) that affect the business and/or the patient. The researcher was driven by a determination to close the gap from KM theory to practice by proposing the primary research output of this research as the *Pharma KM Blueprint*, as an initial step in bridging KM theory to the relevance and regulatory challenges of the Biopharmaceutical sector. See Figure 9-1, for a reminder of the *Pharma KM Blueprint*:

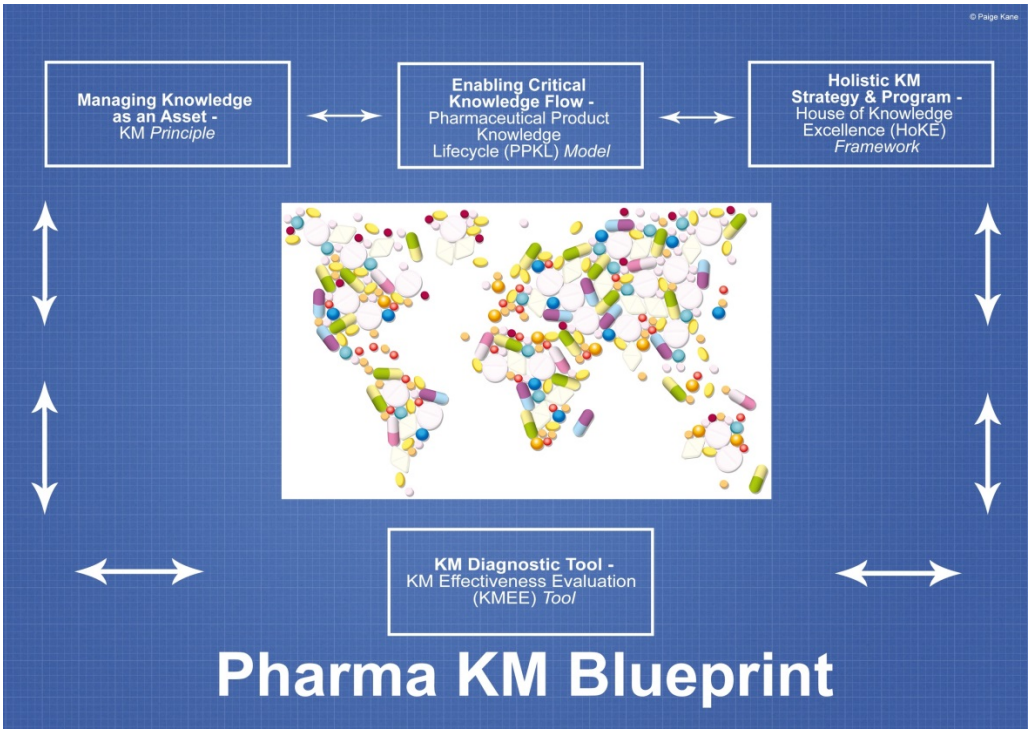

Figure 9-1 Pharma KM Blueprint - Kane 2018

The pharmaceutical sector has a long history of providing valuable medicines to patients around the globe, however, ensuring the reliable supply of high quality, affordable medicines is not without its challenges. As discussed in the introduction of this thesis, pressures within the biopharmaceutical sector are continuing to build; access to medicines, cost pressures, loss of talent, and the increasing complexity of the engineering and science needed to produce the next generation of medicines (EvaluatePharma® World Preview, 2018; Friend et al., 2011; Pugatch Consilium, 2017). The research has examined evidence from APQC that the biopharmaceutical sector lags other industry sectors in its adoption and practice of KM. If this indeed in the case, the laggards must not only catch up with common "good practice" from other sectors but must significantly up their game in order to continue to compete. The evidence suggests that the biopharmaceutical sector will not succeed in proactively driving new novel therapies forward if it maintains its current state of *reactive* knowledge management.

Linking back to the need to identify and use critical knowledge from Chapter Five, Professor Menezes highlighted that the inability to use knowledge can, and does, threaten security of supply of medicines citing repeated FDA 483 and Warning Letter observations, (Menezes, 2016) signifying in his viewpoint, that the sector is not learning from what it knows.

The field of knowledge management continues to present an elusive and ambiguous topic for many. Despite this ambiguity KM was reported as a the top opportunity to

yield productivity gains in the healthcare and biopharmaceutical sectors (Economist Intelligence Unit, 2006). Knoco surveys in more recent years have also identified *improvement of operational effectiveness* as the primary driver for KM (Knoco, 2014, 2017), and McKinsey report that "For many players, the biggest challenge has been simply making enough product to sell" (Otto, Santagostino, & Schrader, 2014). Clearly, the sector, the businesses and the patients stand to benefit from improving operational efficiency.

9.1 Primary Research Output: Pharma KM Blueprint

The main output from this research, developed as a result of the insights gained from the over the course of the study, is presented as the *Pharma KM Blueprint*.

The *Pharma KM Blueprint* (Figure 9-1) is comprised of four elements described in Chapters Five through Eight. The *Pharma KM Blueprint* was developed in response to the need, articulated by the biopharmaceutical sector, for further direction on how to implement a holistic KM strategy, effective KM programs and easy to use KM practices.

The *Pharma KM Blueprint* includes (Figure 9-1):

- **Managing Knowledge as an Asset** – Addressing the need to value and maintain *knowledge assets* in the same way as physical assets within an organization.
- **The Pharmaceutical Product Knowledge Lifecycle Model (PPKL)** - Addressing the challenge of enabling knowledge flow in order to increase visibility, access and use of the product and process
- **The House of Knowledge Excellence (HoKE) Framework** – Demonstrating a practical framework developed to implement a systematic KM program linked to strategic objectives of an organization, incorporating KM practices, pillars

(people, process, technology, governance), and enablers to support the effective management and flow of knowledge assets.

- A **Knowledge Management Effectiveness Evaluation (KMEE)** - Providing a practical KM diagnostic tool that may be used to identify and evaluate areas of opportunity and track progress on closing identified knowledge flow challenges or gaps.

9.2 Secondary Research Output: Industry KM Knowledge Contribution

While the *Pharma KM Blueprint* is the primary contribution to the *cannon of knowledge,* the researcher has relentlessly sought out venues in which to interact with the senior leaders and KM practitioners in the biopharmaceutical sector. As a result, research activities created an energy about the topic of KM and over the four years of research, focus groups were organized by the researcher, as well as either organizing, chairing or presenting research at nine biopharmaceutical symposia in Europe or the United States. These activities resulted in the creation and capture of many of the case studies described in Appendix I.

In addition, significant time was afforded to the ideation and co-creation of "*A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry*", with the researcher leveraging her network of contacts to assist in identification of potential contributions as well as presenting a case study from the Pfizer Knowledge Management Program, developing *The House of Knowledge Excellence Framework* (as primary author), authoring a practical guide on Knowledge Mapping and an additional

collaborative piece on ICH Q12 impacts, entitled "*A Future Perspective: Potential Regulatory Impact from ICH Q12*".

The third notable area of contribution relates to the participation in the Biopharma Operations Group (BPOG) Technical Roadmap (TR) – Knowledge Management. The researcher was a founding member of the team developing the KM TR. In this role, the researcher provided thought leadership and was able to 'pressure test' many of the ideas and assumptions explored in this research project. One original contribution discussed at length with the team members includes the researcher's key principle that knowledge must be treated as an asset (discussed in Chapter Five of this thesis). To the delight of the researcher, this principle was accepted as a core principle and included as a highlighted observation in the BPOG KM TR published in 2017 (BioPhroum Operations Group, 2017). The BPOG KM TR document was a significant commitment to develop materials for the report, the researcher will continue to work with the BPOG KM team to develop a KM pilot in 2019.

9.3 Implications of the research findings for the biopharmaceutical sector

This research provides a foundation upon which the sector can build upon. As noted in the case study review in Chapter Four, organizations are employing a wide variety of approaches in their attempts to enable the flow of knowledge to solve business challenges, however the desire for codified guidance (from industry members, not regulators) is clear. There is a strong need to continue dialogues within the sector to continue to share example and learnings.

In the not too distant past, monoclonal antibody products were novel, now these biologic production platforms are commonplace. Knowledge capture, visibility, flow and rapid learning from new knowledge will be paramount with the arrival of advanced therapeutics and novel therapies. Lack of robust knowledge management practices and programs will not only disadvantage organizations – the ability for organizations to articulate their product and process knowledge is directly linked to the success in the approval for new medicines and the ability to implement post approval changes that can bring value to patients.

9.4 Potential Areas of Future Work

As the practice of Knowledge Management is gaining momentum in the biopharmaceutical sector, the researcher has no shortage of future work recommendations. In fact, although honored to contribute to the cannon of knowledge on the topic of KM for the sector, the feeling of unmet opportunities persists. To this end the researcher would like to offer three opportunities for future work.

Future Work Topic One

The first specific recommendation for future work proposes that a formal KM guidance is developed through an industry collaboration group- such as the ISPE KM Task Team. The researcher is in the process for submitting a proposal to ISPE to develop a guidance" by industry -for industry". Although, as thesis and journal articles are vetted publication routes, the author suggests a group such as ISPE has the mechanisms in place to garner wide participation and/or awareness from health authorities, as well as distribute such a guidance.

Future Work Topic Two

Based on deep thinking and learnings whilst developing the *Pharmaceutical Product Knowledge Lifecycle Model (PPKL)*, the researcher suggests there is potential to further develop a new KM Practice that creates standard work processes to:

1) Enable greater transparency of product knowledge across the lifecycle, through the development of a *Product Knowledge Roadmap or Index.*

2) Capture and curate tacit product and process knowledge created during new product introductions and technology transfers, e.g. A *Book of Knowledge* or a *Product and Process Manual*.

It is currently planned that knowledge management research, relevant to the biopharmaceutical sector, will continue through the Pharmaceutical Regulatory Science Team at DIT, with the enrollment of M. J. Lipa in the doctoral research program. Lipa is a seasoned knowledge management leader and practitioner and will bring key skills and insights to close the "theory to practice" gap.

Future Work Topic Three

Although significant effort was put forth to design, distribute and analyze findings, the number of respondents was not deemed to be statistically significant. While disappointing, not all research will yield a positive result. As the practice of KM continues to grow in the biopharmaceutical sector, an opportunity exists to build on the KM Survey and seek additional responses.

Other topics worthy of consideration include:

- Detailed exploration and recommendations of the knowledge needs/contributions for two items suggested in the drat Q12 –
- Exploration of the role KM in the 'digital' transformation?

9.5 In closing: - Final thoughts for the biopharmaceutical sector:

The biopharmaceutical sector challenges are not unique. In particular the sector should take cues from other regulated industries, such as aerospace, with complex and lengthy product lifecycles, much like the biopharmaceutical sector. Like aerospace, the biopharmaceutical sector must invest in the systems and processes to holistically manage knowledge, both explicit and the invaluable tacit knowledge locked within organizations. Looking towards the future of advanced therapeutics, these novel products bring new challenges in terms of accelerating the development and manufacture of such therapies. For traditional biopharmaceutical products the regulatory paradigm continues to struggle with achieving the aspirations of ICH Q8 - Q12. In the case of advanced therapies the regulatory paradigm is still evolving and is not yet well defined for the therapies of the future, (Paulson & Kane, 2018). The foundations of ICH Q8 -Q12 build on science, application of risk-based approaches and utilization of prior knowledge. The biopharmaceutical sector will require not just adequate, but *excellent* knowledge management programs, systems and approaches in order to meet the future needs of the business, and ultimately, the needs of the patients.

"*Think big, start small, but start"*
M. Lipa on the KM Journey (Martin Lipa, 2015)

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Appendices

Appendix I: Literature Review Index

Appendix II: ISPE Pharma KM Survey Questions

Appendix III: Knowledge Mapping Chapter and Tools: Chapter 26 “Identification of Critical Knowledge – Demystifying Knowledge Mapping” in *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry*”

Appendix IV: Knowledge Management Effectiveness Evaluation (KMEE)

Appendix IA: Chapter Two Literature Review Index – Analysis of Journal Articles

[1]Research and Development [2]Product Realization [3] Manufacturing [4]Other (e.g. Discovery, Marketing, Clinical, etc.)

Ref No.	Analysis of Journal Article: Title	R&D[1]	PR[2]	Mfg[3]	Other[4]	Author	Publication
1	A risk management ontology for Quality-by-Design based on a new development approach according GAMP 5.0		1			Guebitz, Brigitte; Schnedl, Hubert; Khinast, Johannes G	International Journal of Pharmaceutics, 05/2016, Volume 505, Issue 1-2
2	Knowledge management in the QbD paradigm: manufacturing of biotech therapeutics		1			Herwig, C; Garcia-Aponte, OF; Golabgir, A; Rathore, A	Journal of Knowledge Management, 02/2011, Volume 15, Issue 1
3	Knowledge management in secondary pharmaceutical manufacturing by mining of data historians—A proof-of-concept study			1		Meneghetti, Natascia; Facco, Pierantonio; Bezzo, Fabrizio;	Journal of Engineering and Technology Management (JET-M), 12/2005, Volume 22, Issue 4
4	Deterrents to knowledge-sharing in the pharmaceutical industry: a case study			1		Athar Mahmood Ahmed Qureshi , Nina Evans	Journal of Knowledge Management, Volume: 19 Issue: 2, 2015
5	Role of Knowledge Management in Development and Lifecycle Management of Biopharmaceuticals	1	1			Rathore, Anurag S Garcia-Aponte, Oscar Fabián Golabgir, Aydin Vallejo-Diaz, Bibiana Margarita, Herwig, Christoph	Pharmaceutical Research, Volume 34, Issue 2, 2017
6	A Knowledge Management Framework and Approach for Clinical Development				1	Salzano, KA; Maurer, CA; Wyvratt, JM;	Nature Reviews Drug Discovery, 04/2014, Volume 13, Issue 4
7	Advances in knowledge management for pharmaceutical research and development	1				Torr-Brown, S	INTERNATIONAL JOURNAL OF TECHNOLOGY MANAGEMENT, 2009, Volume 47, Issue 1-3
8	Critical factors in adopting a knowledge management system for the pharmaceutical industry				1	Hung, YC; Huang, SM; Lin, QP	The International Journal of Human Resource Management, 09/2003, Volume 14, Issue 6

Ref No.	Analysis of Journal Article: Title	R&D[1]	PR[2]	Mfg[3]	Other[4]	Author	Publication
9	Diffusing knowledge-based core competencies for leveraging innovation strategies: Modeling[1] outsourcing to knowledge process organizations (KPOs) in pharmaceutical networks				1	Gupta, Samir; Woodside, Arch; Dubelaar, Chris; Bradmore, Chris	Knowledge and Process Management, 04/2001, Volume 8, Issue 2
10	Effective knowledge management in translational medicine	1				Szalma, S; Koka, V; Khasanova, T; More...	INDUSTRIAL & ENGINEERING CHEMISTRY RESEARCH, 09/2016, Volume 55, Issue 36
11	Generic Knowledge Strategies in the U.S. Pharmaceutical Industry				1	Paul Bierly; Alok Chakrabarti	CURRENT OPINION IN DRUG DISCOVERY & DEVELOPMENT, 05/2005, Volume 8, Issue 3
12	Integrative knowledge management to enhance pharmaceutical R&D	1				Marti-Solano, M; Birney, E; Bril, A; More...	International Journal of Production Economics, 2009, Volume 122, Issue 1
13	Knowledge and information flows in supply chains: A study on pharmaceutical companies				1	Pedroso, Marcelo Caldeira; Nakano, Davi	Project Management Journal, 04/2013, Volume 44, Issue 2
14	Knowledge networking to support medical new product development	1				Mohan, Kannan; Jain, Radhika; Ramesh, Balasubramaniam	INDUSTRIAL MARKETING MANAGEMENT, 04/2014, Volume 43, Issue 3
15	Knowledge transfer and R & D in pharmaceutical companies: a case study	1				Schweizer, Lars	Knowledge and Process Management, 07/2011, Volume 18, Issue 3
16	Knowledge-sharing enablers and barriers in pharmaceutical research and development	1				Lilleoere, Anne-Mette; Holme Hansen, Ebba	California Management Review, 04/1998, Volume 40, Issue 3
17	Knowledge-sharing Practices in Pharmaceutical Research and Development—a Case Study	1				Lilleoere, Anne-Mette; Hansen, Ebba Holme	COMPUTERS & CHEMICAL ENGINEERING, 1996, Volume 20
18	Managing knowledge assets under conditions of radical change: The case of the pharmaceutical industry	1				Allarakhia, Minna; Walsh, Steven	Technovation, 2011, Volume 31, Issue 2
19	Medinfolink: a practical approach to knowledge management at SmithKline Beecham Pharmaceuticals				1	Robson, A; Bandle, E; Ince, J	TRENDS IN BIOTECHNOLOGY, 07/2015, Volume 33, Issue 7

