2020

Advancing Knowledge Management (KM) as an ICH Q10 Enabler in the Biopharmaceutical Industry

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Advancing Knowledge Management (KM) as an ICH Q10 Enabler in the Biopharmaceutical Industry

A monograph

based on doctoral research by the authors through The School of Chemistry & Pharmaceutical Science, Technological University Dublin

AUTHORS: Paige Kane and Martin Lipa

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PHARMACEUTICAL SCIENCE
& REGULATORY TEAM

TU Dublin Academic Press

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The monograph should be cited as follows:

Kane, P. and Lipa, M. (2020) **Advancing Knowledge Management (KM) as an ICH Q10 Enabler in the Biopharmaceutical Industry**, Dublin: TU Dublin Academic Press

Design by Data Print

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Foreword

This monograph is a publication of original research focused on biopharmaceutical sector Knowledge Management (KM) methodologies and capabilities. The authors, through their research, have developed models, tools and processes which can assist the sector gain greater clarity of the value and merits that KM can offer to organisations.

Kane's research was driven by a determination to close the gap from KM theory to practice.

Her research addresses a void of research in, and understanding of, the concept of KM in the biopharma sector, and proposes a foundational *Pharma KM Blueprint (Kane 2018)*. The *Pharma KM Blueprint* illustrates holistic integration of core KM principles, models and tools to deliver real benefits to the patients and the business.

The Pharma KM Blueprint is comprised of several elements, including:

- **Recognising Knowledge as an Asset** - Identifies the need to value and maintain *knowledge assets* in the same way as physical assets within an organisation

- **The Pharmaceutical Product Knowledge Lifecycle Model (PPKL)** - Addresses the challenge of enabling knowledge flow in order to increase visibility, access to and use of the product and process knowledge assets across the product lifecycle

- **The House of Knowledge Excellence (HoKE) Framework** – Demonstrates a framework developed to implement a systematic KM programme linked to strategic objectives of an organisation, incorporating KM practices, pillars, and enablers to support the effective management <u>and</u> flow of knowledge assets.

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

This research has already spawned additional research on the KM topic, including research by co-author Lipa further exploring the PPKL topic of tacit knowledge in technology transfer. Lipa's research is on-going, but an early output is a confirmation that knowledge transfer as part of technology transfer is often not effective. Lipa goes on to propose a framework for enhancing knowledge transfer known as the *Knowledge Transfer Enhancement (KT^E) Framework*. Research is continuing on this topic and will be the subject of future publications.

It is hoped that these research outputs and corresponding dialogue within the biopharma industry will lead to meaningful improvements for the industry and for the patients who depend on it.

Acknowledgements

Author and Editor Profiles

Paige Kane • PhD, CPIP

Paige Kane PhD, CPIP, is a Director in the Merck Manufacturing Division, and a member of the MMD Knowledge Management (KM) Center of Excellence. She is an industry leader with over 30 years' experience, including with six pharmaceutical companies and the US Government, spending the past 13 years designing and leading KM programmes and approaches for the Pharmaceutical Industry. Prior to her work in KM, Kane led multiple Quality Systems Groups focusing on Automation Compliance Strategies, Change Control, Document Management, Computer/Equipment Validation and Data Integrity for new biotechnology facility start-ups and operations in the US and Ireland. She has experience working across the pharmaceutical product lifecycle in GLP, GCP (Clinical trial oversight and supplies) and GMP in Human and Animal Health.

Kane has led several industry Strategic Teams including ISPE CoPs, and currently leads the ISPE KM Good Practice Guide authoring team. Kane has participated in authoring several industry guidance documents and contributed to many conference sessions and industry papers. She is a co-editor of, and multi-chapter contributor to, 'A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry' (2018).

Martin Lipa • Executive Director at MSD

Martin (Marty) Lipa is an Executive Director at MSD where he leads the Knowledge Management Center of Excellence for Merck Manufacturing. In his current role Marty is responsible for a holistic KM Strategy addressing standardised KM approaches as well as enabling elements of people, process and technology. Marty has over 12 years of KM experience, and related experience as a Certified Lean Six-Sigma Black Belt and in transformational change management and IT. Prior to working in his KM role, Marty had experience in various engineering roles, Technical Operations, shop-floor automation, new GxP facility start-up and Information Technology at sites in the US, U.K., Ireland and Singapore. Marty is an active member of the KM community as a regularly invited speaker on KM. He has published several industry- specific works, including as contributing editor to 'A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry' (2018), as well as papers in various journals.

Marty is currently pursuing his PhD at the Technological University Dublin with a focus on Knowledge Management as an enabler of product and process understanding, with a specific focus on Technology Transfer.

Prof. Anne Greene • Head, Pharmaceutical Regulatory Science Team (PRST), Technological University Dublin

Anne Greene leads the Pharmaceutical Regulatory Science Team (PRST) in TU Dublin, where she is also a senior lecturer and director of several MSc. and BSc. Pharmaceutical Programmes, including the TU Dublin MSc in Pharmaceutical Validation Technology. She has supervised several students to PhD awards in areas of Quality Risk Management, Knowledge Management, Operational Excellence and PAT.

Prior to embarking on an academic career, Anne worked at a senior level for several years in the pharmaceutical sector in Validation and Technical Management roles. She has a PhD in Synthetic Organic Chemistry from University College Dublin, and is currently a member of committee of the Irish Chapter of PDA. Anne is also on the Board of Directors of Regulatory Science Ireland (RSI) and is chair of the Corporate Development Committee.

Dr Nuala Calnan

Dr Nuala Calnan is a twenty-five year veteran of the pharmaceutical industry. Her work as a consultant, academic, author and commentator is directed toward the delivery of patient-focused excellence and has included research for FDA (USA), HPRA (Ireland) and other regulatory agencies on patient safety and product quality in the manufacture and distribution of drugs.

Her current areas of consultancy and research include quality risk management, data integrity, knowledge excellence, metrics design, cost of quality and building patient-focused quality cultures. Nuala co-leads the ISPE Quality Culture Team and is a founding member of the ISPE/ PQLI Task Team on Knowledge Management.

Dr Anne Murphy

Dr Anne Murphy is an Emeritus Research Fellow in TU Dublin. She has had a long career in education as a teacher, academic development practitioner, research supervisor and project manager, specialising in recent years in recognition of prior learning, work-based learning, qualifications frameworks development and TVET systems in the EU and in Serbia, Turkey, Macedonia, Kosovo, Afghanistan, Uzbekistan, Kazakhstan, Russia and Malaysia. She founded the first TU Dublin (formerly Dublin Institute of Technology DIT) open access, online journal in 2003, was instrumental in developing the concept of the TU Dublin Academic Press and was a long-term reviewer for Emerald Publishing. She is currently a CORU public interest panel member for regulation of qualifications in the health and social care professions in Ireland.

Contents

1. Chapter One
Monograph Background and Context

In 2005 The International Conference on Harmonisastion (CH) 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), as shown in the ICH Q10 diagram (**Figure 1.1**).

