Level 3

Volume 17
Issue 2 *Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape Knowledge-Enabled Technology Transfer*

Article 1

6-14-2022

Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape Knowledge-Enabled Technology Transfer

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Steps Towards Digital Transformation in the Pharmaceutical Manufacturing Landscape

Knowledge-Enabled Technology Transfer

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1 Introduction to this special issue of Level 3

In 2002, the FDA published its vision for a risk-based approach to manufacture of pharmaceutical products known as *Pharmaceutical CGMP Initiative for the 21st Century – a Risk Based Approach* [1]. This initiative was intended to modernise the FDA's regulation of pharmaceutical quality. This was not just a vision for the United States, but rather a global vision, and through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), global regulatory authorities and pharmaceutical industry members came together to discuss scientific and technical aspects of pharmaceuticals manufacture and to develop ICH guidelines[1]. The aim of the ICH guidelines was to provide a means to harmonise technical requirements across the ICH regions, namely, EU, US and Japan. Initially, three specific guidelines were developed:

i. ICH Q8: Pharmaceutical Development [2]
ii. ICH Q9: Quality Risk Management [3]
iii. ICH Q10: Pharmaceutical Quality Systems [4]

While published separately, all three were designed to be implemented together and to work together. ICH Q8 provides guidance on the contents of the Common Technical Document (CTD) submitted to regulatory authority inspectors in order to gain a marketing licence. ICH Q9 provides guidance on the principles and examples of tools for Quality Risk Management (QRM) which can be applied to different aspects of pharmaceutical quality. ICH Q10 provides guidance for the requirements of an effective pharmaceutical quality system (PQS), with the goals to achieve product realization, to establish and maintain a state of control, and to facilitate continual improvement.

While the start of the 21st century saw regulatory and industry bodies actively develop guidance on a risk-based approach for pharmaceutical quality, the Pharmaceutical Regulatory Science Team (PRST) in TU Dublin[2] approached the challenge from an academic perspective. Founded in 2005 in response to the drive for a paradigm shift in quality from the international regulatory community, the PRST actively engages with global industry and regulators to address the challenges and opportunities of implementing science and risk-based decision

[1] https://www.ich.org/page/quality-guidelines
[2] http://www.prst.ie

making and manufacturing approaches. The PRST advances such dialogue through research, with an emphasis on the development of patient-focused strategies to enable those involved in the manufacture of commercial drug products to meet evolving international regulatory expectations, thus ensuring the availability of high-quality medicinal products.

This paper introduces this special issue of Level 3 - *Steps toward digitalisation of the pharmaceutical manufacturing landscape: Knowledge-Enabled Technology Transfer*, a collection of papers from PRST members and other colleagues in academia and industry.

2 Key Foundational Concepts

While the theme of this special edition is knowledge-enabled technology transfer, it is important to first orient readers as to *why* this is important, along with understanding key foundational concepts. As such, this paper presents the following three concepts:

1. **The big picture: the PQS as a framework for delivering quality products to patients**. Discussion of the PQS objectives, depiction of the pharmaceutical product lifecycle, and positioning of KM and QRM as enablers. Furthermore, the concept of using the PQS as a mechanism for continual improvement is highlighted.

2. **A closer look at the concept of 'knowledge'**, including the definition of 'knowledge' and 'knowledge management', types of knowledge, and the relationship between data and knowledge.

3. The **importance of technology transfer as a pivotal stage** of the pharmaceutical product lifecycle, and associated challenges with knowledge transfer.

The following sections present further details on each of these concepts.

2.1 The Pharmaceutical Quality System

ICH Q10 provides guidance on the requirements for a PQS and is illustrated graphically in Figure 1.