Ref No.	Analysis of Journal Article: Title	R&D[1]	PR[2]	Mfg[3]	Other[4]	Author	Publication
20	Non-exclusive attention-structure for inter-organizational knowledge flow and performance of the pharmaceutical firm				1	Malik, Tariq	JOURNAL OF PHARMACEUTICAL INNOVATION, 03/2015, Volume 10, Issue 1
21	OntoMODEL: Ontological Mathematical Modeling Knowledge Management in Pharmaceutical Product Development	1				Suresh, P; Hsu, SH; Akkisetty, P	New Technology, Work and Employment, 07/2002, Volume 17, Issue 2
22	Optimizing Knowledge Creation at Bristol-Myers Squibb—a Case Study within Pharmaceutical Development	1				Dali, M; Stewart, A; Behling, RW	Journal of Knowledge-based Innovation in China, 03/2012, Volume 4, Issue 1
23	Project Management Knowledge Flows in Networks of Project Managers and Project Management Offices: A Case Study in the Pharmaceutical Industry				1	Müller, Ralf; Glückler, Johannes; Aubry, Monique	Library Review, 03/2006, Volume 55, Issue 3
24	Sourcing knowledge: R&D outsourcing in UK pharmaceuticals	1				Howells, J; Gagliardi, D; Malik, K	Governance, 01/2011, Volume 24, Issue 1
25	Structural social capital evolution and knowledge transfer: Evidence from an Irish pharmaceutical network	1				Filieri, R; McNally, RC; O'Dwyer, M	R&D Management, 03/2008, Volume 38, Issue 2
26	The growth and management of R&D outsourcing: evidence from UK pharmaceuticals	1				Howells, Jeremy; Gagliardi, Dimitri; Malik, Khaleel	Journal of Workplace Learning, 02/2009, Volume 21, Issue 2
27	The limits of knowledge management				1	McKinlay, Alan	THERAPEUTIC INNOVATION & REGULATORY SCIENCE, 09/2016, Volume 50, Issue 5
28	The role of Knowledge Management in the pharmaceutical enterprise				1	Pappa, DD; Stergioulas, LK; Telonis, P	Expert Systems With Applications, 06/2012, Volume 39, Issue 8
29	Knowledge-sharing enablers and barriers in pharmaceutical research and development	1				Anne-Mette Lilleoere, Ebba Holme Hansen	Journal of Knowledge Management, Volume: 15 Issue: 1, 2011
30	Knowledge management receptivity at a major pharmaceutical company				1	Jay Liebowitz	Journal of Knowledge Management, Volume: 4 Issue: 3, 2000
31	The nuances of knowledge creation and development in Indian pharmaceutical industry	1				N.L. Sharma, Susobhan Goswami	Journal of Knowledge Management, Volume: 13 Issue: 5, 2009

Ref No.	Analysis of Journal Article: Title	R&D[1]	PR[2]	Mfg[3]	Other[4]	Author	Publication
32	Heedful interrelating, knowledge sharing, and new drug development				X	Styhre, A; Ollila, S; Roth, J; Williamson, D; Berg, L	Journal of Knowledge Management, Volume: 12 Issue: 3, 2008
33	Designing workspaces for cross-functional knowledge-sharing in R & D: the “co-location pilot” of Novartis	X				Annina Coradi , Mareike Heinzen , Roman Boutellier	Journal of Knowledge Management, Volume: 19 Issue: 2, 2015
34	Enabling knowledge creation: learning from an R&D organization	X				Jonas Roth	Journal of Knowledge Management, Volume: 7 Issue: 1, 2003
35	Shaping knowledge management: organization and national culture				X	Rémy Magnier-Watanabe, Dai Senoo	Journal of Knowledge Management, Volume: 14 Issue: 2, 2010
36	Knowledge management and drug development	X				Stuart Koretz, Greg Lee	Journal of Knowledge Management, Volume: 2 Issue: 2, 1998
37	Organizational characteristics as prescriptive factors of knowledge management initiatives				X	Rémy Magnier-Watanabe, Dai Senoo	Journal of Knowledge Management, Volume: 12 Issue: 1, 2008
38	Knowledge Management Benchmarks				X	Rory L. Chase	Journal of Knowledge Management, Volume: 1 Issue: 1, 1997
39	Knowledge management practices in Indian industries – a comparative study				X	Deepak Chawla, Himanshu Joshi	Journal of Knowledge Management, Volume: 14 Issue: 5, 2010
40	Design-for-Six-Sigma to Develop a Bioprocess Knowledge Management Framework		X			Junker, B., Maheshwari, G., Ranheim, T., Altaras, N., Stankevicz, M., Harmon, L., … D’anjou, M.	PDA Journal of Pharmaceutical Science and Technology, 65(2), 140–165, 2011

Appendix IB: Chapter Two Literature Review Index – Analysis Symposia/ Conferences

[1] Health Authorities, [2] Academia, Knowledge Management thought leaders

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes	Venue
1	Knowledge Management and ICH	Stephan Roenninger, PhD	Amgen, Inc	1			KM & Quality Risk Management	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
2	Knowledge Management: Opportunities and Challenges for Legacy Products in an Outsourced Environment Operations/Supply Chain, Shire Pharmaceuticals	Eda Ross-Montgomery, PhD	Shire Pharmaceuticals	1			Product and Process Knowledge	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
3	The Data Management Foundations of Effective Knowledge Management in Process Development and Manufacturing	Justin Neway, PhD	Accelrys, Inc.	1			Product and Process Knowledge	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
4	Knowledge for the Future	Cindy Hubert	APQC			1	KM Sponsorship/ Business Value	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
5	Platform Knowledge Management	David Reifsndyer, PhD	Genentech	1			Product and Process Knowledge	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
6	European Regulatory Perspective of Knowledge Management	Tor Graberg	Medical Product Agency		1		Regulatory collaboration & sharing	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
7	Knowledge at NASA	Edward Hoffman, PhD	NASA			1	Accelerated Learning	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes	Venue
8	Seamless Process Knowledge Lifecycle – Preserve, Manage and Exploit Product and Process Knowledge	Paige Kane, Joe Brennan	Pfizer	1			Product and Process Knowledge	2014: PDA Knowledge Management Workshop - Bethesda, MD May 2014
9	Understanding the Role of Knowledge Excellence in Delivering Outcomes that Matter to the Patient	Nuala Calnan, PhD	Dublin Institute of Technology			1	Patient protection	2015 ISPE/FDA/PQRI Quality Manufacturing Conference - Washington DC, USA June 2015
10	Managing What We Know- How Pfizer Global Supply is implementing a holistic KM Strategy	Paige Kane	Pfizer	1			Holistic KM Program	2015 ISPE/FDA/PQRI Quality Manufacturing Conference - Washington DC, USA June 2015
11	Knowledge and Risk Based Strategies for Lifecycle Management: A Regulatory Perspective	Christina Capacci-Daniel, Ph.D.	FDA		1		Regulatory collaboration & sharing	2015 ISPE/FDA/PQRI Quality Manufacturing Conference - Washington DC, USA June 2015
12	Managing What We Know - How Pfizer Global Supply is implementing a holistic KM Strategy	Paige Kane	Pizer	1			Holistic KM Program	2015 DIA Annual Meeting-Washington DC USA, June 2015
13	Compliance and Change Control: Checking that the Manufacture/CMC is Maintained in Accord with the Terms of the License	Peter Lassoff, Pharm.D.	Qunitiles	1			Regulatory filings and KM	2015 DIA Annual Meeting-Washington DC USA, June 2015
14	Recommendations for a streamlined, global assessment of CMC changes and optimized dossier preparation process	Kim Northam	Accenture	1			Regulatory filings and KM	2015 DIA Annual Meeting-Washington DC USA, June 2015

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes	Venue
15	Enabling Knowledge Flow	Cindy Hubert	APQC			1	Business acceleration/ risk mitigation	2015: KMDublin2015, March 2015, Dublin Ireland
16	Knowledge Management: A Regulatory Perspective	Jacques Morenas PhD	ANSM		1		Regulatory collaboration & sharing	2015: KMDublin2015, March 2015, Dublin Ireland
17	The Future of Regulatory Science - thinking Globally, Domestically and Collaboratively	Emer Cook	EMA - European Medicines Agency		1		Regulatory collaboration & sharing	2015: KMDublin2015, March 2015, Dublin Ireland
18	RSI Knowledge Management Symposium opening remarks	Pat O'Mahony PhD	HPRA		1		Patient protection	2015: KMDublin2015, March 2015, Dublin Ireland
19	Challenges in Knowledge Sharing	Dr. Yukio Hiyama	MHLW (retired) - Ministry of Health, Labour and Welfare		1		Seeking knowledge/ accelerated learning	2015: KMDublin2015, March 2015, Dublin Ireland
20	NASA Project Knowledge and Complex Missions	Ed Hoffman PhD	NASA			1	Seeking knowledge/ accelerated learning	2015: KMDublin2015, March 2015, Dublin Ireland
21	Enhancing Post Market Surveillance- An analysis of self-reported health outcomes and safety data from web-based sources for FDA/CDRH	Mark Wolf PhD	SAS Institute for FDA		1		Patient protection	2015: KMDublin2015, March 2015, Dublin Ireland
22	A Practical approach to managing knowledge in MMD	Martin Lipa	Merck	1			Holistic KM Program	2015: KMDublin2015, March 2015, Dublin Ireland

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes	Venue
23	Pfizer Global Supply's journey leveraging knowledge management (KM) for product and process understanding	Paige Kane	Pfizer	1			Holistic KM Program	2015: KMDublin2015, March 2015, Dublin Ireland
24	Integrating Knowledge Management with Quality management Systems	Barbara Allan PhD	Eli Lilly & Company	1			KM & Quality Management System	2015: KMDublin2015, March 2015, Dublin Ireland
25	Knowledge Management: Basic Understanding and Practical Implementation	Stephan Ronniger, PhD	Amgen	1			KM & Quality Risk Management	2015: KMDublin2015, March 2015, Dublin Ireland
26	Creating a Successful KM Capability: A leader's responsibility	Dr. Michael Thien	Merck	1			KM Sponsorship/ Business Value	2015: KMDublin2015, March 2015, Dublin Ireland
27	Management of Knowledge from a CROW perspective	Daphne Smyth	ICON			1	Knowledge Flow	2015: KMDublin2015, March 2015, Dublin Ireland
28	Implementing Knowledge Management- Industry Perspective	Jodi Schuttig	Merck	1			Case Study Implementing KM	2016 DIA Annual Meeting - Philadelphia PA, June 2016
29	Knowledge Management - Why wonder when you can know	James Roberts	GlaxoSmithKline	1			Laboratory Data and Knowledge	2016 DIA Annual Meeting - Philadelphia PA, June 2016
30	CMC Data Readiness and Future Proofing for IDMP	Kim Northam	Accenture	1			Regulatory Submissions	2016 DIA Annual Meeting - Philadelphia PA, June 2016

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes	Venue
31	Crowd Sourcing Technical Knowledge with a Wiki	Roland Zhou	Biogen	1			Product and Process Knowledge	2016 ISPE Annual Meeting- Atlanta, GA September 2016
32	Prior Knowledge Usage in the age of ICH Q12	Dr. Jose Menezes	4Tune Engineering			1	Product and Process Knowledge	2016 ISPE Annual Meeting- Atlanta, GA September 2016
33	Leveraging Knowledge in the BioPharma Industry	Paige Kane	Pfizer	1			KM Industry Overview	2016 ISPE European Conference- Frankfurt, Germany March 2016
34	Knowledge Management - a key to data integrity	Paige Kane	Pfizer	1			KM and Data Integrity	2016 ISPE European Conference- Frankfurt, Germany March 2016
35	Knowledge Management in the context of ICH Q12	Ingrid Markovic	US FDA		1		Regulatory collaboration & sharing	2016 ISPE/FDA/PQRI Quality Manufacturing Conference - Bethesda, MD USA, June 2016
36	Exploring the link between Knowledge Management (KM) and Quality Risk Management (QRM)	Mariah Deguara-Pagan	Pfizer	1			Product and Process Knowledge	2016 ISPE/FDA/PQRI Quality Manufacturing Conference - Bethesda, MD USA, June 2016
37	The relationship between Data Integrity and Knowledge Management	Paige Kane	Dublin Institute of Technology			1	KM and Data Integrity	2016 ISPE/FDA/PQRI Quality Manufacturing Conference - Bethesda, MD USA, June 2016
38	Knowledge Management, Effective Learning, and Paying Attention	Matthew Neal	LIQUENT	1			Accelerated Learning	2017 ISPE Annual Meeting - San Diego, CA USA, October 2017

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes	Venue
39	The Current State of KM in the Biopharmaceutical Industry	Paige Kane	Dublin Institute of Technology			1	Pharmaceutical Industry Survey Results Overview	2017 ISPE Annual Meeting - San Diego, CA USA, October 2017
40	A Vision for Prior Knowledge and How to Management as an Asset	Martin Lipa	Merck	1			Identification of critical knowledge/ Product and Process Knowledge	CASSS CMC Strategy Forum – Washington D.C., USA, January 2018
41	Knowledge Management: How Knowledge is Captured, Maintained and Leveraged Across the Product Lifecycle	Michelle Twomey	Pfizer	1			Product and Process Knowledge/ KM Tools	IFPAC - N. Bethesda, Maryland USA, February 2018
42	Using Knowledge Mapping to Extract a Decade of Technical Expertise	Steph Friedrichsen	Lilly	1			Identification of critical knowledge/ KM Tools	APQC 2018 Annual KM Conference – Houston Texas USA April 2018
43	Knowledge as an Asset: Accelerating Knowledge Availability Across the Lifecycle	Paige Kane	Dublin Institute of Technology			1	Identification of critical knowledge/ Product and Process Knowledge	2018 PDA Europe Conference – Berlin Germany, June 2018
			Total	25	8	10		

Appendix IC: Chapter Two Literature Review Index – Case Studies Published in A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry (Calnan, Lipa, Kane, & Menezes, 2018) – Released June 2017

[1] Health Authorities, [2] Academia, Knowledge Management thought leaders

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes
1	Communities of Practice: A Story About the VTN and the Value of Community	Renee Vogt, Joseph Schaller & Ronan Murphy	Merck	1			Collaboration and knowledge sharing
2	Knowledge Management Case Study: The Practical Application of a User-Facing Taxonomy to Improve Knowledge Sharing and Reuse Across the Biopharmaceutical Product Lifestyle	Adam Duckworth, Vince Capodanno, Thomas Loughlin	Merck	1			Finding Explicit Knowledge
3	The House of Knowledge Excellence: A Framework for Success	Paige Kane & Marty Lipa	Dublin Institute of Technology & Merck	1			Holistic KM Program
4	Industry Perspective: KM Evolution at Pfizer	Paige Kane & Alton Johnson	Pfizer - Global Supply	1			Holistic KM Program
5	Industry Perspective: KM Evolution at Merck	Marty Lipa & Jodi Schuttig	Merck	1			Holistic KM Program
6	Integrating Knowledge Management with Quality Management Systems	Barbara Allen PhD	Lilly	1			KM & Quality Management System

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes
7	Working with the IS/IT Function to Set Your Knowledge Management Project up for Success	Joseph Horvath PhD	Takeda	1			KM Implementation - IT systems
8	Knowledge Management Implementation: A Guide to Driving Successful Technology Realization	Doug Redden	Industry Consultant			1	KM Implementation - IT systems
9	Why KM is Good Business and Makes Good Business Sense	P.K. Yegneswaran PhD, Dr. Michael Thien & Marty Lipa	Merck	1			KM Sponsorship/ Business Value
10	A People Approach to Managing Knowledge: Who Are You Working For?	Sian Slade & Catherine Shen	BMS	1			Knowledge Flow
11	Identification of Critical Knowledge: Leveraging Knowledge Mapping to Enhance the Value of Knowledge	Paige Kane	Dublin Institute of Technology			1	Knowledge Flow
12	Let's Talk About Knowledge Management: Learning from the Library of Alexandria Disaster	Matthew Neal & Sandra Bush	Amgen	1			Learning from previous knowledge
13	Developing a Lessons Learned Process - Where Lessons Are Learned: A Case Study of Pfizer Pharmaceutical Sciences	Phil Levitt PhD	Pfizer - Pharmaceutical Sciences	1			Learning from previous knowledge
14	Capturing Critical Process and Product Knowledge: The Development of a Product History File	Dave Reifsnyder, Kate Waters & Kayhan Guceli	Genentech-Roche	1			Product and Process Knowledge