Figure 1.1 — *ICH Q10 PQS Diagram inclusive of a product lifecycle (updated to enhance graphic quality)- (International Conference on Harmonisation, 2008)*

Even though KM only found its way formally into the biopharmaceutical sector regulatory guidance in 2005, in fact KM concepts had 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 emphasis on 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 2015, the 10 year anniversary of ICH Q10, a two-day Knowledge Management international conference *KM Dublin 2015* ("Knowledge Management From Discovery to Patient: Enabling *Knowlege* Flow, Delivering

Safe & Effective Products," 2015), jointly organised by the Irish Regulatory Agency (HPRA), Regulatory Science Ireland (RSI) and the Pharmaceutical Regulatory Science Team (PRST), was held in Dublin Castle, Ireland. *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 and forty attendees. 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.

While it has been over a decade since KM emerged as a Pharmaceutical Quality System (PQS) enabler in ICH Q10, there is evidence that knowledge management is not well understood as a management practice because of the considerable focus placed on the science, technology and regulation necessary to deliver the sector's complex array of biopharmaceutical products (Lipa, Kane, & Greene, 2019). In 2014, the authors of this monograph embarked on this research study into the topic of KM, and as the study progressed, so too did the level of industry interest in, and discussion on, the topic of knowledge management.

The research examined 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, models, tools and processes were developed to assist the sector gain greater clarity of the value and merits of KM and offer ways 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 utilisation specifically in the Biopharmaceutical Sector. The research focused on addressing this gap by examining the then current KM methodologies and capabilities in order to gain insights into how to best utilise existing, new, and emerging biopharmaceutical knowledges to realise the ambitions of ICH Q10, stated as, 'enhance the quality and availability of medicines around the world in the interest of public health', (International Conference on Harmonisation, 2008). In addition, the research endeavored to close the gap between KM theory and practice and provide KM practitioners with fit-for-purpose models in the biopharmaceutical environment.

The main output from this research study is a new framework entitled The *Pharma KM Blueprint* which is presented in **Figure 1.2** below, and discussed in this monograph.
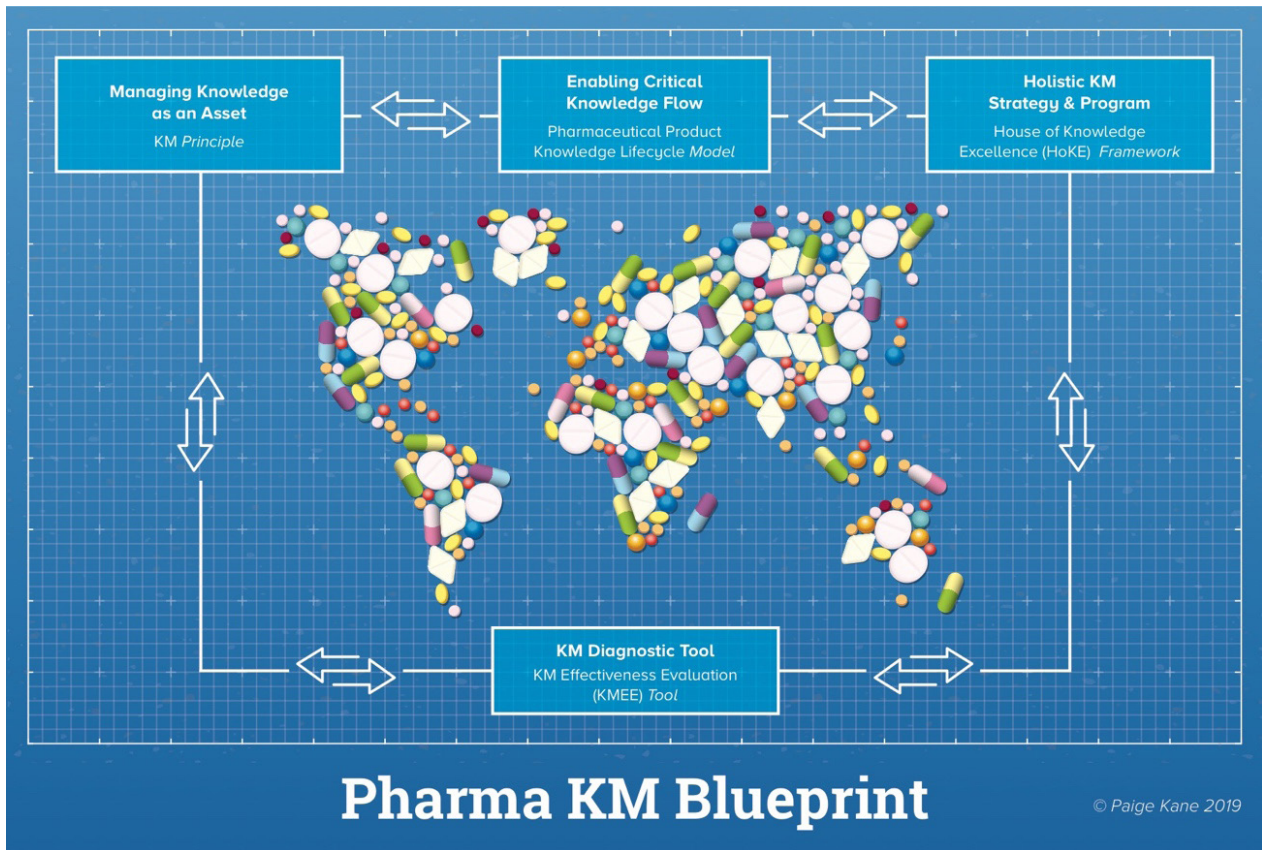
Figure 1.2 — *The Pharma KM Blueprint- (Kane, 2018a)*

The model is built on the **_Principle_** of the need to *Manage Knowledge as an asset*. It comprises of two **Frameworks** that provide methods of how to Manage Knowledge as an asset, and a *KM **Diagnostic Tool***, which can be used to evaluate the *Effectiveness of an organisation's KM approach*.

Subsequent chapters of this monograph discuss the elements of the Pharma KM Blueprint as follows:

- Chapter 2 - **Managing Knowledge as an Asset** – addresses the need to value and maintain knowledge assets in the same way as physical assets within an organisation

- Chapter 3 – **The Pharmaceutical Product Knowledge Lifecycle Model** - addresses the challenge of enabling knowledge flow in order to increase visibility, to access and use the product and process knowledge assets across the product lifecycle

- Chapter 4 - **The House of Knowledge Excellence Framework** – demonstrates a framework developed to implement a systematic KM programme linked to strategic objectives of an organisation, incorporating KM practices, pillars (people, process, technology, governance), and enablers to support the effective management and flow of knowledge assets.

- Chapter 5 – A **Knowledge Management Effectiveness Evaluation** - provides a practical KM diagnostic tool that may be used to identify and evaluate areas of opportunity and to track progress on closing knowledge gaps.

In addition, the monograph concludes with a final chapter (Chapter 6) in which a high-level overview of subsequent research by Lipa is given, building on the research of Kane, into Knowledge Management during Technology Transfer. In that chapter, a framework to improve KM effectiveness at Technology Transfer is presented.

2. Chapter Two
Managing Knowledge as an Asset

This Chapter presents the first element of the *Pharma KM Blueprint*, namely, managing knowledge as an asset. In a seminal publication from 2014 Lipa *et al*. described the paradox of how the ability to transfer and apply knowledge is acknowledged as a competitive advantage, but that however, "knowledge is seldom treated like a crucial asset" (Lipa, Bruno, Thien, & Guenard, 2014). This topic was further explored at a breakout group led by the authors in the KM Dublin 2015 conference, resulting in a deeper exploration of the *knowledge asset* concept and greater understanding of what constitutes crucial or *critical knowledge* (Kane, 2018b) Participating in this breakout group were key biopharmaceutical industry experts, together with thought leaders from the American Productivity and Quality Center (APQC).