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes
15	Integrating Knowledge Management Capabilities for Product Development	Anando Chowdhury	Merck	1			Product and Process Knowledge
16	Knowledge Management Elements in Support of Generation of CMC Regulatory Documentation	Beth Junker PhD	Merck	1			Product and Process Knowledge
17	Knowledge Driven Product and Process Lifecycle Management: Introducing Quds Elements into Legacy Products	Marco Strohmeier, Christelle Pradines, Francisca F. Gouveia, Jose C. Menezes	Roche	1			Product and Process Knowledge
18	Knowledge Management Case Study: Using Near Real-Time Data Analytics and Performance Metrics to Ensure a Robust and Resilient Supply Chain	Eda Ross Montgomery, Mani Sundararajan, David Lowndes & Gabriele Ricci	Shire	1			Product and Process Knowledge
19	Accelerating the Opportunity for the Pharmaceutical Industry through KM	Lauren Trees & Cindy Hubert	APQC			1	Accelerated Learning
20	An Academic Perspective: ICH Q10 Knowledge Management: The Orphan Enabler	Nuala Calnan, Anne Greene & Paige Kane	Dublin Institute of Technology			1	Effective PQS Enablement
21	An Academic Perspective: Effective Knowledge Assessment	Mohamed Ragab & Amr Arisha	Dublin Institute of Technology			1	Identification of critical knowledge / improving organizational performance

No.	Title	Author	Organization	Industry	HA[1]	Other[2]	Themes
22	The Theory of Knowledge Management	Stefanie N. Lindstaedt, Paul Czech & Angela Fessi	Graz University of Technology			1	Data to knowledge
23	A Regulatory Perspective: From Data to Knowledge on Quality Defect Reporting for Regulators	Nuala Calnan PhD	Dublin Institute of Technology			1	Patient protection
24	A Future Perspective: Potential Regulatory Impact from ICH Q12	Bill Paulson & Paige Kane	IPQ/Dublin Institute of Technology			1	Efficient regulatory review
25	A Perspective from NASA: Knowledge Services and Accelerated Learning in NASA: The REAL Knowledge Approach	Ed Hoffman & Jon Bolye	NASA			1	Identification of critical knowledge/ accelerated learning
26	A Regulatory Perspective: Knowledge Management at Swissmedic	Michael Renaudin & Hansjurg Leuenberger	Swiss Medic		1		Enabling knowledge workers
27	A Patient Perspective: Who Moved My Facts?	Dave deBronkart & Lucien Engelen				1	Seeking knowledge/ knowledge acquisition
			TOTAL	16	1	10	

Appendix II: ISPE Pharma KM Survey Questions (2017)

ISPE KM Pharma survey questions were designed to be quantitative in nature whenever possible to facilitate comparative analysis to the APQC and Knoco surveys (APQC, 2015; Knoco, 2017). In the majority of cases, questions were used verbatim from the APQC and Knoco surveys. Additions are noted, and additional selection criteria are highlighted in red text. Biopharmaceutical Sector question were vetted with the ISPE KM Task Team.

#	Survey Questions for ISPE KM Benchmarking Survey	Survey Section	Survey Originator
1	Please give the name of the organization to which your answers refer, or the part of the organization, if different parts apply KM differently. (The name of the organization will be kept confidential, and not shown in the final report. We ask for the name in order to aggregate responses from multiple people within the same organization).	**Demographics**	Knoco
	(Fill in the blank)		Knoco
2	Which of the following best describes your organization?	**Demographics**	ISPE Add
	Pharma/Bio Pharma/Medical Device Company		ISPE Add
	Medical Device Company		
	Biopharmaceutical Company		
	Pharmaceutical Company		
	Biopharmaceutical/Pharmaceutical Company		
	Contract Manufacturing/Contract Research Organization		
	Supplier/Technology Organization		ISPE Add
	Consulting/ Service Provider		
	Health Authority		ISPE Add
	Academic		ISPE Add
	Other: Please specify (fill in the blank)		ISPE Add
3	Which of the following best describes your own role (current or previous) within the organization your are describing?	**Demographics**	Knoco
	Leading a KM initiative within the organization		Knoco
	A full time member of a KM initiative team		Knoco
	A part time member of a KM initiative team		Knoco
	A KM role within the operational part of the organization		Knoco
	A role within a community of practice		Knoco
	No specific KM role		Knoco
	I consult to the organization (not an employee)		Knoco
	I have studied the organization (not an employee)		Knoco
	Other: Please specify (fill in the blank)		Knoco
4	**Please list the functional organization where you work-**	**Demographics**	ISPE Add
	Research & Development		ISPE Add
	Commercial Manufacturing		ISPE Add
	Quality Assurance /Quality Control		ISPE Add
	Regulatory Affairs		ISPE Add
	Clinical Supplies Manufacturing		ISPE Add
	Clinical Research		ISPE Add
	Technical Operations		ISPE Add
	Information Technology		ISPE Add
	Other (please list)		ISPE Add
5	Roughly how many staff currently work for your organization (if you are replying on behalf of your part of the organization, select the number based on that scope)? Please select the closest number from the list below.	**Demographics**	Knoco
	10		Knoco
	30		Knoco
	100		Knoco
	300		Knoco
	1000		Knoco
	3000		Knoco
	10000		Knoco
	30000		Knoco
	100000		Knoco
	300000		Knoco
	1000000		Knoco
6	Which of the following best describes the current status of KM within this organization (or part of the organization)?	**Demographics**	Knoco
	We do not intend to start KM (then you get Q #9)		Knoco
	We are investigating KM but have not yet started		Knoco
	We are in the early stages of introducing KM		Knoco
	We are well in progress with KM		Knoco
	KM is embedded in the way we work		Knoco
	We have tried KM and given up		Knoco
7	What regions of the world are covered by your KM program/effort? (Select all that apply, but select only those regions where the KM program has a significant presence or audience.)	**Demographics**	APQC
	North America		APQC
	South America		APQC
	Europe		APQC
	Middle East/Africa		APQC
	Asia Pacific		APQC

#	Survey Questions for ISPE KM Benchmarking Survey	Survey Section	Survey Originator
8	How many years has your company being doing Knowledge Management? Please select the closest number from the list below.	**Demographics**	Knoco
	0		Knoco
	0.5		Knoco
	1		Knoco
	2		Knoco
	4		Knoco
	8		Knoco
	16		Knoco
	32		Knoco
	Don't know		Knoco
9	**(If answer is "do not intend to start" from question 6, you get question 9)** Because you have decided not to adopt KM, **we will only ask you one question, then the survey is finished. thank you**	**Page for organizations that decided not to start**	Knoco
9.1	Please put the following reasons in order of their importance in you or your senior managers **deciding not to adopt KM**, with 1 being the highest importance. Choose n/a for all that do not apply	**Page for organizations that decided not to start**	Knoco
	Our culture is not ready for KM		Knoco
	We think it would be too expensive		Knoco
	We have other priorities at the moment		Knoco
	KM is not relevant to us		Knoco
	We don't know enough about KM		Knoco
	Experiences at other companies lead us to believe it will fail		Knoco
	There is no requirement to adopt KM		ISPE Add
	We don't think it will add value		Knoco
	We already do it under another name - please list name		Knoco
9.2	Why did you abandon KM? (Choose as many options as are relevant)	**org have given up**	Knoco
	Internal Reorganization		Knoco
	Cultural barriers proved too strong		Knoco
	KM did not deliver the expected benefits		Knoco
	KM was taking too long to deliver		Knoco
	The technology did not deliver as expected		Knoco
	Lack of involvement from staff		Knoco
	Other: Please specify (fill in the blank)		Knoco
10	At the moment, roughly how large is the KM team that runs the KM program in your (part of the) organization? Please choose the number that you believe most closely matches the team size (zero if you have no team)	**Time and Resources**	Knoco
	0		Knoco
	1		Knoco
	2		Knoco
	4		Knoco
	8		Knoco
	12		Knoco
	20		Knoco
	30		Knoco
	50		Knoco
	I don't know		Knoco
11	To which department does the KM team report?	**Time and Resources questions**	Knoco
	Business Improvement/ Operational Excellence		Knoco
	Engineering/ Technical Services		Knoco
	Information Technology		Knoco
	Human Resources		Knoco
	Innovation		Knoco
	Internal Communications		Knoco
	Learning and Development/Training		Knoco
	Legal		Knoco
	Operations (e.g. Manufacturing Ops)		Knoco
	Research & Development/Technology Development		Knoco
	Projects		Knoco
	Quality		Knoco
	Separate line to Sr. Mgmt. (e.g. direct reporting to a Sr. manager or management		Knoco
	Strategy		Knoco
	N/A - No KM Team		Knoco
	Not decided yet		Knoco
	Other: Please specify (fill in the blank)		Knoco
12	Which of these reporting structures is closest to the situation in your organization?	**Time and Resources questions**	Knoco
	KM Team reports to an individual		Knoco
	KM Team reports to a committee		Knoco
	KM Team reports to an individual supported by a steering committee		Knoco
	KM Team is fully autonomous and self steering with no reporting lines		Knoco
	I don't know		Knoco

#	Survey Questions for ISPE KM Benchmarking Survey	Survey Section	Survey Originator
13	*Other than the KM Team and it's leadership* , which of these other KM roles currently exist in the organization? Please choose all that apply	**Time and Resources questions**	Knoco
	Community of Practice Leader		Knoco
	Community of Practice Facilitator (in addition to the Leader)		Knoco
	Knowledge Management Champion or Coach		Knoco
	Knowledge Manager for a department or division		Knoco
	Knowledge Manger for a specific project		Knoco
	"Owner" for a specific knowledge project		Knoco
	Content management support		Knoco
	KM Technology support		Knoco
	No other roles		Knoco
	Other (please specify)		Knoco
14	What is the organizational scope of your KM initiative or program?	**Scope, focus areas and value delivery for KM**	Knoco
	The whole organization		Knoco
	Many divisions, business stream or regions		Knoco
	One division, business stream or region		Knoco
	One pilot area		Knoco
	Not determined yet		Knoco
	I don't know		Knoco
15	What functions are within the scope of your KM initiative or program? (check all that apply)		ISPE Add
	Research & Development		ISPE Add
	Commercial Manufacturing		ISPE Add
	Clinical Supplies Manufacturing		
	Quality Assurance /Quality Control		
	Regulatory Affairs		ISPE Add
	Clinical Research		ISPE Add
	Contract Manufacturing Organization/ Contract Research Org (CMO/CROs)		ISPE Add
	Other - please list		ISPE Add
15a	**Branching Question for each function selected**		ISPE Add
	We do not intend to start KM		Knoco
	We are investigating KM but have not yet started		Knoco
	We are in the early stages of introducing KM		Knoco
	We are well in progress with KM		Knoco
	KM is embedded in the way we work		Knoco
	We have tried KM and given up		Knoco
16	Rank the following business drivers for KM in order of their importance in your organization (1 is the primary driver for doing KM, 2 is secondary driver and so on). Choose n/a where not appropriate or applicable	**Scope, focus areas and value delivery for KM**	Knoco
	Provide a better service to customers and clients		Knoco
	Improve operational effectiveness		Knoco
	Impact safety and the environment		Knoco
	Enable company growth		Knoco
	To increase internal efficiency (time and cost)		Knoco
	Retain knowledge at risk of loss		Knoco
	Improve innovation		Knoco
	Regulatory expectation (e.g. ICH Q10)		ISPE Add
	Rapid product development		ISPE Add
	knowledge and risk based decision making		ISPE Add
	Improve regulatory and change processes		ISPE Add
17	Please indicate the approximate employee audience for **your organization's KM tools, approaches, and initiatives**. (If different tools, approaches, and initiatives have different audiences, please indicate the total number of employees covered by all.)	**Scope**	APQC
	Fewer than 100		APQC
	100 - 999		APQC
	1,000 - 9,999		APQC
	10,000 - 49,999		APQC
	50,000 - 99,999		APQC
	100,000 or more		APQC

#	Survey Questions for ISPE KM Benchmarking Survey	Survey Section	Survey Originator
18	Rank the following in order of primary focus of your KM program (1 is the primary focus, 2 is the secondary and so on) Choose n/a where not appropriate	**Scope, focus areas and value delivery for KM**	Knoco
	Improved access to documents (including search and portals)		Knoco
	Connecting people through communities or networks		Knoco
	Learning from experience		Knoco
	Knowledge retention		Knoco
	Innovation		Knoco
	Creation and provision of best practice		Knoco
	Improved management of documents		Knoco
	Knowledge based science/engineering		Knoco
	Training and development		Knoco
	Providing knowledge to customer facing staff (support or sales)		Knoco
	Big data		Knoco
	Accessing external knowledge and intelligence		Knoco
	Other (please specify)		ISPE Add
19	What of these have been the main barriers to KM so far? Please rank these in order of priority with 1 being the greatest barrier	**Governance and Change**	Knoco
	Lack of defined KM approach (incl. vision/strategy)		Knoco
	Lack of prioritization and support from leadership		Knoco
	Cultural issues		Knoco
	Lack of KM incentives		Knoco
	Incentives for wrong behaviors (e.g. internal competition, inability to charge time to KM activities)		Knoco
	Lack of KM roles and accountabilities		Knoco
	Lack of support from departments such as IT and HR., etc.		Knoco
	Insufficient technology		Knoco
	Other (please specify)		ISPE Add
20	How has KM been implemented in your organization? Please choose the answer closest to your situation.	**Governance and Change**	Knoco
	Introduce technology and hope for viral growth		Knoco
	Introduce and promote technology		Knoco
	Introduce processes (e.g. CoPs, lessons learned, etc.)		Knoco
	A KM pilot phase followed by a roll out phase		Knoco
	Top down directive to the entire company		Knoco
	KM by stealth/Guerrilla KM		Knoco
	As a change management approach		Knoco
	Not decided yet		Knoco
	Other (please specify)		Knoco
21	If you have gathered these metrics, how useful have they been in steering your KM program? (Vital, Useful, Interesting, No value, Too early to tell, Not used)	**Governance and Change**	Knoco
	Activity levels (tweets, posts, lessons)		Knoco
	Maturity Metrics		Knoco
	Knowledge reuse		Knoco
	read levels for online material/answers		Knoco
	Value added through KM		Knoco
	User ratings for online material/content		Knoco
	Compliance w/KM expectations/policy		Knoco
	Number of users/number of community members		Knoco
22	Which of these cultural issues have proven to be barriers to your KM initiative? (please select all that apply)	**Governance and Change**	Knoco
	Lack of empowerment		Knoco
	Lack of honesty in sharing		Knoco
	Lack of performance drive		Knoco
	Preferring invention to re-use		Knoco
	Lack of acceptance of new ideas ("Not invented here")		Knoco
	Secrecy		Knoco
	Lack of openness for sharing		Knoco
	Short term thinking		Knoco
	Internal competition		Knoco
	Lack of challenge to the status quo		Knoco
	None of the above		Knoco

#	Survey Questions for ISPE KM Benchmarking Survey	Survey Section	Survey Originator
23	For which of these purposes do you use a defined Process as part of your KM program? (as an example, an After Action review is a process for knowledge and lessons from teams and projects, a Knowledge Cafe is a process for Discussing and sharing knowledge within a group)	**Knowledge Management processes**	Knoco
	Transferring knowledge and experience from one person to another		Knoco
	Identification of good practices		Knoco
	Capturing knowledge and lessons from teams and projects		Knoco
	Transferring knowledge and experience from one team to another		Knoco
	Creating new knowledge		Knoco
	Capturing knowledge from individuals		Knoco
	Reviewing past lessons and knowledge		Knoco
	Discussing and sharing knowledge within a group		Knoco
	Combining knowledge into best practices		Knoco
	Organizing core product and process knowledge		ISPE Add
	None of the above		Knoco
24	Which of the following are currently in place at your organization, as far as you know?	**KM processes**	Knoco
	KM Success Stories		Knoco
	KM reference materials		Knoco
	Knowledge Management Strategy		Knoco
	KM Champions within divisions and organizational units		Knoco
	KM Business case		Knoco
	Incentive program		Knoco
	Defined approach to KM (e.g. KM framework)		Knoco
	KM policy or equivalent		Knoco
	Senior KM Champion		Knoco
	KM Training		Knoco
	KM Metrics		Knoco
	KM Vision		Knoco
	None of the above		Knoco
25	How effective is current knowledge sharing across boundaries with external partners (very poor, poor, acceptable, good, very good, don't know/ or N/A)		ISPE Add
	External manufacturing/ testing partners (e.g. CMO/CRO's)		APQC
	Suppliers		ISPE Add
	Technology partners (e.g. cloud services, software as a service)		ISPE Add
	Product In-licensing partners		ISPE Add
	External sources of ideas/innovations (e.g. academic, industry groups)		APQC
26	How do you expect your organization's level of knowledge sharing with the following groups to change over the next 3 years? (Increase significantly, Increase slightly, Stay the same, Decrease slightly, Decrease significantly, No sharing with this group)	**Predictions for the Next Three Years**	APQC
	External manufacturing/ testing partners (e.g. CMO/CRO's)		APQC
	Suppliers		ISPE Add
	Technology partners (e.g. cloud services, software as a service)		ISPE Add
	Product In-licensing partners		
	External sources of ideas/innovations (e.g. academic, industry groups)		APQC
27	Please indicate how important the following priorities are to your organization's 2017/2018 KM agenda. For definitions or further information about the priorities listed, see Pac's Knowledge Management Glossary. Unimportant, Slightly important, Somewhat important, Important, Very important	**Specific Plans and Initiatives for 2017/18**	APQC
	Developing a KM Strategy		ISPE Add
	Capturing content and explicit knowledge		APQC
	Eliciting and transferring tacit knowledge		APQC
	Improving content management, infrastructure, and search		APQC
	Enabling sharing and collaboration within and across teams/units		APQC
	Increasing engagement in KM tools and approaches		APQC
	Promoting a knowledge-sharing culture		APQC
	Using data and analytics to improve the flow of knowledge and expertise		APQC
	Increasing the maturity of the KM program/effort		APQC
28	Overall, how positive do you feel about the future strategy and direction of your organization's KM program/effort?	**Plans and Initiatives for 2017/18**	APQC
	Very positive		APQC
	Positive		APQC
	Moderately positive		APQC
	Slightly positive		APQC
	Not at all positive		APQC
	N/A		APQC

#	Survey Questions for ISPE KM Benchmarking Survey	Survey Section	Survey Originator
29	Please indicate which of the following your organization currently ***has in place or plans to implement*** in 2017/18. (Please select all that apply.)	**Plans and Initiatives for 2017/18**	APQC
	Lessons learned database		APQC
	Expertise location system		APQC
	Process or system to capture/transfer critical knowledge		APQC
	Process or system to capture/transfer best practices		APQC
	Enterprise wiki		APQC
	Enterprise content system or portal		APQC
	Enterprise collaboration platform		APQC
	Enterprise social media platform/capabilities		APQC
	System for enterprise video content (e.g., internal YouTube channel)		APQC
	Mobile apps offering employees access to content or collaboration		APQC
	KM Strategy		ISPE Add
	Product Knowledge Strategy		ISPE Add
	Product knowledge tools		ISPE Add
	Technology platforms		ISPE Add
	Process knowledge platforms		ISPE Add
	Risk Assessment Database/System		ISPE Add
30	Does your organization plan to ***significantly promote increased adoption, participation, or use*** of any of the following in 2017/18? (please select all that apply)	**Specific Plans and Initiatives for 2017/18**	APQC
	Lessons learned database		APQC
	Expertise location system		APQC
	Process or system to capture/transfer critical knowledge		APQC
	Process or system to capture/transfer best practices		APQC
	Enterprise wiki		APQC
	Enterprise content system or portal		APQC
	Enterprise collaboration platform		APQC
	Enterprise social media platform/capabilities		APQC
	System for enterprise video content (e.g., internal YouTube channel)		APQC
	Mobile apps offering employees access to content or collaboration		APQC
	KM Strategy		ISPE Add
	Product Knowledge Strategy		ISPE Add
	Technology platforms		ISPE Add
	Process knowledge platforms		ISPE Add
	Product knowledge tools (databases, search, etc.)		ISPE Add
	Risk Assessment Database/System		ISPE Add
31	How well do you believe the ICH Q10 enabler of Knowledge Management is understood in your organization	**Pharma Industry Specific**	ISPE Add
	Understood and implementing		
	Understood but not implementing		
	Poorly understood		
	No understanding		
	I don't know		
32	Are you aware of the upcoming product lifecycle management guidance from ICH (Q12)?	**Pharma Industry Specific**	ISPE Add
	Yes		ISPE Add
	No		ISPE Add
33	If you are aware of the upcoming product lifecycle management guidance from ICH (Q12) is your company proactively evaluating/ assessing the impact (if any).	**Pharma Industry Specific**	ISPE Add
	Yes		ISPE Add
	No		ISPE Add
	I don't know		ISPE Add
33a	If your company has or is in the process of assessing the impact of ICH Q12, what methodologies are being leveraged for this activity?	**Pharma Industry Specific**	ISPE Add
	Please list		ISPE Add
34	Based on your specific industry sector, which of the following (if any) could benefit from additional KM focus/application? Check all that apply	**Parma Industry Specific**	ISPE Add
	New Product Development		ISPE Add
	New drug application processes		ISPE Add
	Technology Transfer		ISPE Add
	Change Control - Mfg sites		ISPE Add
	Deviation Management		ISPE Add
	Risk Assessment		ISPE Add
	Annual Product Review		ISPE Add
	Post approval changes/regulatory changes		ISPE Add
	Continual Improvement of our products		ISPE Add
	Employee up skilling		ISPE Add
	Other - please list up to 3		ISPE Add

Appendix III: Knowledge Mapping Chapter and Tools: Chapter 26 "Identification of Critical Knowledge – Demystifying Knowledge Mapping" in *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry*" (Kane, 2018)

Appended is the full text of the original work of the researcher. This chapter helps bridge KM theory to practice using Knowledge Mapping to identify critical knowledge.

26

Identification of Critical Knowledge: Demystifying Knowledge Mapping

Paige E. Kane
with a special contribution from Christopher Smalley

CONTENTS

Identifying critical knowledge and where it can be found is crucial to enabling the effective flow of that knowledge to enhance timely decision making. This chapter provides examples of how to map your organization's knowledge and assess critical knowledge gaps in order to improve access, flow, and reuse of critical knowledge by the people who need it, when they need it.

Editorial Team

What Is Critical Knowledge?

The harmonized guidance document ICH Q10 *Pharmaceutical Quality System* (*PQS*) (ICH Harmonized Tripartite Guideline, 2008) describes the key components of an effective Pharmaceutical Quality System as well as defining the product lifecycle stages as product development, technology transfer, manufacturing, and product discontinuation. Throughout these various product lifecycle stages a variety of data, information, and knowledge are created. Significantly, ICH Q10 was the first pharmaceutical regulatory guidance to highlight the need for knowledge management, which is listed as one of the two enablers for an effective PQS. The other PQS enabler is defined as Quality Risk Management (QRM).

Due to the globally regulated nature of the pharmaceutical industry, there are also clear expectations within the various regional regulations* regarding the management of data and information related to each product; whether in regards to licensing a new product, details relating to the facility, or about the manufacturing process. More recently, as the industry has matured, companies have increased their organizational capabilities for capturing and processing data and information. However, the question still remains as to how well the industry actually performs in regards to learning from what it captures and reusing data, information, and knowledge to create new insights. Are learnings feeding the product and process improvement? Are they improving the operations of facilities that manufacture and supply said products to the market? Are they ultimately passing on the benefits of the learnings and improvements to the patient?

For many years the pharmaceutical industry has been building capabilities to collect and synthesize data and information for use with new product development, regulatory submissions, event resolution, enhancing process capabilities, and to meet other regulatory commitments. Arguably, a key challenge inherent in these data and information capture is the identification and retention of *critical knowledge*.

> Sally retired from the company; she was the *go to person* for anything to do with product XYZ as she worked on it for 20 years: "Sally seemed to know every scientist that ever touched product XYZ. When we lost her, we lost the link to that product knowledge, I'm sure we did experiments that I can't find now… . I'm frustrated I'll have to do them over… . ."

* For example good manufacturing practices (GMPs), good clinical practices (GCP), and good laboratory practice (GLP)—collectively referred to henceforth as *GxP*.

Does this example sound plausible? The scientists, development team, and process chemists are all *knowledge workers* (Drucker, 1999). The members of the quality team and all the experts instrumental in technology transfer activities (whether a new product introduction or moving an existing product to a new site) are also knowledge workers. Can they easily find the knowledge they need? As *knowledge workers*, the tools and process of the *day job* are quite different than 20 or 30 years ago. Has the industry kept pace with tools and processes suitable for the needs of knowledge workers?

This chapter seeks to understand what is critical knowledge? Is it the same as, or limited to, regulated *GxP* information? If not, then what it is, and why might it be different?

It is the opinion of this author, that critical knowledge includes content, information, and personal knowledge that can add value to the business or the patient. It can therefore be identified from a number of additional and varied sources beyond the traditional *GxP* lens, including the following:

- Lessons learned
- Product or process expertise
- Expertise or *know-how* of how things work, whether it be a technical or a business process

Typically business processes are not regulated by health authorities; however, the knowledge of *how things work* and *how things get done* is critical to an efficient and effective workflow and could have an impact on the ability to consistently deliver high quality medicines to the patient. Often times this knowledge is not recognized as *critical* until someone leaves their role or even more challenging, exits the company. By which point it is often difficult or impossible to capture or recover the respective knowledge. This dilemma of *knowledge loss* is not specific to the pharmaceutical industry; however, there may be a false sense of security regarding the ability to recreate such knowledge within the pharmaceutical industry due to the focus on retention of regulated data, records, and information.

Focusing back to ICH Q10, knowledge management (or managing what we know) is listed as one of the two enablers to an effective Pharmaceutical Quality System. ICH Q10 has set down clear expectations from the regulatory authorities that industry and companies should leverage and utilize the knowledge that they have in order to improve the products, the process, and the delivery to the patient. In order to achieve this improvement we need to understand not only what the critically regulated information and knowledge might be, but we also need to layer in the critical business and technology knowledge that may not be considered *regulated*.

Before we start let us review some of the following key definitions:

- *Data*: Symbols that represent the properties of objects and events (Ackoff, 1989).

- *Information*: Information consists of processed data, the processing directed at increasing its usefulness, for example, data with context (Ackoff, 1989).
- *Content*: The topics or matter treated in a written work.*
- *Tacit knowledge*: Knowledge that you do not get from being taught, or from books, and so on but get from personal experience, for example, when working in a particular organizational knowledge that you do not get from being taught, or from books, and so on but get from personal experience, for example, when working in a particular organization.†
- *Explicit knowledge*: Knowledge that can be expressed in words, numbers, and symbols and stored in books, computers, and so on: knowledge that can be expressed in words, numbers, and symbols and stored in books, computers, and so on.‡
- *Functional knowledge*: Knowledge created within a specific function within an organization (e.g., specifications created by the engineering organization, batch record review processes created by the quality organization).
- *Community or network based knowledge*: Knowledge that is leveraged or curated by a community or a network (e.g., listing of subject matter experts, documents within a particular area of practice, and online discussion boards for a community or network).
- *Process knowledge* (*business or technical*): The knowledge gained from business or technical processes. An example could be reports, e-mail, or lessons learned from a technical transfer activity between two sites (business process), or process diagrams and reports providing process efficiencies for a viral removal step from a manufacturing process.
- *Knowledge*: In the purest sense, as defined by the Cambridge Dictionary†,‡: awareness, understanding, or information that has been obtained by experience or study, and that is either in a person's mind or possessed by people. However, in the context of an organization, knowledge can be a combination of content, information, as well as explicit and tacit knowledge. For simplicity in this text, references to information, content, tacit, and explicit knowledge may be generally referred to as knowledge.

* Merriam Webster online dictionary.
† Cambridge online dictionary.
‡ Cambridge online dictionary.

Introduction to Knowledge Mapping

Knowledge mapping is one useful knowledge management (KM) practice that is been successfully used in many industries to identify and catalog critical knowledge.

Grey describes a knowledge map as "a navigation aid to explicit (codified) information and tacit knowledge, showing the importance and the relationships between knowledge stores and dynamics." (Grey, 1999)

There are several approaches to knowledge mapping, which are discussed in an article published by Jafari (Jafari and Akhavan, 2009) examining multiple knowledge mapping techniques from an academic perspective:

- Yellow paging
- Information flow analysis
- Social networking analysis
- Process knowledge mapping
- Functional knowledge mapping

Although each of the noted methodologies has merit, this chapter will focus on *functional knowledge mapping* and *process knowledge mapping*. These methodologies require little or no capital investment and have proven effective in many sectors, including pharmaceuticals.

> Pinpointing these gaps and barriers [of knowledge] helps the KM core team develop a targeted plan to tackle them in the right way, in the right order, with the right resources.
>
> **APQC***

APQC has conducted pointed research describing knowledge management maturity. Figure 26.1 shows the relationship of knowledge mapping to an overall KM program maturity and the impact of leveraging knowledge mapping as an enabler to progressing KM maturity.

Use Cases for Knowledge Mapping

A knowledge map can help generate the *lay of the land* for a functional group, a community of practice/network, or process (business or technical). The knowledge map provides a visual representation of the content and

* APQC (American Productivity and Quality Center) Not for Profit research organization based in Houston, Texas, United States.

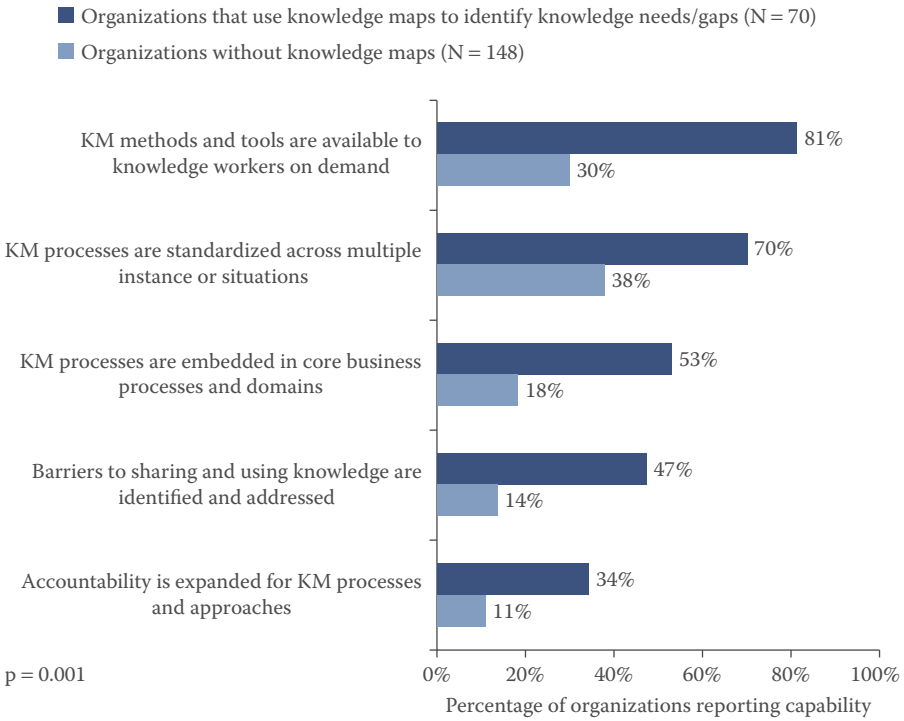

FIGURE 26.1
How Knowledge Mapping relates to KM Maturity (APQC 2016).

knowledge generated, which can be beneficial to describe actual or expected contributions of a group or the current content and knowledge components of a process. These knowledge maps can be visually represented in a spreadsheet, a text document, or other format. Some examples of use cases for knowledge mapping are listed below:

1. *On-boarding new employees* (*new to group or an organization*): When orienting new employees the knowledge map can be leveraged to describe outputs and knowledge created by the group.
2. *Improvement of internal knowledge capture and reuse processes*: Evaluation of existing content and knowledge management approaches can further develop group understanding and, in turn, lead to improved knowledge capture and reuse processes.
3. *Internal reorganization*: When groups are reorganized, technical and business processes that generate critical knowledge may move to new groups. A knowledge map provides a quick reference to ensure the knowledge is accounted for and is managed properly.

If a knowledge map does not exist, it could be a good opportunity to describe the knowledge created by a group and a map as to where it resides.

4. *Development of a new communities of practice* (*CoP*) *or network*: Knowledge mapping can identify the knowledge that already exists and the knowledge that is needed in the future.
5. *Merger and acquisitions*: Leveraging existing knowledge maps (or developing) provide efficiencies when describing knowledge created and curated by respective groups/organizations/communities and networks during merger and acquisition evaluation and following integration activities. Often, only documents are reviewed during these activities not taking in account of the *know how* and *know what*.