2.1 Valuing Knowledge as an Asset

Linking quality and knowledge management has been, and remains, a foundational component of the mission of APQC. APQC's founder Jack Greyson was one of the creators of the *Malcolm Baldridge National Quality Award* (MBNQA). The MBNQA recognises US organisations for performance excellence. Not surprisingly then, knowledge management is a core capability included in the evaluation process for the MBNQA award, and it is in supporting materials for applying for this award that a definition for "knowledge assets" appears. This definition of a knowledge asset provides, in the opinion of the authors, the most comprehensive definition of knowledge assets in the literature review undertaken for this body of research. This definition and description are given below:

> *'The term "knowledge assets" refers to the accumulated intellectual resources of your organisation. It is the knowledge possessed by your organisation 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 organisation's knowledge assets. Knowledge assets are held not only by an organisation, but reside within its customers, suppliers, and partners as well. Knowledge assets are the "know how" that your organisation has available to use, to invest, and to grow. Building and managing its knowledge assets are key components for your organisation to create value for your stakeholders and to help sustain overall organisational performance success.' (Steel, n.d.)*

Building on this concept of knowledge assets, Lim et al. noted, that for organisations 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 the personal experience of the authors, validated by the themes elicited from the industry consultations and discussions at KM Dublin 2015 conference, a key observation was that:

> *The biopharmaceutical sector had not yet come to the realisation 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 as equivalent to physical assets, such as plant, equipment or lab bench technologies.*

In valuing knowledge assets, the authors considered that, in fact, physical assets and knowledge assets have several characteristics in common as follows:

- **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 programme) or sharing an expert who 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, organisations 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 organisation.

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'. He 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 Framewor*k developed by the State of Victoria (AUS), as a starting point to consider when managing knowledge assets, as in **Figure 2.1** below.

PLANNING

Asset management strategy
Planning for uncertainty
Business cases
Risk management
Cost/benefit analysis
Accounting treatment
Non-asset alternatives

ACQUISITION

Acquisition process
Risk evaluation
Procurement method

Leadership and accountability

Governance
Attestation
Performance management
Achievement of Government outcomes
Continuous improvement and flexibility

DISPOSAL

Retirement
Replacement
Renewal
Redeployment

OPERATION

Monitoring
Maintenance
Information management
Asset valuation
Utilisation
Functionality

Figure 2.1 — *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 authors suggest in **Table 2.1** what this might mean in terms of KM for a biopharmaceutical organisation, and posed key questions to address in the four stages for knowledge assets.

Table 2.1 — 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 those who need 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[1]: 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 with maintenance, a role should exist to manage the whole lifecycle of the knowledge asset, and that includes a systematic process for disposal.

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[1]   Removal of knowledge assets may be subject to records retention policies.

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

2.2 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 [2] 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 have matured, companies have increased their organisational 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. Indeed, Oliver notes that pharma data are doubling every five months and that:

> *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)*

A key question for the authors is what, if any, of this data might be considered *critical*?

Furthermore, the authors pondered that if technology is not delivering the desired outcomes, what about the people? Are they delivering desired outcomes? While the 1990's brought an early focus on the role of people in the knowledge creation process (Nonaka & Takeuchi, 1995), more than 30 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 organisations. One wonders 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 respondents noted that 'production system issues leading to drug shortages or near misses were present

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

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[3] within organisations:

> *"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*

An APQC benchmarking report published in 2018 also confirms that the biopharmaceutical sector has been slow to adopt KM approaches. It reports that only 4% of biopharmaceutical KM programmes have reached a standardised maturity level of "3" or better, in comparison to 18% across all other sectors. (Trees & Hubert, 2018, p. 50). In contrast, an earlier, 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 into 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 organisation. 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 2017 ISPE Pharmaceutical KM Survey[4], where only 25% of respondents indicated that KM was embedded in the way they work. Therefore, with KM adoption in the biopharmaceutical sector clearly lagging behind 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, to our patients.

Arguably, a key challenge inherent in those data and information capture is the conversion of those 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.

Returning 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 organisationally critical knowledge

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[3] 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.

[4] 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

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.

2.3   Stemming the Loss of Critical Knowledge

In the opinion of the authors, 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 programmes 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 organisation to consistently deliver high quality medicines to the patient. Often times this knowledge is not recognised or valued as 'critical' until someone leaves their role, or even more challenging, exits the company. By which point it is difficult or impossible to recover or reconfigure the original knowledge asset(s). The challenge 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 organisational capability, never more so than 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 utilised to help identify knowledge and its relative importance to the organisation. A proven knowledge mapping tool, specifically designed for use within the biopharmaceutical sector, has been developed and used successfully by one of the authors of this monograph (Kane, 2018b). 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 4, and which is the third element of the Pharma KM Blueprint.

2.4   Conclusion

In conclusion, the authors acknowledge 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, 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 also advocates that the manner in which explicit knowledge and content is stored and curated[5] 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 3 will outline the next key element blueprint, the *Pharmaceutical Product Knowledge Lifecycle (PPKL) Model*, which discusses the importance of enabling knowledge assets to flow across the product lifecycle.

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[5]   **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.

3. Chapter Three
Pharmaceutical Product Knowledge Lifecycle (PPKL) Model

This chapter presents the second element of the *Pharma KM Blueprint*, namely 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. Firstly, the terms, *knowledge* and *knowledge management* (KM) are referenced across ICH guidance documents Q8 -Q11 (International Conference on Harmonisation, 2012) and in the ICH Q12 (International Conference on Harmonisation, 2019) 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 utilised across the lifecycle. Industry consultation undertaken as part of our research identified a specific request to better define the relationship between the product lifecycle and KM (Kane, Lipa, & Hubert, 2015).

Secondly, in the context of making product knowledge visible, enabling knowledge flow, and increasing availability, the authors believe the lifecycle phases as depicted in ICH Q10[6] do not represent actual practice in the *context of knowledge management* and *knowledge flow*. They therefore offer a re-imagined model to emphasise the critical role that knowledge plays in the pharmaceutical product lifecycle. It is the opinion of the authors that the very absence of knowledge from the product lifecycle model, depicting how the product and process knowledge assets are created and transferred into other organisational knowledge outputs, directly contributes to the ambiguity and compartmentalisation of lifecycle knowledge, and greatly inhibits the intended benefits sought by the ICH suite of quality documents.

3.1   Product Knowledge – the Regulatory Landscape

ICH Quality guidance issued during the period of 2005-2012 created awareness of risk-based science approaches to ensuring pharmaceutical product quality. The ICH Quality guidance documents share common expectations of leveraging product and process knowledge as an enabler to effective risk-based science.

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 realisation of intended benefits.

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

"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."