Understanding What Is Important

Identification of knowledge via knowledge mapping can also help identify its relative importance—as not all knowledge is equally important. Indeed the manner in which knowledge and content is stored and curated* should be commensurate with the relative importance of the knowledge. This concept is aligned with the recommendation in the ISPE GAMP© Electronic Records and Signature guidance (ISPE Guide, 2005) noting "application of appropriate controls commensurate with the impact of records and the risks to those records."

Knowledge mapping can also assist with *reverse engineering* the methodology and rationale of how information, content, or knowledge is currently captured (see use case 2 in the previous section). Current methods for capturing knowledge and content could be fit for the purpose for those immediately involved in the process; however, it may be difficult for others outside of the said process to find and leverage knowledge if customers of the knowledge have not been identified (refer back to the example of Sally having the knowledge of *know what* and *know who*).

When thinking about mapping knowledge it can be helpful to first categorize how knowledge in the organization is generated. The notion of categorization is intended to help later in determining how to initiate a knowledge mapping exercise and who should be involved.

* *Curate something* (especially on the Internet) to collect, select, and present information or items such as pictures, video, and music, for people to use or enjoy, using your professional or expert knowledge. Oxford Learners Dictionary online.

1. Knowledge is generated *within organizational structures or functional areas*, for example, development, manufacturing, quality assurance, engineering, operational excellence, learning and development organization.
    a. Knowledge generated by *short-term teams to address a project*—this is typically curated via an existing organizational structure.
2. Knowledge is generated by *longer standing cross-functional constructs such as communities of practice or technical networks* (the key here is these are not functional groups as noted in example 1).
3. Knowledge that is generated during a business or a technical process. Business and technical processes may span multiple functional groups or organizations (e.g., deviation management, technology transfer, and regulatory submissions).

The following sections describe considerations for knowledge mapping that is useful whether the knowledge in question has been:

1. Generated within an organization
2. Generated by a community of practice/network
3. Generated during a business or technical process

Mapping Functional Knowledge

Mapping functional knowledge is typically a *reactive* activity as the function in question already exists and has already generated and stored knowledge in some manner. Nevertheless, it is an effective tool to improve the capture, storage, and reuse of functional knowledge and to identify potential gaps and efficiencies. In addition, when mapping existing knowledge, it provides an opportunity to apply a lens from the customer standpoint; is the knowledge produced in a consistent and accessible format by all that need it?

Questions to consider for mapping functional knowledge (as well as limited duration team activity):

- What is the type of knowledge or content created? (Reports, evaluations, and decisions in the form of e-mails, memo's, procedures, and so on.)
- If the knowledge or content comes from somewhere else, who or where does it come from?
- What format is it in?
- Who are the primary customers for this knowledge?
- Are there any secondary customers for this knowledge? (e.g., those people that seem to use your knowledge output for additional research, product improvements, and so on—not the primary customer that originally requested it or is the normal *customer*.

- Where does this knowledge or reside?
- What is the risk if this knowledge is lost?

How to initiate a knowledge mapping session will be discussed later in this text *conducting a knowledge mapping session*.

Mapping Communities of Practice or Technical Networks Knowledge

Communities of Practice (CoP) and networks are a different use case for knowledge mapping. As communities of practice tend to be composed of like-minded people from multiple organizations or diverse functional groups, the knowledge needed may not exist. Unlike mapping for a functional group, the mapping exercise can also be used to brainstorm the knowledge needed and then determine if it exists and prioritize the need. If the knowledge does not exist, the community or network may choose to create it for the benefits of the members. APQC recommends creating a knowledge map when designing a community of practice at the outset.*

Below is an example of how a community could create knowledge:

> Risk assessment (RA) is an area that has many interested groups across a company or division. There are many types of risk assessments, including safety, quality, suppliers, product development, and the programs that support the assessments. There may not be one place to find risk assessment best practices or to share learnings. A community would be interested in taking an inventory of such practices, experts, documents, and learnings and make them more *consumable* or usable by others in the community. In this case they would be interested not only in what knowledge they currently have but also what knowledge they need. The community may host seminars or best practices sharing sessions virtually that could be recorded; this is a new piece of knowledge that can be leverage widely in this community. They also could create a place to list experts, share lessons learned, and best practices. These new databases or lists could house critical knowledge for the practice of *risk assessment*.

When developing a knowledge map for a community or network that does not exist, it is useful to ask the following questions:

- What are the *big* topics for the community? (Could be a brainstorm activity)
- For these *topics* what knowledge is needed?
- For the knowledge needed:
  - Does it exist?
  - If so, where or who will it come from?

* Based on the APQC Community of Practice Methodology.

- If not, does it need to be created (also, note the urgency of the need)?
- What format is it in?
- Who are the primary customers for this knowledge or content?
- Who were the secondary customers for this knowledge or content?
- Does it need to be validated (verified) before it can be shared?
- What is the risk if this knowledge or content is lost?

Mapping Business Processes Knowledge

When evaluating a business or a technical process it is beneficial to leverage existing process mapping tools and techniques. In the event that process mapping tools are now commonly leveraged, it is possible to utilize similar templates as for mapping functional knowledge. Typically, tools such as a SIPOC diagram (suppliers, inputs, process, outputs, and customers) (Johnston and Dougherty, 2012), work flow diagrams, swim lane exercises, and so on provide a nice framework to develop a knowledge map. For each step in the business process, the existing process flow diagram could be overlaid with the following considerations:

Is there any knowledge or content generated from this step? If so

- Where is it located?
- Who generates it?
- What format is it in? (explicit e.g., reports, memos, and e-mails, or tacit in someone's head)
- Who can access it?
- Who are the primary customers for this knowledge or content?
- Who were the secondary customers for this knowledge or content?
- What is the risk if this knowledge or content is lost?

Collating the responses from these questions across the process provides a rich source describing knowledge created and which of that is the most critical knowledge. It should be noted that explicit knowledge is much more tangible and easier to describe, define and organize, as illustrated by this chapter on knowledge mapping. Many other chapters in this book will present insights on the importance of tacit knowledge and practices to get it to flow.

The following perspective by Christopher Smalley shares some insights to identify tacit knowledge in the flow of work. Chris has spent 34 years in the biopharma industry and has witnessed firsthand the importance of tacit knowledge. These examples and many more like them could be very valuable when mapping knowledge of a function, community or a process (technical or business).

TACIT KNOWLEDGE
BY: CHRISTOPHER SMALLEY

In the regulated biopharmaceutical industry, there is a clear expectation to capture data, information, and knowledge. With that being said, there are several facets to knowledge, just as there are several iterations of data and information that contribute to knowledge. The most used knowledge, but least defined and characterized, is *tacit* knowledge.

Tacit knowledge is knowledge based on human memory and is comprised of that person's experiences, which include learning and education. It defines the difference between someone who purports to be a teacher but is simply reading from a book or the documentation of others, and the learning is identified as being routine. Contrast this with a true teacher who makes the training material come alive with real-life experiences and achieves an apprenticeship-like learning.

Tacit knowledge can also be learned alone. A mother may tell her child innumerable times that the stove is hot and they should not touch it. If the child learned, that would be an explicit knowledge. As parents know, most times it is only when the child touches the stove, experiencing the heat and then the pain, did they learn tacit knowledge. The experience becomes the lesson, not the teaching.

How might an organization use and benefit from tacit knowledge? Production organizations use tacit knowledge when they acknowledge the value and contributions of senior, experienced operators over junior operators or those new to a process. Although all operators have equal access to procedures, recipes, tools, and equipment, the experienced operators are able to identify key decision points and respond to keep processes from foaming, failing, alarming, or in some way deviating from the intended outcome. So, the organization benefits in this way.

Using a car for our example, the gas gauge provides data on how much fuel remains in the car's tank. This is a valuable data, but this data can be used to create information. When coupled with the odometer, the data from the gas gauge can measure the number of miles per gallon that the car is achieving. If that information on fuel economy is trended, it provides knowledge about how the car is performing. If the trend shows that fuel economy is declining, then additional sources of data can be brought into play. One might be to check the air pressure in the tires—another data source. Another might be the driver listening to the sounds that the transmission is making—is it taking longer time before it shifts to a higher gear indicating that there might be a problem with the transmission. All of the sources of data described up to this point are referred to as explicit data—the data are read-off

(*Continued*)

of an instrument or device and are unambiguous. The last piece of information described was the car driver listening—or equipment operator listening, as it were. In listening for perhaps a higher pitch whine in the transmission, or feeling for the shutter of the shift, the equipment operator is developing tacit information. Tacit knowledge may not be adequately articulated verbally, but it can be as important, or even more important, than explicit knowledge in understanding systems and processes.

So, let us now move into examples of tacit knowledge in pharmaceutical applications. We all have heard the *urban legends* of tacit knowledge, but let us look at two examples:

Tablet compression: A supervisor had years of experience as a table compression operator before being promoted into supervision. On this day, he stopped to speak with a current operator whose equipment was running a 500 mg tablet at 92% of machine rated speed. The supervisor told the operator that he had a bad punch and needed to tear down the machine. If you are familiar with this type of equipment, you would know that tearing down a tablet compression machine, except for PM, is a major undertaking and is not performed without good cause. The operator performed the teardown and found an upper punch that had a crack in the neck. The crack was not yet showing up in the normal monitored parameters such as tablet weight, appearance, hardness, and the like, but was detected by the supervisor's ear.

Tablet coating: The use of natural materials in any manufacturing process will accentuate the importance of tacit knowledge. Shellac is a natural material used for coating, and depending on the volume of tablets that need to be coated, the traditional copper coating pan with manual ladling of the coating solution is used. In this case, the coating specialist was adding shellac to a pan of tablets, adjusting the hot air and exhaust, rotational speed of the pan, and other parameters consistent with the batch record. When it came time to add the last ladle of shellac, the coating specialist threw the shellac on the back of the pan, where it dried onto the pan and not the tablets due to the hot air. When asked, the coating specialist explained that he had to add the amount of shellac called for in the batch record, but if he added that all to the tablets, he would wind up with one large unworkable mass. The coating specialist's tacit experience taught him that applying all of the shellac to the tablet would not result in acceptable tablets.

(*Continued*)

So, both stories tell of how tacit knowledge contributes to making better pharmaceuticals and helps to explain why an operator trained in the procedures and following the batch record might not be successful in manufacturing a satisfactory batch. *The challenge for the organization is to capture this tacit knowledge, and make it institutional knowledge by updating batch records and procedures by incorporating that tacit knowledge.*

It is incumbent for the industry to encourage and share such expressions of tacit knowledge and leverage knowledge management practices (e.g., knowledge mapping, lessons learned, and communities of practice) to capture and apply such learnings.

Conducting a Knowledge Mapping Activity

Plan and Define

Generating a knowledge map can be as simple as completing a template; however, in the experience of the author, using a standard methodology to plan and define the activity provides additional benefit. It helps set the stage, manage the process and expectations regarding participation as well as defining the required outputs.

Leveraging learning's gained from standardized *Lean Six Sigma* processes, the author developed a process for knowledge mapping. This process includes the following steps: plan, define, analyze, review, recommend, and implement. These steps provide a robust mapping process as well as a mechanism to provide feedback and recommendations (Figure 26.2).

Planning is an important phase of the knowledge mapping exercise, as it sets the stage for the level of engagement required from participants and

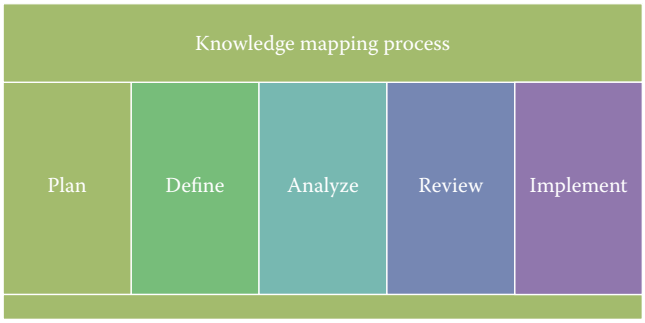

FIGURE 26.2
Knowledge mapping process elements.

TABLE 26.1

Knowledge Mapping—Phased Requirements and Deliverables

	Who	Timing[a]	Output
Planning	KMapping[b] Facilitator with target audience and management	~1 hour[a]	Agree timing, agenda, attendees, and output
Define	Facilitator with target audience	~1 hour[a] with target audience	Draft knowledge map
Analyze	Facilitator	~1–3 hours[a]	
Review	Target audience	~1 hour[a]	
Recommend	Facilitator	~1 hour[a] with target audience management	KMapping[b] assessment report
Implement	Target audience	TBD depending on observations and resources	Target audience implement changes as agreed

[a] Estimated based on activity.
[b] Knowledge mapping.

outlines the expected deliverables. Table 26.1 outlines a typical knowledge mapping plan.

A key success factor is to ensure that appropriate sponsorship from local and senior management is in place. The next step is to carefully consider the make-up of the participants. Then, with suitable template questions in hand the *define* stage of the knowledge mapping exercise can begin.

There are multiple ways that knowledge mapping exercises can be facilitated; however, the following considerations are suggested for a *functional group*:

- *Facilitator*: An experienced knowledge mapping SME*/facilitator—it is also helpful if the facilitator is familiar with the terminology of the focus area under consideration but not required.
- *Size of focus group*: 10 or less but must be relevant for the scope of team, for example, if it is a large group consisting of 500 people and multiple functional areas, it is best to divide up into subteams—facilitated separately and complied later.
- *Attendees*: Best to include a mix of colleagues at all levels in the organization.
- *Focus group type*: "*In person*"—meaning meeting may take place with attendees either physically present or virtually via an online meeting tool.
- *Timing*: One hour for initial mapping process, for larger groups, not more than 1.5 hours at a time.

* Subject Matter Expert.

The following considerations are suggested for a *Community of Practice or Network*:

- *Facilitator*: An experienced knowledge mapping SME/facilitator—it is also helpful if the facilitator is familiar with the terminology of the focus area under consideration but not required.
- *Size of focus group*: 10 or less but must be relevant for the scope of the community or network. Often this would be the core team of the CoP or network that is responsible for curation of the community or network.
- *Focus group type*: *In person*—meaning meeting may take place with attendees either physically present or virtually via an online meeting tool.
- To determine the needs of the community or network, it is useful to conduct a brainstorming activity prior to leveraging the templates to determine the major topic areas. This can be accomplished face-to-face or virtually, however it must be planned to ensure success. Once identified, the evaluation of the existence of required knowledge can be captured on the templates. For knowledge that does not exist, prioritization of knowledge generation can be identified via modification of the template columns.
- *Timing*: Up to one hour for initial brainstorming and then an additional hour for capturing the state of the respective knowledge.

Facilitation

When facilitating a knowledge mapping exercise the dialog created during the session is extremely valuable and often highlights the different ways knowledge is currently generated and captured within a group. These knowledge pathways are often not formally documented and may not even be previously recognized by the group. The inconsistency of generating content and knowledge in different formats may or may not be an issue to the organization; however, it may not be known that colleagues are generating content in multiple formats and this may present difficulties in knowledge sharing and access in the future. In the experience of the author, feedback from knowledge mapping sessions routinely contain sentiments such as

- "I had no idea that XXX team used our reports."
- "I keep that material on my hard drive as I am the only one that uses it, I did not know XYZ was interested in it."
- "This was an interesting conversation, we never take the time about how we work, we just do it."

- "It is not even Sally's job to be the go to person for this knowledge, but she seems to be-based on this conversation today."
- "I didn't know that [… .] had that information."

Due to the rich dialog and active learning during the activity, it is recommended that participants join the focus group at the same time and not complete a knowledge mapping template on their own. Two template examples are provided in the appendices at the end of the chapter.

I Have a Map, Now What? Analyze and Review

Once the knowledge map is captured the *analyze* phase can begin. It is good practice to send the captured map upon original completion to the group that participated in the generation. It is helpful to give the participants an additional opportunity to provide information in the event something was missed or captured incorrectly prior to starting the define phase. *Analyze* is the stage when the *know-how* of the facilitator comes to fruition. The facilitator will review the capture from the session (the knowledge map template) and assess the vulnerability of the respective knowledge elements in the context of the customers, findability, and loss aspects of the knowledge. The facilitator can then take the findings and contextualize the risk and suggest a best practice location(s) for storage and accessing of such knowledge if they could be improved. All recommendations must be aligned with the mission of the group, company, and within bounds of regulatory requirements.

Knowledge mapping facilitator skillset:

- Good team facilitation skills
- Understanding of KM capabilities of the organization
- Understanding of content management policies and tools for the organization
- Understanding of records management policies for the organization (GxP records, vs. nonregulated)
- Ability to develop a proposed plan of action resulting from the knowledge mapping exercise
- Ability to engage stakeholders, including management, for the initiation of the knowledge mapping exercise, as well as the readout

Recommend and Implement

In order to action learnings from a knowledge mapping exercise, the learnings and results must be compiled in a manner that is understandable and can be implemented.

A standard template for reporting the knowledge mapping activity and output is recommended. Suggested items include the following:

- Date and list of attendees (including facilitators).
- Timeline for reviewing and developing recommendations.
- Brief statement regarding any insights gleaned from the conversation/knowledge mapping activity in the defined phase.
- Highlight areas that would benefit from modifying the mechanism how knowledge elements are created or stored (e.g., content created is stored typically on hard drives, making it not accessible for others, or several colleagues in the same group create very different knowledge outputs, is that an area that would benefit from standardizing the format?
- Highlight any best practices noted that may be shared with other groups that did not participate in the exercise but could benefit.
- Highlight any KM practices or partners that may be able to assist with implementation.

It is important to note: what has *not* been recommended is the facilitation group takes responsibility for implementing the learnings. It is very important for groups to own the responsibility for collecting and curating their respective knowledge. Good curation behaviors are learned in an organization and in order to sustain best practices for creating, retention, and reuse of knowledge, the people that create knowledge must sense of ownership. With that being said, the knowledge management team or experts in the content management group may be able to assist with the implementation of learnings from knowledge mapping activities.

Summary

Taking the time to thoughtfully evaluate the knowledge created or needed by a functional area, community, a technical, or a business process can greatly improve how others can leverage that knowledge when needed. Remember the example of Sally?

> "I really miss Sally but so thankful that we have a map of her 'go to' places for product XYZ. That spreadsheet has really paid off in saving me time! Also I had to call a scientist for some background information the other day regarding an old report, and thankfully the group that produces those reports was also on the map that Sally contributed to...."

Knowledge mapping can be a useful KM practice to add to the knowledge management practitioner's tool kit. Within the pharmaceutical industry and respective organizations, there is a goldmine of knowledge—as a previous colleague used to say: "We have more knowledge than we could buy [via consultants], if we could just find it" (Christopher Smalley, 2007). All businesses could benefit from finding the right knowledge at the right time. For the pharmaceutical industry, efficient and effective leveraging of knowledge further enables the ability to effectively deliver life changing and lifesaving products to patients in a timely manner.

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Appendix I: *Functional Knowledge* Map Template Example

Date **Group** **Attendees:**

Functional Work Stream	Knowledge Element Created	What Format	Who Generates?	Primary Customer for K[a]	Secondary Customer for K?[a]	Where Does It Reside?	What Is the Risk If Lost? (H, M, L)	Gaps Identified	Notes/ Comments

[a] Knowledge.

Appendix II: *Community of Practice* Template Example

Date Group Attendees:

Community Topics/	Knowledge Element Needed	Does It Exist?	Who Has It?	What Format?	Primary Customers for K?[a]	Secondary Customer for K?[a]	Need Validation?	What Is the Risk If Lost? (H, M, L)	Gaps Identified	Notes/ Comments

[a] Knowledge.

Appendix IV: Research Outputs related to the Development of the KMEE:

The following list catalogues the range of research outputs created during the development of the *Knowledge Management Effectiveness Evaluation (KMEE)* diagnostic tool:

A. Assessment Methodology & Tool / Overview and Sponsor Alignment and Gap Closure Prioritization & KM Plan Template Presentation (PowerPoint)
B. KMEE Workshop Preparation Methodology & Checklist (Word)
C. KMEE Capture and Scoring Template (Excel)

Appendix IV A: Assessment Methodology & Tool / Overview and Sponsor Alignment Presentation (PowerPoint)

Knowledge Management Effectiveness Evaluation (KMEE)

KM Maturity Model & Action planning diagnostic

Paige Kane – Dublin Institute of Technology

KM Effectiveness Evaluation (KMEE)

Tool used to assess the adoption of available KM processes within a team or functional area. The KMEE provides a baseline KM maturity as well as recommendations to better manage knowledge within the area of evaluation. In addition, team members benefit from the reflection time and can share successes that may be leveraged by other members of their teams as well as across the network.

Business Questions

- How can we identify opportunities to make it easier to find *what we need - when we need it?*
- What do we need to do to ensure we steward our knowledge in order to prospectively use our knowledge for continual improvement, and have the ability to rapidly address issues?

Result & Deliverables

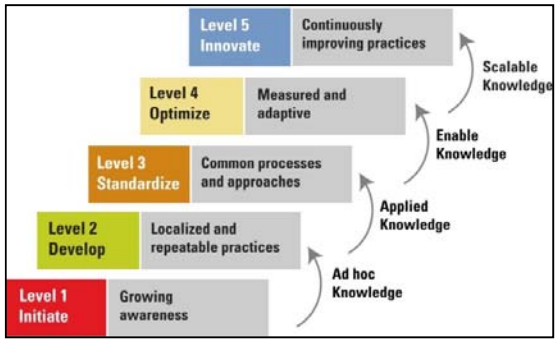
- KM **Maturity Baseline** developed
- Maturity **Assessment Data**
- Recommendation and ***KM Plan with suggested prioritization*** *(developed in partnership w/ area)* for the gap closure

Business Outcome

- Standardized knowledge processes that further enable the team to deliver on time, right the first time.
- Ability to proactively use knowledge for continual improvement to find what or who you need when you need it

- Workshop Format (1.5 hrs.) led by KM w/a business lead
- 15 min pre-work by attendees
- 2-3 hrs. pre-work by facilitation team, including the business lead
- ~ month to compile results (baseline KM maturity), suggested action plan with prioritization

APQC KM- CAT™

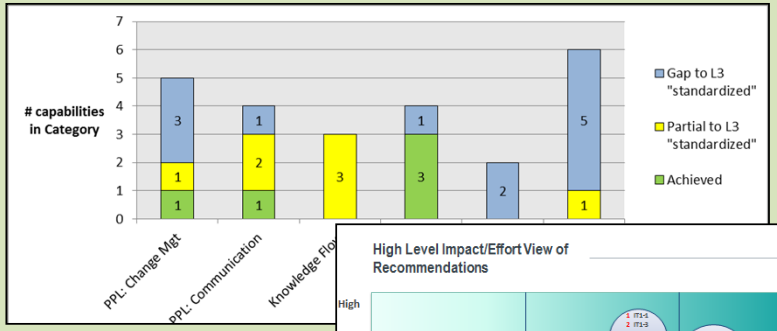


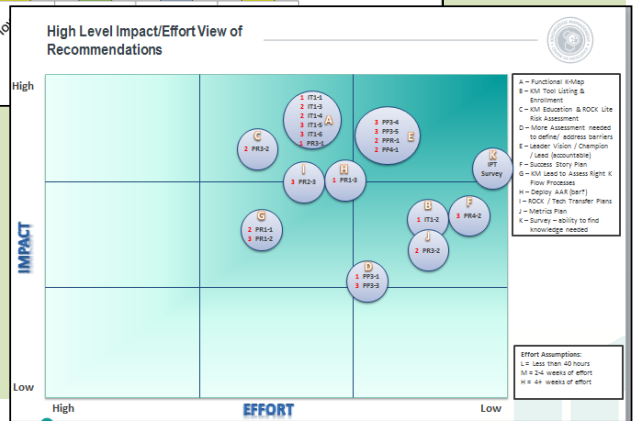
KMEE 28 capabilities in 3 focus areas

- People = 11
- Process = 12
- Content & IT = 5

# of capabilities

L1 (Initiate) = 4
L2 (Develop) = 7
L3 (Standardize)= 9
L4 (Optimize) = 5
L5 (Innovate) = 3





Enabling the flow of Knowledge

Business Questions we need to answer

- How can we identify opportunities to make it easier to find *what we need - when we need it?*
- What do we need to do to ensure we steward our knowledge in order to prospectively use our knowledge for continual improvement, and have the ability to rapidly address issues?

Result & Deliverables

- KM **Maturity Baseline** developed via the KM Effectivity Evaluation (KMEE)
- Maturity **Assessment Data**
- Recommendation and ***KM Plan with suggested prioritization*** *(developed in partnership w/ area)* for the gap closure

Business Outcome

- Standardized knowledge processes that further enable the team to deliver on time, right the first time.
- Ability to proactively use knowledge for continual improvement to find what or who you need when you need it

***complements the APQC KM-CAT for division/enterprise maturity assessment**

A KM Maturity Model Approach

(With business impact and effort implementation plan to drive value)

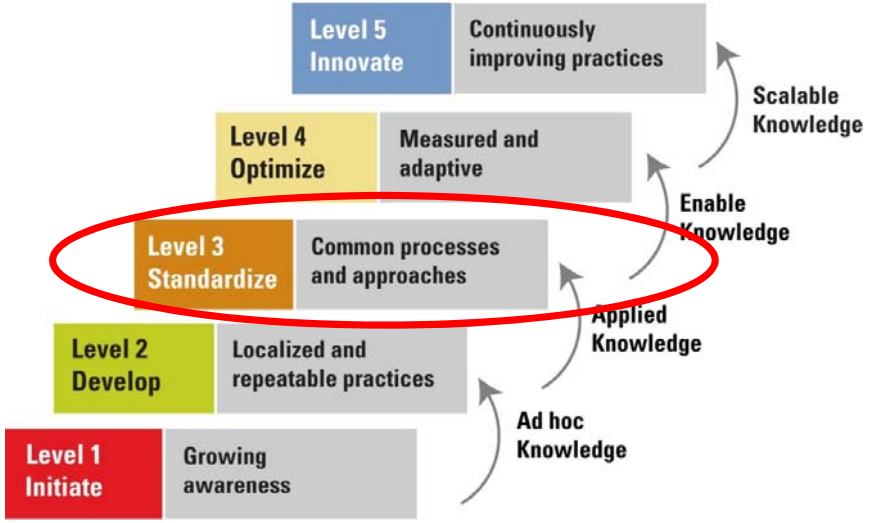
KMEE identifies 28 capabilities in 3 focus areas

- People = 11 capabilities
  - Change Management & Communication
- Process = 12 capabilities
  - K Flow, Approaches & Tools, Measurement
- Content & IT = 5 capabilities
  - Content Management Processes

# of capabilities in each level of maturity for the Assessment

- L1 (Initiate) = 4
- L2 (Develop) = 7
- L3 (Standardize)= 9
- L4 (Optimize) = 5
- L5 (Innovate) = 3

APQC's KM Maturity Model™



Suggest goal to reach Level 3 "Standardize" by XXX - TBA

Note: the original APQC KM Maturity Assessment for KM Programs encompasses 4 major focus areas and over 120 capabilities. The KMCAT was leveraged to provide the ability to roll up observations if the organization takes on an full KMCAT .

Three Components of the Assessment

Workshop

- Pre-survey – participants
- Pre work – KM Team and Business lead to customize questions for the business area (2-3 hrs.)
- In person workshop 1.5 hrs. size should less than 10 but represent all group/ team functions

Benchmarking Assessment & Evaluation

- Workshops output transcribed, evaluated & prioritized based on effort/ impact to site
- Participation from KM Team and business lead

Recommendations

- Detailed recommendations for gap closure
- Report out to leadership & agree next steps

Roles and Responsibilities: Contracting the KMEE

What the business can expect from the KM Team	What the KM Team expects from the business
Plan: • Assist the Business Lead with sponsor engagement • Update KMEE questions with examples relevant to the group (if needed) and send out pre-survey **Execute diagnostic:** • Facilitate the workshop & collect data **Assess & Improve:** • Summarize the data –(significant activity) • Propose action plan to close gaps – need participation from the Business Lead • Propose KM solutions based on gaps, oversee the solution implementation in partnership, and responsible for standard work associated with KM solutions. • Re-assess if needed	**Plan:** • Availability of appropriate resources to participate in workshop • 'Sponsor the pre-survey of area' Sponsorship cascade • Workshop Logistics (e.g. room, invites, etc.) **Execute diagnostic:** • Business Lead assists in facilitation and workshop execution **Assess & Improve** • Sponsorship to review findings, prioritize and sanction action plan • Resources need to be freed up to do this work and set up for success in their workload. • Ensure accountability for results of action plan (e.g. Tracking of progress / metrics)

What Not to expect from the KM Team
• Stewarding AND any content generation as it relates to the business. • KM group is not responsible for closing all gaps but those that are KM related • Funding for gap closure

Example KMEE Report

- **Overview**
- **Assessment data w/detailed recommendations**
- **Impact/ effort evaluation**
- **Potential Plan**

KMEE Assessment : [Topic/Date]

Assessment Workshop Overview

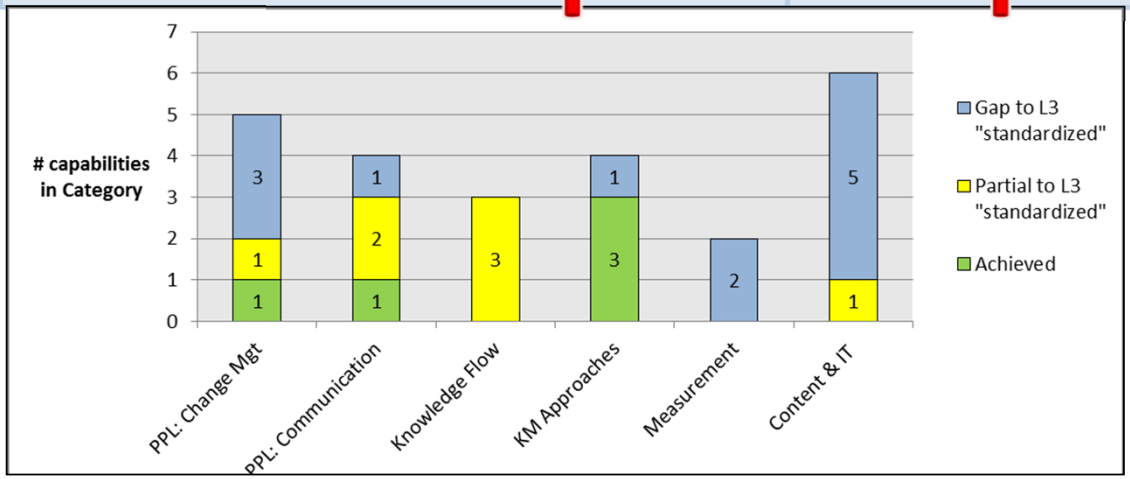
- **Facilitators**: xxx
- **Attendees:** xxxx

What is working well

✓

Assessment Workshop Insights

Example Template



- Chart is an "model" view of Team KM Maturity
- 22 Capabilities to reach Level 3 (L3) ***"Standardization"***
- Partial = some examples but not consistent across the team
- Impact and effort factored into recommendations (see excel)

Assessment Output - EXAMPLE

Example Template

Question #	Category	Site Based Descr[group]ion	Participant 3	Participant 5	Participant 7	Participant 9	Participant 10	Assessment	Recommendation	Linkr to?	Effort	Impact	Sug. Priority
IT1-1	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	Standard processes to create, maintain, store and access documents are in place. List examples of standard processes used.			Yes - for procedures, batch records, protocols, reports, risk assessments, MIDAS No - for procedural attachments, non batch-related certs, memos, method statement	No - many tools exist but we do not have a standard process * we do not utilize MIDAS outside of SOPs and BRs		Not Achieved - Standard processes for GMP documents but not for other documents - recommend a procedure for XYZ, if not for the site or functions	(1) Create XYZ functional knowledge map to determine content created; (2) better define what should be in MIDAS, and define standardized storage location for non-GMP docs (TK or other team site) as well as naming conventions; (3) document as a business process and deploy, including training; (4) establish stewardship / ownership	IT1-1 PR3-1	M	H	1
IT1-2	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	Existing KM information technologies (IT) and tools are leveraged and used where possible. List examples, e.g. document repositories, search, ...	DNS and VAC(?) library MIDAS SharePoint Team Site	SharePoint Trackwise Entropy (?) MIDAS DAS	No - only aware of SharePoint, Trackwise, MIDAS	In small pockets VTN (in area) TK (very limited) AAR (not trained but used) ROCK (no) MIDAS needs to roll out	VTN's such as QRM, etc. Capital project team spaces such as Asite MIDAS for doc approvals	Not Achieved - as by most accounts this is limited, but we may want to give this one to them, and then add a recommendation for a roll out...	(1) Create a list of tools based on XYZ functional k-map from IT1-1 and items listed here (e.g. VTN) (2) Prioritize the list for relevance to the site (e.g. focus on BSP VTN) and deploy via brief awareness session and reference documents - (3) Include in project/team onboarding and make available for those already on project (ppt + lunch & learn?) (4) Share leader expectations via concept of "we can't afford a Knowledge Mine", and what elements of the KM Policy (e.g. behaviors) are expected to help ensure this		L	M	1
		A standard set of											