In November 2019 ICH Q12 was published (International Conference on Harmonisation, 2019) and it focuses on established conditions and post-approval changes with modest additional KM guidance. Q12 highlights the following:

a) A 'PQS includes appropriate change management, enabled by knowledge management, and management review'

b) 'Provisions should be made for sharing knowledge (e.g. in quality agreements and/or contracts) that relates to product and process robustness or otherwise informs changes between the MAH and relevant manufacturing stakeholders'

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

Figure 3.1 depicts the diagram from the Q12 which places highlights Knowledge Management as a key component of the Change Management process.
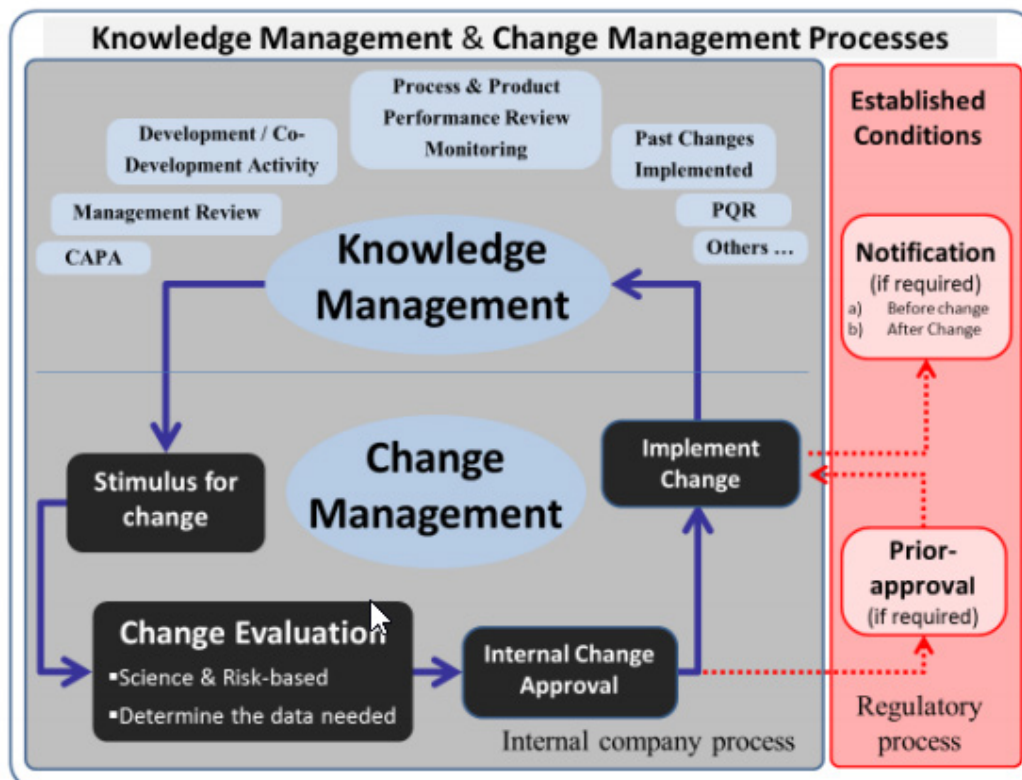

Figure 3.1 — *ICH Q12 - Putting Knowledge Management as a key component of Change Management (International Conference on Harmonisation, 2019, p. 19)*

The authors suggest that organisations could greatly benefit from further guidance to assist in forming a holistic end-to-end (E2E)[7] 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[8] 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 authors conclude that expectations from a regulatory perspective could in fact be over-burdensome, and therefore not welcomed by the sector as a whole.

3.2   The ICH Q10 Product Lifecycle

Returning to ICH Q10, the product lifecycle provides a foundation of shared understanding for the lifecycle phases of a medicinal product as shown in Figure 3.2 below.

Figure 3.2 — *ICH Q10 PQS Diagram inclusive of a product lifecycle (updated to enhance graphic quality) (International Conference on Harmonisation, 2008, p. 21)*

The authors suggest 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 since 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

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

[8]   The authors are 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

myriad of groups involved in capturing knowledge assets can leave organisations in a quandary as to how to enhance visibility and utilisation 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 organisation looks end-to-end at the flow of its knowledge assets, transcending organisational structure, geographies and other boundaries. In practice, enabling knowledge flow across the multiple phases of the product lifecycle can be very difficult.

3.3   Connecting Product and Process Knowledge

Product and process knowledge is created constantly through a variety of business processes, dialogues 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. Returning to a quote from O'Dell that "knowledge is sticky', two challenges were identified by the authors in connecting knowledge, the first of which is enhancing the visibility of lifecycle knowledge assets. and the second is enhancing the flow of those knowledge assets. These were 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 organisational knowledge flow challenges**, developing best practices and biopharmaceutical use cases … and creating real-time, networked knowledge management systems throughout the biopharmaceutical industry.*

The authors, reflecting on the insights gain from the industry consultations and direct experience, summarise possible reasons for these challenges as follows:

- Guidance is lacking on product lifecycle knowledge lifecycle and the knowledge generated within the lifecycle phases and activities
- The industry recognises 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)

In an attempt to address these challenges, the authors turned to ICH Q10 and suggested a modified version of the lifecycle depiction, as discussed in the next section.

3.4 Reimagining the ICH Q10 Product Lifecycle Model

Every day that the pharmaceutical product is manufactured, more knowledge is created and more is learned about the process and the product. Taking into account the tremendous amount of knowledge that is generated across the organisation (internal and potentially external to the Marketing Authorisation Holder) across the lifecycle of a product, the authors asserts that:

- If a primary goal of ICH Q10 is *product realisation* which requires that an organisation applies the best of what it knows (its 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….

this requires a re-imagination of the ICH Q10 depiction of the product lifecycle. The authors believe a new articulation of the lifecycle could be developed which would better align with the non-linear nature of product development, manufacture and knowledge transfer throughout the life of the product.

The authors propose four areas of opportunity to enhance the ICH Q10 model.

1. Technology Transfer could be 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).

2. Addition of a new lifecycle phase of *New Product Introduction* (NPI) to replace the Technology Transfer lifecycle phase to cover the initial commercialisation of the product, which is a highly "knowledge rich" activity.

3. Introduce a new *activity* for *Technical Product Support and Continual Improvement across* the lifecycle.

4. 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 authors propose 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 shown in **Figure 3.3**.
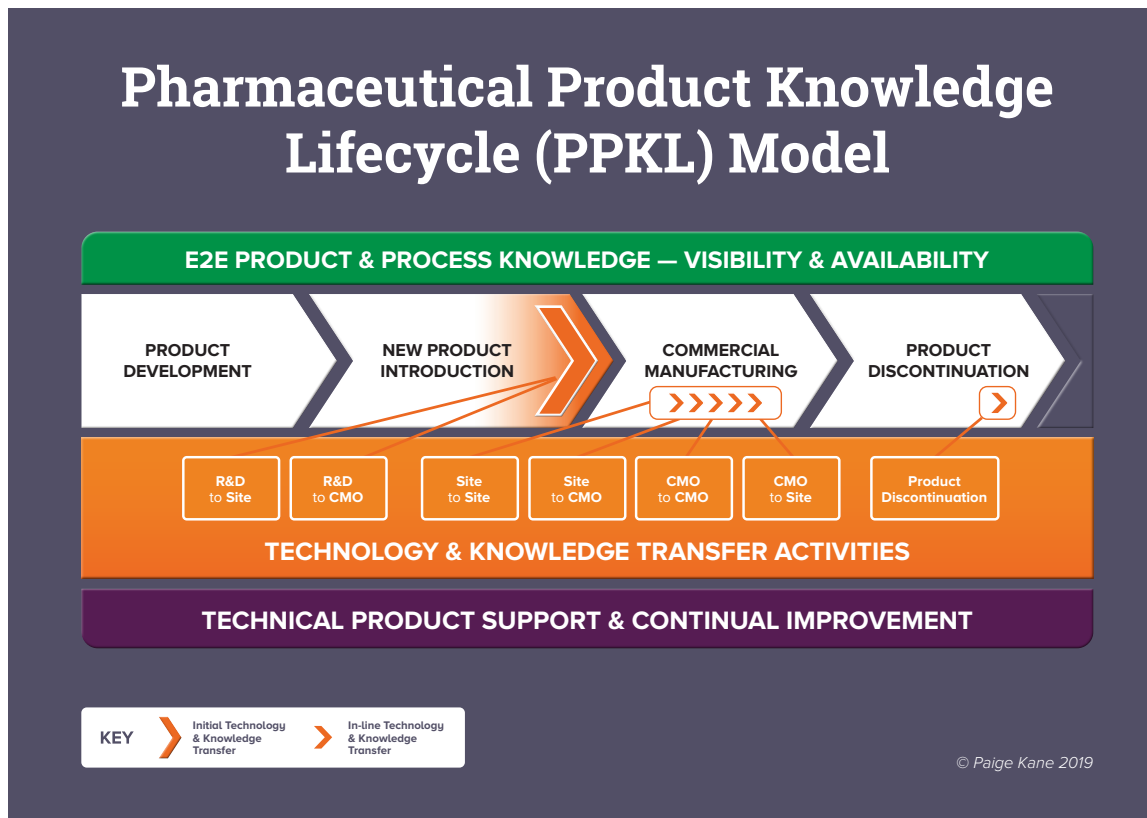
Figure 3.3 — *Pharmaceutical Product Knowledge Lifecycle Model (PPKL) – research output Kane 2018*