- Post it notes from participants transcribed & evaluated
- Recommendations, effort/impact and priority suggested for 22 capabilities to “standardize”
- Many recommendations may cover multiple capabilities

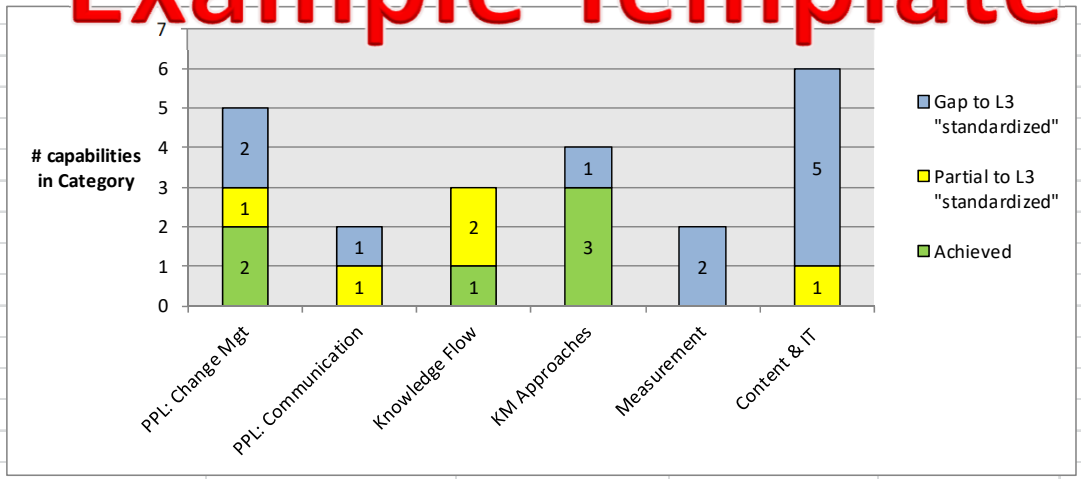
Excel file with full evaluation and recommendations – participants blinded

Attach raw data and recommendations

KMEE Heat Map

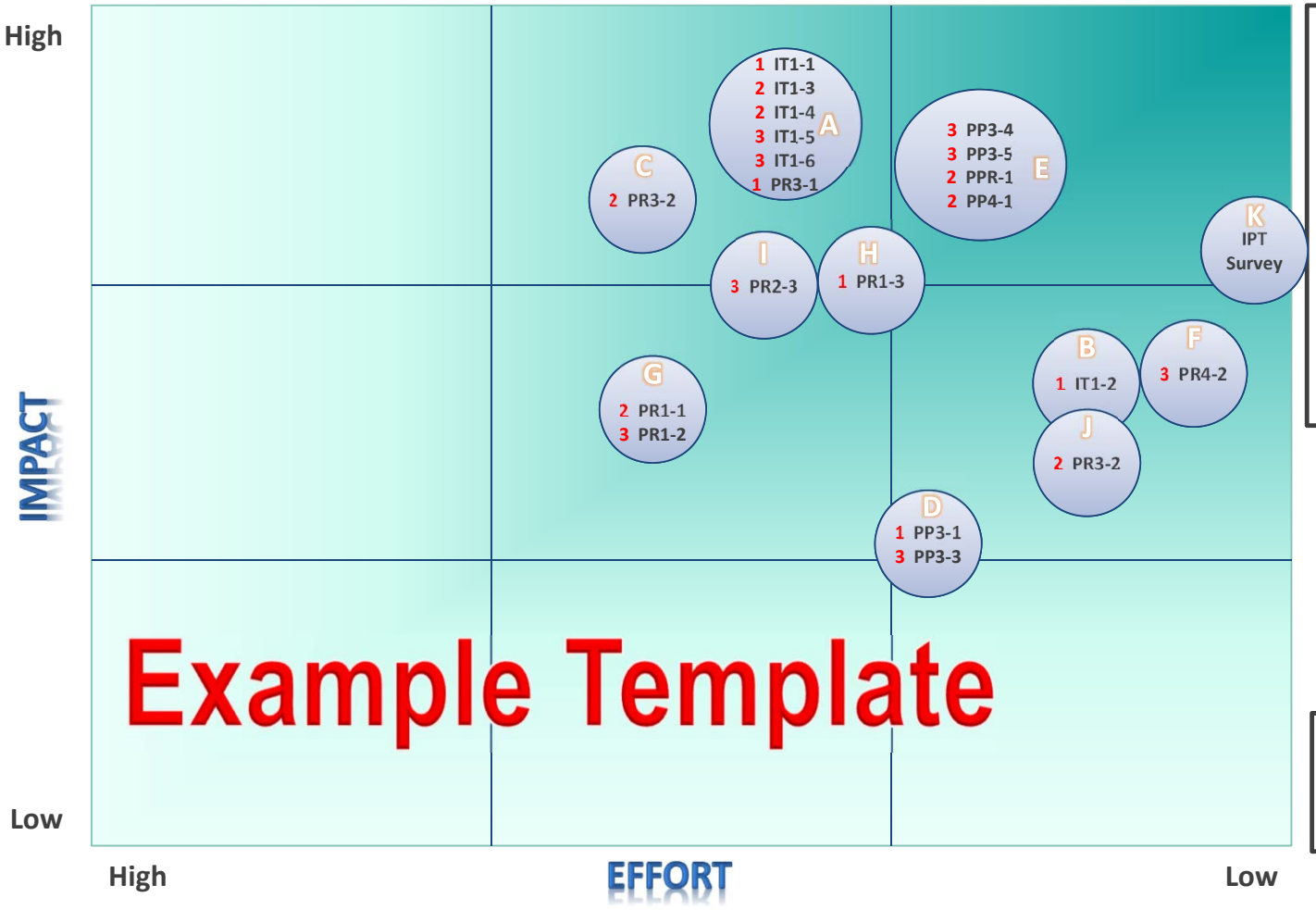
	Team Evaluated						
	People (PP3)	**People (PP4)**	**Process (PR1)**	**Process (PR2)**	**Process (PR3)**	**Content & IT (IT1)**	
	PPL: Change Mgt	PPL: Communication	Knowledge Flow	KM Approaches	Measurement	Content & IT	
Total	9	2	4	7	2	6	
To L3	5	2	3	4	2	6	
	L1	L2	L2	L2	L1	L1	
	L2	L3	L3	L2	L2	L1	
	L3		L3	L3		L2	
	L3		L4	L3		L2	
	L3			L4		L3	
	L4			L5		L3	
	L4			L5			
	L4						
	L5						TOTAL
Achieved	2		1	3			6
Partial to L3 "standardized"	1	1	2			1	5
Gap to L3 "standardized"	2	1		1	2	5	11
							22

Example Template



22 Capability to L3
5 - L4 Capabilities
3 - L5 Capabilities

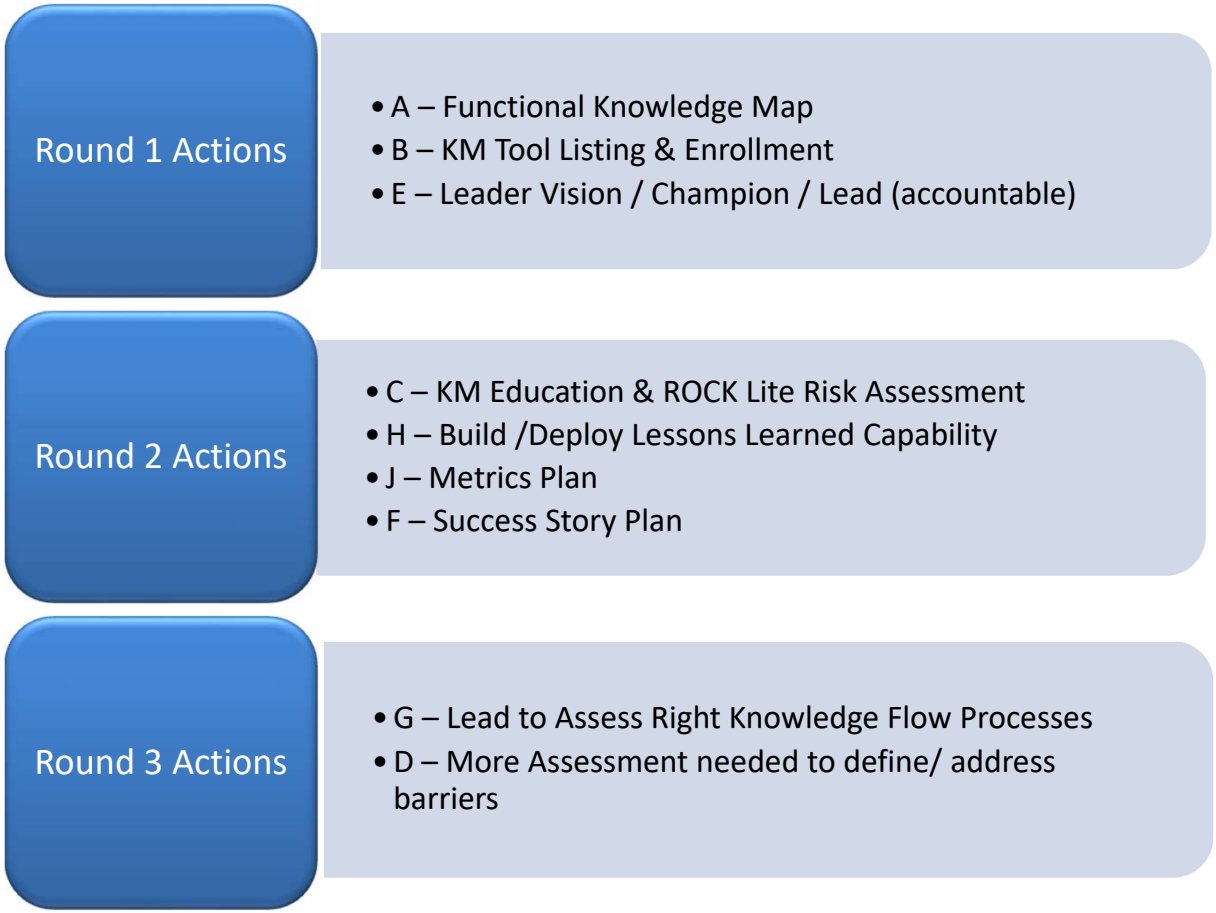
High Level Impact/Effort View of Recommendations



A – Functional K-Map
B – KM Tool Listing & Enrollment
C – KM Education & ROCK Lite Risk Assessment
D – More Assessment needed to define/ address barriers
E – Leader Vision / Champion / Lead (accountable)
F – Success Story Plan
G – KM Lead to Assess Right K Flow Processes
H – Deploy Lessons Learned
I – ROCK / Tech Transfer Plans
J – Metrics Plan
K – Survey – ability to find knowledge needed

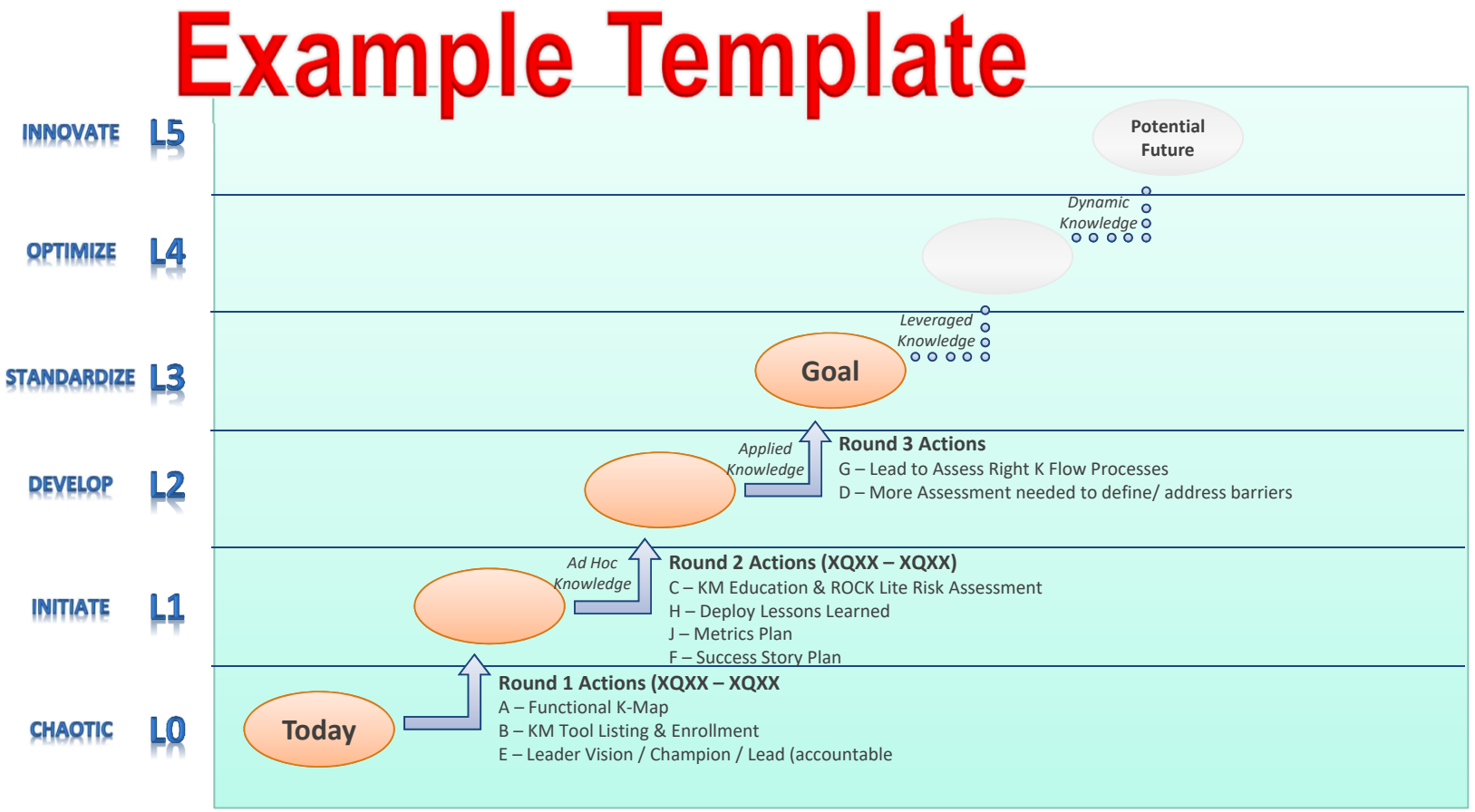
Effort Assumptions:
L = Less than 40 hours
M = 2-4 weeks of effort
H = 4+ weeks of effort

EXAMPLE Plan to Address Gaps



Example Template

Potential Gap Closure Plan



Appendix IV B: KMEE Workshop Preparation Methodology & Checklist (Word)

Appendix IV B: KMEE Workshop Preparation Methodology & Checklist (Word)

Two methodologies have been employed in delivery of the *Knowledge Management Effectiveness Evaluation (KMEE)* assessment. The first methodology is via a virtual setting were the assessment was conducted using an online meeting tool, the other was a physical face to face workshop, where all members involved in the assessment must be present in the room. Each methodology is described below. The selection of participants was nearly identically, with the exception that if the assessment is conducted in the workshop format, all participants were required to be present in person.

Selection criteria provided to the functional areas to solicit KMEE participants is listed below.

- Participants should represent cross section of knowledge workers, both experienced and newer to the company, supervisory and non-supervisory and leaders/decision makers
- Have experience using KM tools and processes (do not need to be "expert")
- Support or work within critical business areas/processes within the function.
- If workshop style, could participate in person

Virtual Session Methodology (for use when functions span geographies and/or face to face workshop is not possible):

A group, up to 6 participants, is scheduled for one hour to administer the assessment. A conscious decision was taken to not allow teams or individuals to view or complete the assessment without a KM practitioner scribing and endure the capability descriptions are clearly understood. Rationale was to encourage conversation amongst team members and also explore different perspectives when participating in the assessment. The scribe would capture the response in the column that related to the respondent's functional area. If examples of the capability were not provided, the scribe left the section blank.