3.4.1   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 emphasises that the 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.*

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

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

- ISPE: Good Practice Guide: Technology Transfer [Third Edition] (ISPE, 2018)

- 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 describe 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 (Lipa, Kane, Greene 2019). 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 characterise 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, and troubleshoot for a short transitional period of time in order to share their knowledge of the product and process, and to 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. Little time is left for training and coaching the new team responsible for commercial production of the product(s) post-handover.

The authors suggest that Technology Transfer (TT) 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 organisation by reducing operational costs and resources post-transfer. Work is on-going on developing these practices, and Chapter 6 of this monograph presents some outputs of early research in this area.

Another misunderstanding that the authors have 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[9] within the expert focus groups and KM Task Teams has observed that, for small molecule products one could expect four or more TT events as the company continues to optimise production and minimise costs over the product lifecycle. Indeed, technology transfers may be on-going 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

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

a new organisation (CPhI Pharma Insights, 2016). This phenomenon is illustrated on the adapted lifecycle model by showing multiple TT chevrons occurring throughout the product lifecycle in Figure 3.3 above.

Furthermore, 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 3.3 with a final chevron, acknowledging this transfer in the product discontinuation lifecycle phase.

The biopharmaceutical sector is not alone in addressing the challenges to transfer critical knowledge across organisational boundaries. In 2012, APQC, at the request of 15 organisation across multiple industries, conducted research to seek out best practices in improving the flow of knowledge during process development (APQC, 2012a). Table 3.1 presents four high level knowledge flow best practices and associated sub-activities, identified by this APQC research, for organisations to consider.

Table 3.1 — 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.

Table 3.1 — APQC best practices of improving the flow of knowledge during process development (APQC, 2012a)	
3. **Create organisational 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 organisational support. e) Use trained change agents. f) Build and maintain a centralised, 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 programme's impact over time.

These strategies identified by APQC could benefit the biopharmaceutical sector if 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. The authors believe that, 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 centralised, searchable repository for critical process development knowledge', would be particularly beneficial to the success of the overall transfer process.

Returning 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 organisation boundaries. In addition, ICH Q12 states:

> *'Provisions should be made for sharing knowledge (e.g., in quality agreements and/or contracts) that relates to product and process robustness or otherwise informs changes between the MAH and relevant manufacturing stakeholders (research and development organisations, manufacturers, CMOs, suppliers, etc.). '(International Conference on Harmonisation, 2019, p. 31)*

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.

Finally, to complete 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 3.3**). This phase is intended to depict the initial and finite activities specifically related to the first instance of commercialising of given product, which 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 organisation, the success of which hinges on the ability of that organisation to create, capture, communicate and curate new knowledge about that product.

3.4.2   Reimagining the ICH Q10 Product lifecycle Model – Technical Product Support and Continual Improvement

The next element of the adapted lifecycle model the authors addressed was 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 organisation will continue to learn and build knowledge about the respective product. This can occur during *New Product Introduction*, and on-going *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 optimisation.

The authors suggest an E2E workstream of *Technical Product Support and Continual Improvement which begins at the New Product Introduction* phase when the manufacturing process is locked in order to perform technology transfer to the initial receiving site. These support and improvement activities continue across the product lifecycle until the product is discontinued. When, 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.

If a formal process is used to capture, collate and curate the critical aspects of product and process knowledge gained from the on-going 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. 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 designed to 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 organisation 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.

A review of the literature identified two specific examples of organisations 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 Kane was involved in developing, in conjunction with other colleagues in Pfizer. One key element common to these two business processes is the inclusion of roles and responsibilities for creation and maintenance of the product and process knowledge assets. However, dedicated roles for E2E preservation and curation of product and process knowledge are not be well defined across the industry, and this 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 discussed in Chapter 2 of this monograph 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. Improvement of operational effectiveness is recorded as 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 could be the development of a practical KM practice or methodology to deliver greater transparency of product knowledge across the product lifecycle, conceptually a *Product Roadmap* that would 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.

3.5   The Pharmaceutical Product Knowledge Lifecycle (PPKL) Conclusions

In summary, the authors in this chapter present 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 4 will next introduce the *House of Knowledge Excellence (HoKE) Framework*, as a strategic and a programmatic approach to managing knowledge in organisations.

4. Chapter Four
The House of Knowledge Excellence (HoKE)

This Chapter presents the third element of the *Pharma KM Blueprint*, namely the *House of Knowledge Excellence (HoKE) Framework*.

The HoKE framework provides an opportunity to define what the authors 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 it is 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 behaviours of the employees or knowledge workers within the organisation. Employees must be encouraged and enabled to think and act differently in how they seek and share knowledge.

The authors propose 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 to 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 a literature review, very few biopharmaceutical organisations have implemented a programmatic approach to knowledge management to date. Where organisations 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 organisations may use to assist in either the development of a KM strategy, the roll out of a holistic KM programme, 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 realise the true business benefits of being excellent in the capture, curation and use of our knowledge.

The framework was developed by the authors and published in 2018 as a book chapter entitled *The House of Knowledge Excellence – A Framework for Success* (Kane & Lipa, 2018). The HoKE framework is presented below in Figure 4.1, however, for more detail, it is recommended that readers consult the complete chapter in the published book.
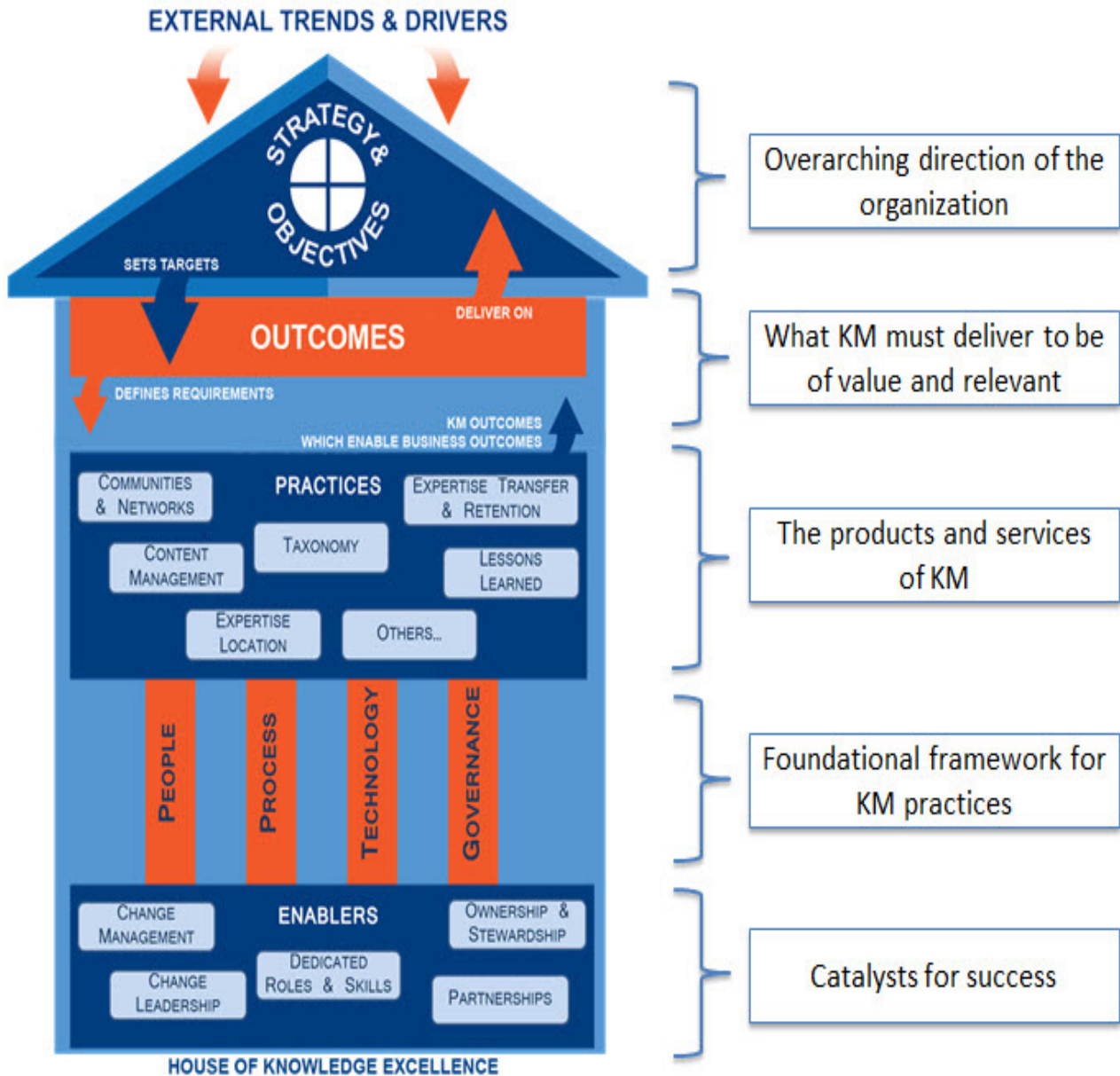
Figure 4.1 — *House of Knowledge Excellence (HOKE) -(Kane & Lipa, 2018, p. 219)*

5. Chapter Five
Knowledge Management Effectiveness Evaluation (KMEE)

This chapter presents 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 authors to facilitate a structured evaluation of the effectiveness of how an organisation 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 one of the author's organisations. Following the completion of the *APQC KM CAT™* evaluation, the author recognised 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 frontline team or shop-floor level.

While a "one size fits all" evaluation methodology might be considered optimal in application, customising the scoring tool has proved important to create the practical linkages between KM theory and practice. Evaluating organisational KM maturity scored using the KM-CAT™ tool for a large organisation 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 frontline team members are captured. This chapter provides a real-world example of the application of the KMEE evaluation tool within one of the author's organisations (a large multinational biopharmaceutical company).

5.1 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 organisational change effort.

It is worth reviewing an observation on KM Maturity by 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 organisations but, more importantly, is making managers lose faith in knowledge management as a strategic enabler. (Kruger & Snyman, 2007)*

The authors have 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. It was found that in practice, the *KM CAT™* tool was informative to assess *KM Program* and high-level organisational maturity. A key benefit of using the *KM CAT™* is the ability to benchmark the maturity value for a given organisation 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 into the performance of individual businesses included in the index average. This reflection, and the need to close the 'knowing – doing gap', lead the authors back to the Kruger and Snyman observation above. Diving deeper into the maturity assessment, the challenge with the *KM CAT™* was multifaceted. 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 were 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 recognised 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[10] 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.

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[10] 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 authors considered one simple solution would be to take the KM-CAT™ deeper in to the organisation, however they did not believe the sentiments presented around relevance, terminology, and reporting detail would be addressed by the KM-CAT™ alone. Based directly on this feedback, they 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 baseline to further measure specific team capability
- Was capable of articulating gaps within the teams
- Included a scoring template that could recognise the achievement of individual capabilities
- Included a scoring template that enabled prioritising 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 discussing the details of the resulting KMEE Diagnostic tool developed by the authors, it is first useful to understand the key features and scoring mechanisms embedded within the APQC KM-CAT™ tool.

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

According to APQC the *APQC's Knowledge Management Capability Assessment Tool™* (KM-CAT™) helps an organisation assess its capabilities and maturity in knowledge management (KM) and to 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 organisation 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 organisational 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 as shown in **Table 5.1** below.

Table 5.1 — APQC KM-CAT™ - Four major sections with subcategories	
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 organisation is aware that it has a problem retaining and sharing knowledge.

- **Level 2** — initial knowledge approaches are in place. The focus is on helping localised knowledge flow and adding value.

- **Level 3** — the knowledge flow processes are standardised, and the focus is on meeting business requirements, achieving results, and developing a supporting infrastructure.

- **Level 4** — the KM efforts align with the organisation'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 organisation in order to be considered to have achieved that level. To further explain the scoring, an excerpt of the KM-CAT™ KM Approaches & Tools section is shown in **Table 5.2** below:

LEVEL	ACHIEVED Y/N	CAPABILITY
Table 5.2 — Example of APQC KM-CAT™ data collection sheet for a given 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.

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 organisation would not score KM maturity at Level 2.

The authors recognise that, while there are many positives with the KM-CAT™, the scoring methodology and process is particularly challenging when trying to evaluate and engage functional teams. While the overall rationale for scoring[11] is sound, the results as presented by the APQC methodology, are not particularly insightful at the function level. **Table 5.3** describes challenges and potential solutions the authors considered when designing an updated tool.

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[11] Scoring methodology is similar to that of Malcolm Baldrich Quality Award, in which APQC was also involved in the development

Table 5.3 — 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

5.3   Need for a supplemental tool for localised functional KM Assessments

While acknowledging that the KM-CAT™ is suitable for measuring overall organisation and KM programme maturity /capability, the authors endeavored to create a focused capability diagnostic tool aimed at smaller groups/teams such that it:

1) Is customised to reflect specific KM tools and processes within the organisation – drives engagement at the individual or team level, and not at the KM Programme level. In addition, the customisation 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 prioritise gaps identified.