The facilitated discussion yielded rich discussion amongst the assessment participants and created a "safe" environment to explore barriers. Due to the size and complexity of some organizations, and the limited time for the assessment, follow-up was required for several of the functional areas. While discussing capabilities, not only were gaps identified but also examples of what was working well in the respective groups. Based on the rich conversation during the assessment the report out template was enhanced to capture insights as practices/examples of what was working well to enable knowledge flow in the groups.

Assessment of the responses per capability was performed after the virtual session by the researcher (who had been trained by APQC in the KM-CAT methodology and scoring).

Workshop Style Methodology:

A group, up to 12 participants, was scheduled for 1.5 hours to for the assessment. As comparable to the virtual session, a conscious decision was taken to not allow teams or individuals to view or complete the assessment in advance (similar rationale for the virtual session). Preparation and implementation of the workshop required more time than the virtual session for the following reasons:

- Logistics of booking a room that was suitable for a workshop format (wall space to accommodate flipcharts, etc.)
- Preparation of the questions – printing them out individually to be divided into 3 groups
- Assembly of materials needed to run the workshop (sticky notes, flip charts, pens, tape, etc.)
- Assignment of participants to one of 3 groups (A, B, or C) and assigning them a number so that responses could be easily attributed easily person/ functional group.

Administration of the KMEE workshop required the following:

Participants divided into three groups that rotate around the room. Capability questions divided by section i.e. PP3, PP4, PR1, PR2, PR3, IT1 and sections were arranged in a manner that each of the three groups had a similar number of capabilities to discuss (average ~ 8 questions per group) in each rotation.

Each group was given approximately 20 minutes per rotation.

Responses are captured on individual sticky notes, each participant was encouraged to respond, even if the answer was 'no' and ensure each sticky note response was labelled with the unique participant number. Participants could add their number to an existing sticky note if they were in full agreement with the response.

All responses captured on sticky notes must be transcribed post workshop

KM Effectiveness Evaluation (KMEE) Checklist

KMEE Workshop Design

☐ **Business lead**: Obtain sponsorship buy – in (inclusive of the pre – survey to the full team)

☐ (Both) Agree date of the Workshop – 1.5 hrs for groups that have 1-8 sub functions

☐ **KM Team:** Review assessment questions with the **business lead** & update any questions that need additional contextualization for the workshop, specific to the function (1-2 hrs for this task)

☐ **Business lead**: Book a room conducive for workshops format - ***book for a min of 2.5 hrs to allow time for room setup.***

Room Set up: (see photos)

☐ **KM Team:** Flip Charts on the wall – 1 -2 per station (3 stations)

☐ **KM Team:** Suggested organization of questions for each breakout group:

- PP3* & PP4
- PR2* & PR3
- IT1* & PR1

Items w/*, plan on 2 sheets to capture feedback due to # of questions

☐ **KM Team:** Set up the participant Matrix so that response can be tracked back to each functional group

Work Shop Preparation

☐ **KM Team**: Prepare intro slide deck, w/results of survey if available

☐ **KM Team**: Identify facilitation team (suggest 3 break out groups and one lead for each)

☐ **KM Team:** print out questions for workshop

☐ **KM Team/Business lead:** Assemble post it notes, tape, flip charts, sharpies & pens for workshop

☐ **KM Team:** Pre meeting day before with all facilitators and business lead (1 hr)

Facilitation Tips: (see photos)

☐ **KM Team:** Break out Facilitator - Ensure each person writes their number on each response (sticky note)s

During Each rotation the facilitator will:

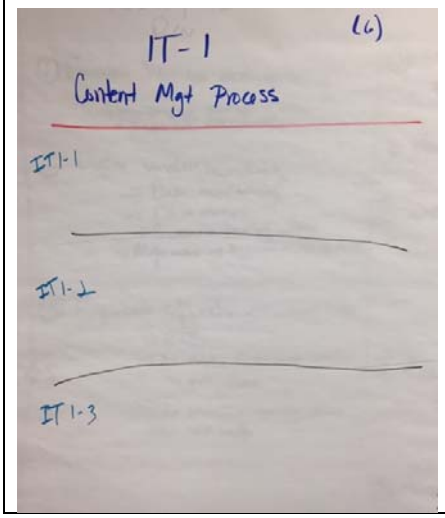
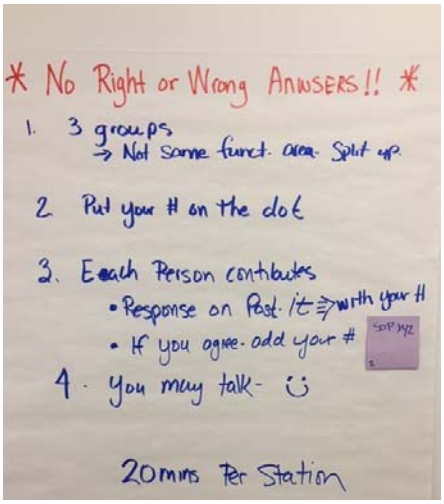
- Facilitator to stay with the station where they start, the groups will move
- Facilitator will read the question to the group and explain the intent
- Help with thinking for responses (ask probing question, maybe share examples to help participants)
- Ensure response is legible and participant number is on the response

If participants have the same response, or see someone has put their same response, they may add their number to someone else's response

Post Workshop Activities

☐ **KM Team:** label each post it w/question number & take pictures of all post it notes on charts to ensure things don't move in transit	☐ **KM Team:** Keep the 1 page print outs and put the post it notes on them for transport and transcription-
☐ **KM Team:** Transcribe post it notes, with photos to excel sheet (take pictures of charts)	☐ **KM Team:** assesses results. Norm with a co facilitator on suggested capability ratings
☐ **KM Team:** Prioritize gaps per chart	☐ **KM Team:** Develop heat map w/results
☐ **KM Team:** Finalize survey results	☐ **KM Team:** Develop recommendations/ report and review draft with business lead
☐ **KM Team:** Set up meeting w/Sponsor and Business lead to review draft outcomes	☐ **Business lead** to take ownership and develop path forward to implement plan

Set Up Examples

Workshop Participation Matrix

Functions expected/ Name of Participant	Group*	Number*
Sample group Quality Ops/ Sue Smith (example)	A	1
Sample group XX Team/ Juan Fine	B	2
Sample group YY Team	C	3
Sample group Validation (in this example did not come, so not assigned)		
Sample Group AAA Team	C	4
Sample group Micro (in this example did not come, so not assigned)		
Sample group XX Team	A	5
Sample Group AAA Team	A	6
Sample group Biologics	B	7
Sample group Quality Ops	B	8
Name of Facilitator (group A)	A	n/a
Name of Facilitator (group B)	B	n/a
Name of Facilitator (group C)	C	n/a

*Assign these at the workshop when you know who is actually there

Note: participant feedback has indicated they would prefer the facilitators do not break up people from the same group as they find it valuable to discuss the responses

Appendix IV C: KMEE Capture and Scoring Template (Excel)

Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
1	1	IT1-1	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	General document management processes are in place.	General document management processes are in place. What are they?								
1	2	IT1-2	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	Existing information technologies (IT) and tools are leveraged and used where possible.	Existing KM information technologies (IT) and tools are leveraged and used where possible. (xxx, xxx, xxx, Enterprise Search								
2	3	IT1-3	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	Content is identified and organized at business unit or domain.	Knowledge/Content is identified and organized at a group level or workflow level (may be sporadic)- list the methodology								
3	4	IT1-4	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	Standardized taxonomies for classifying core knowledge assets exist.	Your group uses a standard naming convention for storing content - what is the methodology?								
3	5	IT1-5	CONTENT AND IT: (IT1) CONTENT MANAGEMENT PROCESS	Content management workflows are standardized.	Content management workflows are standardized.- all colleagues know where to store their content on shared spaces with supporting document management practices - list the practices								

Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
1	6	PP3-1	PEOPLE: (PP3) CHANGE MANAGEMENT	Current state assessment of successes and problems in knowledge sharing include the identification of potential barriers and competing issues impacting knowledge flow required for business results.	Have you done an assessment to gauge KM issues in your group/site? If so do you know the issues and barriers?								
2	7	PP3-2	PEOPLE: (PP3) CHANGE MANAGEMENT	Education and training plans are in place to support initial KM projects.	All colleagues in your group have been trained on the core KM approaches for all "x" - i.e. XXXX								
3	8	PP3-3	PEOPLE: (PP3) CHANGE MANAGEMENT	Barriers to sharing and using knowledge are identified and addressed.	Your group has identified barriers to sharing and using knowledge and have addressed them (with help from the KM team if needed) - list the barriers and solutions								
3	9	PP3-4	PEOPLE: (PP3) CHANGE MANAGEMENT	Accountability is expanded for knowledge flow processes and approaches.	Groups outside of the official KM group are working to ensure that knowledge flows across the site/business (e.g. process, tech teams, etc.) - list how this happens								
3	10	PP3-5	PEOPLE: (PP3) CHANGE MANAGEMENT	KM advocates are in place across the enterprise.	Colleagues who are responsible for advocating for KM projects / approaches are in place in your organization (site for sites and center groups for center)								
4	11	PP3-6	PEOPLE: (PP3) CHANGE MANAGEMENT	Formal recognition is given for KM efforts, success, and lessons learned.	Formal recognition is given for KM efforts, success, and lessons learned within your group and across other groups -give examples								

Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
4	12	PP3-7	PEOPLE: (PP3) CHANGE MANAGEMENT	KM training is provided to new-hires to help make KM a part of the culture.	Overview of the "x"/Site KM approaches are provided to new hires or colleagues that have joined "x" from another part of the company								
4	13	PP3-8	PEOPLE: (PP3) CHANGE MANAGEMENT	KM advocates have accountability for KM results.	Colleagues responsible for advocating for KM projects / approaches (site for sites and center groups for center) have accountability/ success for group KM approaches in their Performance Review								
5	14	PP3-9	PEOPLE: (PP3) CHANGE MANAGEMENT	KM is aligned with talent management and leadership development.	Talent management processes leverage KM approaches/ processes (e.g. current Bio, ELS) to ensure that talent & experience is visible to all colleagues- also leaders leverage r/Bios to ID potential diverse candidates for new development opportunities/ roles								
2	15	PP4-1	PEOPLE: (PP4) COMMUNICATION	KM advocates discuss the value of KM to the business with senior leaders and key stakeholders.	KM advocates (site or program colleagues) have been identified for your group and engage with leaders and managers to discuss the KM approaches/ projects and value to the group								

Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
3	16	PP4-2	PEOPLE: (PP4) COMMUNICATION	Success stories from initial KM projects are broadly communicated.	Has your site or group communicated any success stories levering KM, if so what or what are the opportunities?								

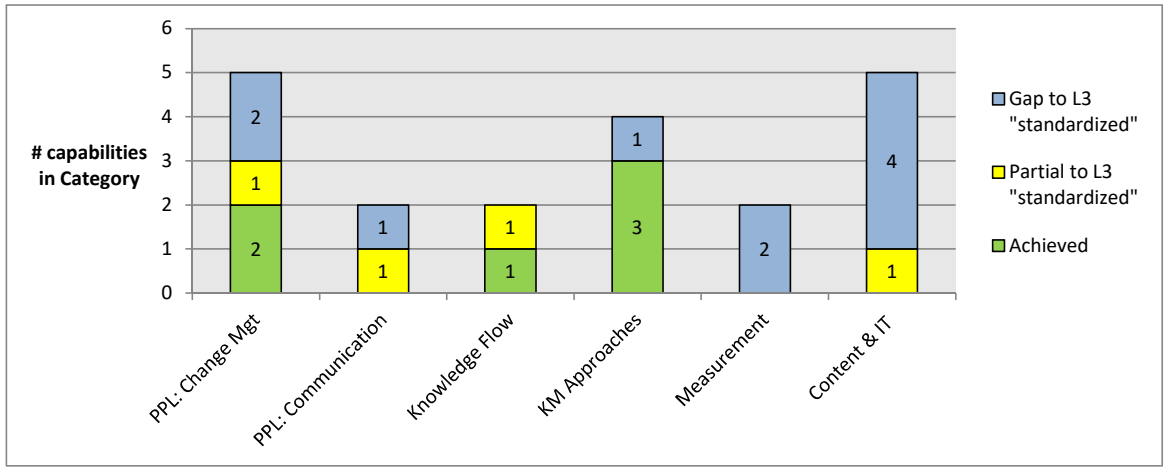
Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
2	17	PR1-1	PROCESS: (PR1) KNOWLEDGE FLOW PROCESS	**Stabilized** knowledge flow processes are embedded in KM approaches e.g., Communities of Practice, Lessons Learned, After Action Review, etc.	List the processes that enable knowledge to flow across groups, projects, etc. Examples could be Lessons Learned, CoPs, discussion boards								
3	18	PR1-2	PROCESS: (PR1) KNOWLEDGE FLOW PROCESS	**Standardized** knowledge flow processes are used across multiple instances or situations.	What are the **standardized** processes to enable the flow of knowledge across multiple groups in the organization								
4	19	PR1-3	PROCESS: (PR1) KNOWLEDGE FLOW PROCESS	Knowledge flow processes are embedded in core business processes and domains.	Your group us leveraging KM concepts of knowledge flow and capture into the design of "systems", business processes (e.g. process, "x" Investigations using KM techniques. Etc.)								
2	20	PR2-1	PROCESS: (PR2) KM APPROACHES	Knowledge maps for each initial KM focus areas identify content and knowledge needs/gaps.	Your group has participated in a Kmapping exercise and gaps have been identified. List the date of the exercise								
2	21	PR2-2	PROCESS: (PR2) KM APPROACHES	Core business processes that require enhanced knowledge flow identified.	Your group understand what core business processes would benefit from applying the "KM" lens to help with knowledge flow- list them								

Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
3	22	PR2-3	PROCESS: (PR2) KM APPROACHES	Standard methods are used to capture and retain valuable individual knowledge	We have a methodologies (plural) for capturing the knowledge of individuals.								
3	23	PR2-4	PROCESS: (PR2) KM APPROACHES	KM maturity and capabilities are assessed.	KM maturity and capabilities are assessed using the "assessment"/APQC Tool - list date								
4	24	PR2-5	PROCESS: (PR2) KM APPROACHES	KM competency maps exist for individual roles and/or jobs.	Individual roles / jobs within the group clearly state what knowledge is needed and **generated** in the specific role								
5	25	PR2-6	PROCESS: (PR2) KM APPROACHES	KM approaches, methodologies and tools are integrated with process improvement, organizational development, and learning approaches.	List the KM approaches, methodologies and tools you use that are integrated with process improvement, organizational development, and learning approaches. E.g. when we do an OpEx project, innovation project, troubleshooting, etc., are we also using the KM tools/methodologies								
5	26	PR2-7	PROCESS: (PR2) KM APPROACHES	KM becomes a "core competency" of the organization.	What is the evidence that KM is a "core competency" and competitive advantage of your group								
1	27	PR3-1	PROCESS: (PR3) MEASUREMENT	An assessment of critical knowledge in current business processes / domains is conducted.	Has your group participated in a Knowledge Mapping exercise. If so have you implemented the remediation plan?								

Level	Q #	Section #	Category	APQC Described Capability	Customized Description of Capability	Participant 1	Participant 2	Assessment	Recommendation	Links to?	Effort	Impact	Sug. Priority
2	28	PR3-2	PROCESS: (PR3) MEASUREMENT	Local KM activity measures are in place and used.	KM Advocate or group leader measuring/ monitoring the use of KM activity within the group e.g. the participation in discussion (list which ones relevant for [group]) boards, the updating of profiles in xx etc. - list the examples								

Team Evaluated

	People (PP3)	People (PP4)	Process (PR1)	Process (PR2)	Process (PR3)	Content & IT (IT1)	
	PPL: Change Mgt	PPL: Communication	Knowledge Flow	KM Approaches	Measurement	Content & IT	
Total	9	2	3	7	2	5	
To L3	5	2	3	4	2	5	
	L1	L2	L2	L2	L1	L1	
	L2	L3	L3	L2	L2	L1	
	L3		L4	L3		L2	
	L3			L3		L2	
	L3			L4		L3	
	L4			L5			
	L4			L5			
	L4						
	L5						TOTAL
Achieved	2		1	3			6
Partial to L3 "standardized"	1	1	1			1	4
Gap to L3 "standardized"	2	1		1	2	4	10
							20



20 Capability to L3
5 - L4 Capabilities
3 - L5 Capabilities