5) Provides templates for reporting and action planning. i.e. Pre-populated templates with specific recommendations, outlining the benefit to the organisation for closing the gap.

5.4 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 organisation whose primary responsibly was supporting product realisation and continual improvement, and did not have a responsibility for developing the overall Divisional KM programme.

2) Capabilities deemed relevant from the APQC KM-CAT™ tool were then supplemented with specific organisational "translations" of the capability to clarify the requirements and relevance.

3) Capabilities were organised via the sections and sub-sections of the original APQC KM-CAT™ tool, and each of the criteria for the maturity level were 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 authors determined that 28 individual capabilities arranged into 3 sub-categories/focus areas would be most suited to individual groups within the biopharmaceutical organisation seeking to improve its KM maturity and knowledge flow.

These are shown in **Table 5.4** below:

Table 5.4 — 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 these sections have sub-categories 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 sub-categories 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 5.5**:

Table 5.5 — Capability description within maturity levels depicted		
Level	**Description of Maturity Level**	**Number of Capabilities**
1	Initiate	4
2	Develop	7
3	Standardise	9
4	Optimise	5
5	Innovate	3

The modified KMEE evaluation tool is now shown in the next three tables. **Table 5.6** related to *Content and IT* capabilities, **Table 5.7** evaluates *People* capabilities, **Table 5.8** evaluates Process and Knowledge Flow capabilities.

Table 5.6 — 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 organised 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 5.7 — 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 colleague's 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 organisation 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

	Table 5.7 — KMEE People Capabilities		
Level	**Category**	**APQC Capability Description**	**KMEE Function Specific Description of Capability**
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 programme 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 5.8 — 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	Standardised knowledge flow processes are used across multiple instances or situations.	What are the standardised processes to enable the flow of knowledge across multiple groups in the organisation
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, organisational 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 organisation.	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

5.4.1 Scoring Methodology:

To evaluate the modified KMEE tool, a series of focus groups were performed to assess if each capability criteria (using the customised questions) were met. A scoring mechanism was designed to reflect capability attainment, which was visually represented in a heat map. Examples of focus groups heat maps are presented for a team with low KM maturity versus a team demonstrating higher KM maturity in **Tables 5.9** and **5.10** respectively below:

PP3 Change Management	PP4 Communication	PR1 Knowledge Flow	PR2 KM Approaches	PR3 Measurement	IT1 Management Processes
Table 5.9 — Focus group demonstrating low KM Capability: Green cells indicate achieved, Grey indicate N/A					
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:

PP3 Change Management	PP4 Communication	PR1 Knowledge Flow	PR2 KM Approaches	PR3 Measurement	IT1 Management Processes
Table 5.10 — Focus group demonstrating higher KM Capability: Green cells indicate achieved, Grey indicate N/A					
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 example teams, who all belong to the same organisation, one can recognise 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.

In this example, a business decision by the leadership of the case-study organization, all teams aim to reach a Level 3 in maturity as the initial maturity performance improvement target.   As such, a report was developed to show the gaps (if any) to reach capability of 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 5.1** is an example of how these results were visualised for leadership to aid their comprehension and ownership of the organisational changes required.
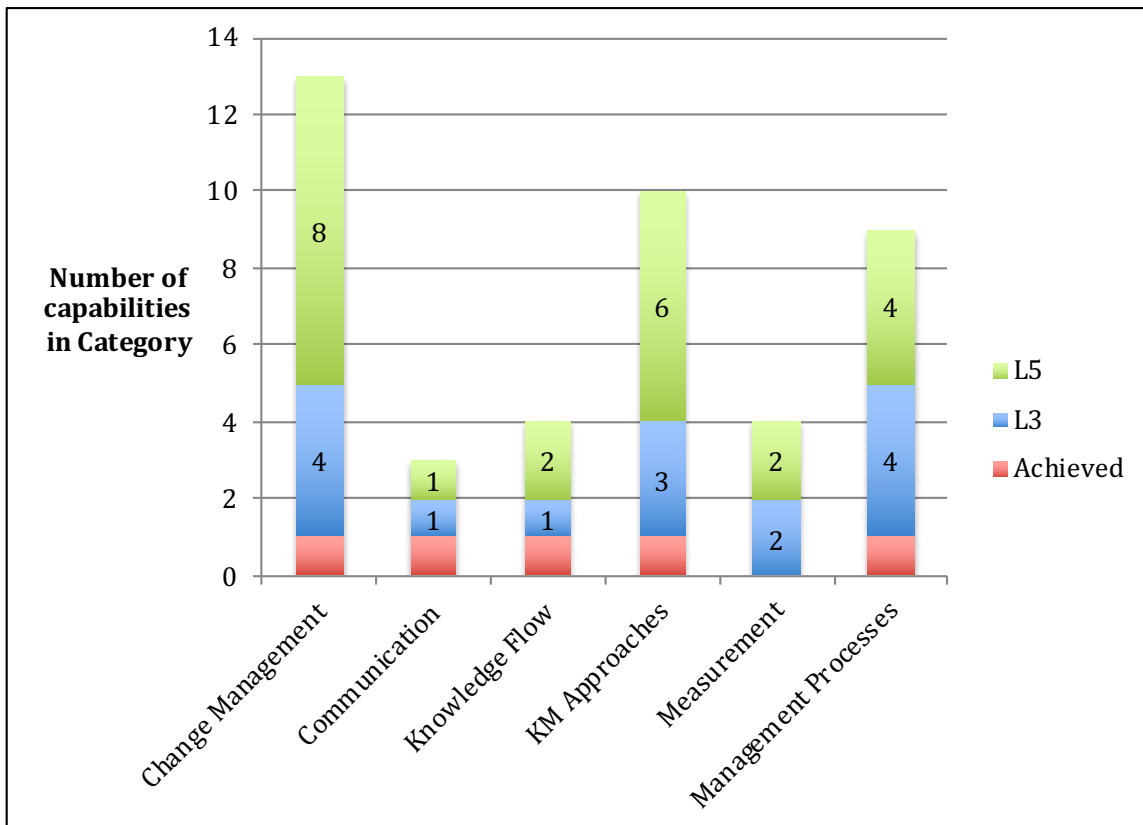

Figure 5.1 — *Blue indicates the number of capabilities required to fill the gap to achieve level 3 maturity, Green is the gap of capabilities to reach level 5 maturity.*

5.4.2   KMEE Reporting and KM Plan – A Roadmap to KM Capability Improvement

To assist each functional area, a KM plan template was developed to suggest opportunities and methodologies to close the gaps, as well as to articulate business benefits to build KM capability. The full report provided to each team was presented and included the following:

- 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)[12]
    » Recommendation for closing the gap

- Prioritisation 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 full case study described in the previous sections is published as a component of Kane's PhD thesis and can be found in the TU Dublin Arrow site *https://arrow.dit.ie/sciendoc/210/* .

5.5   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 organisations, right down to front line team member level.

It could be argued that the model is very closely linked to the APQC KM-CAT™, that was by design. However, feedback from the management teams involved in the case study pilots 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.

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[12]   As the business focus was to have all groups achieve a level 3 (L3) capability, focus was on closing the gaps for L3 for the fiscal year of the study.

6. Chapter Six
Evolving Research: Presentation of a Framework to Enhance Knowledge Transfer

This chapter concludes the monograph by presenting early stage research into effective Knowledge Management during Technology Transfer in the format of a *Knowledge Transfer Enhancement Framework* (KT^E Framework).

The KT^E Framework evolved over a series of brainstorming meetings and workshops, based on the experience of the authors (including experience with KM best practices across industries), and by applying a well-known Lean Six Sigma improvement methodology of *Plan, Do, Check, Act* (or PDCA). The KT^E Framework (Figure 6.1) is divided into four stages, namely:

- **Stage 1**: KT Readiness Planning
- **Stage 2**: KT Execution
- **Stage 3**: KT Effectiveness Assessment
- **Stage 4**: KT Action Plan.

The KT^E Framework is depicted in **Figure 6.1.**
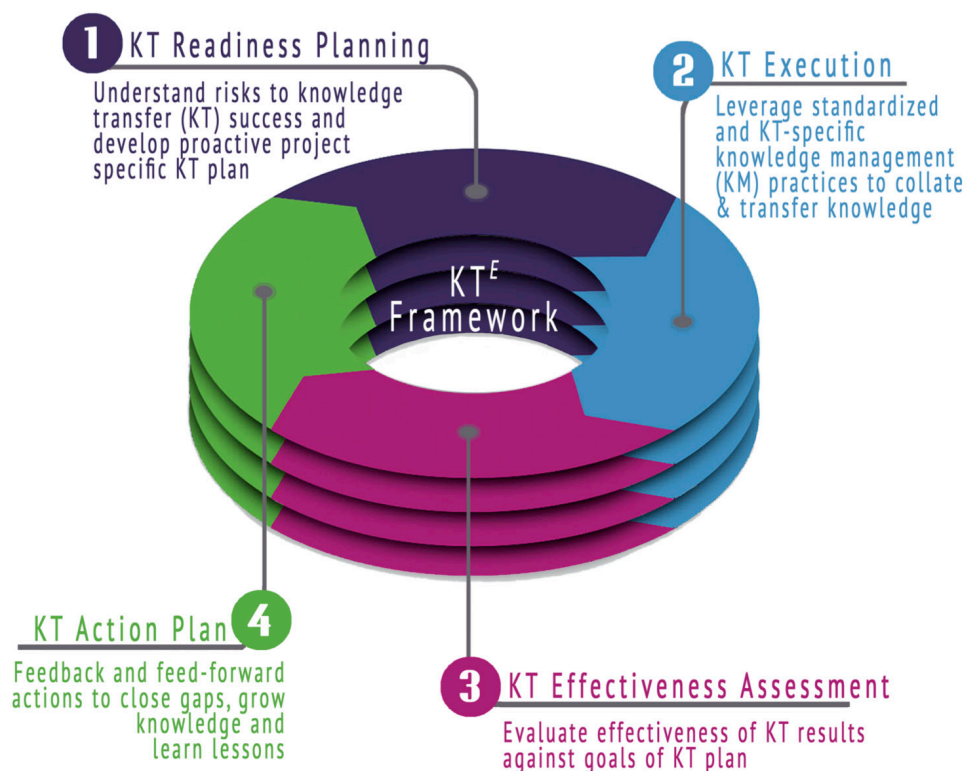
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Figure 6.1 — *The KT^E Framework (original contribution Lipa 2020)*

Further detail on the purpose and intended outcome of each of the four stages is presented in **Figure 6.2**.

Figure 6.2 — *Expanded KT^E view of purpose and intended outcome of each of the four stages (original contribution Lipa 2020)*
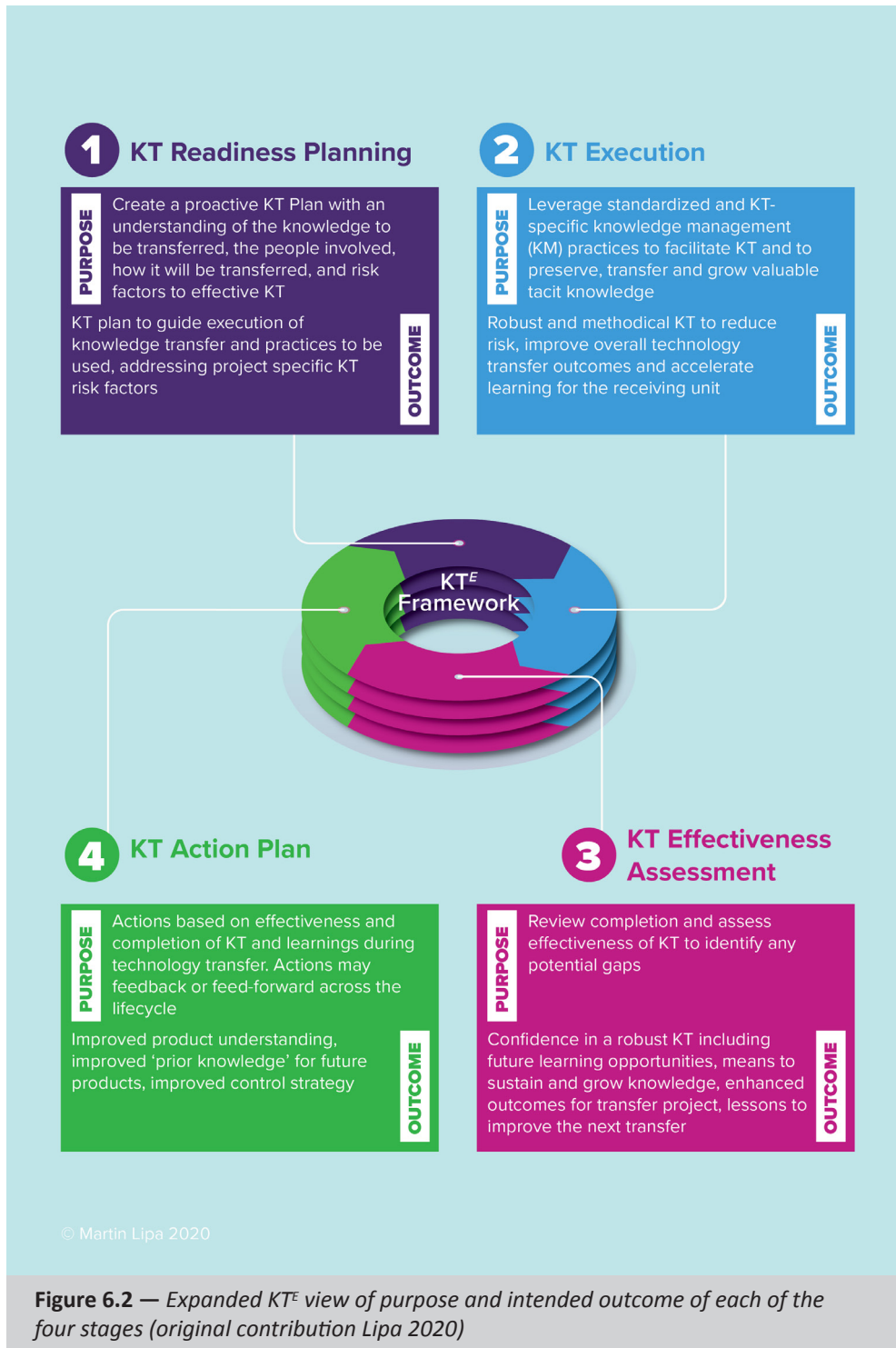
Work is on-going and it is anticipated that the development of this framework and an associated toolkit to enhance knowledge transfer will be published in the near future.

7. Chapter Seven
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