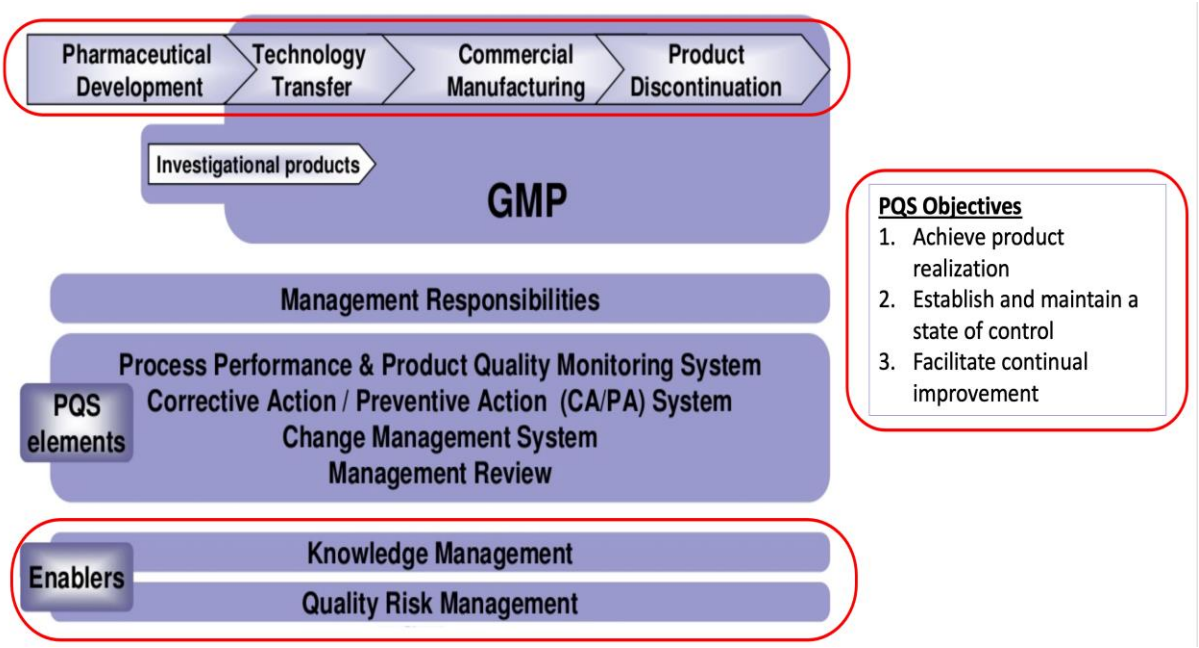

Figure 1 – The Pharmaceutical Quality System [4]

The ICH Q10 guideline proposed four stages of the pharmaceutical product lifecycle and positions quality risk management (QRM) and knowledge management (KM) as dual enablers to pharmaceutical quality.

2.1.1 Objectives of the ICH Q10 Pharmaceutical Quality System

ICH Q10 outlines three main objectives, summarized by the authors as follows [4]:

1. **Achieve Product Realisation:** To establish, implement and maintain a system that allows the delivery of products with the quality attributes appropriate to meet [all stakeholders].

2. **Establish and Maintain a State of Control:** To develop and use effective monitoring and control systems for process performance and product quality, thereby providing assurance of continued suitability and capability of processes.

3. **Facilitate Continual Improvement:** To identify and implement appropriate product quality improvements, process improvements, variability reduction, innovations and pharmaceutical quality system enhancements, thereby increasing the ability to fulfill quality needs consistently.

2.1.2 The Pharmaceutical Product Lifecycle

ICH Q10 outlines four stages of the pharmaceutical product lifecycle, *Pharmaceutical 3Development, Technology Transfer, Commercial Manufacturing,* and *Product Discontinuation*, as depicted in Figure 1. The associated goals for these stages [4] are summarized by the authors as follows:

1. **Pharmaceutical Development**
    - Design product and process to consistently deliver the intended performance and to meet the needs of parties
    - Exploratory and clinical development studies

2. **Technology Transfer**
    - Transfer product/process knowledge between development and manufacturing and within or between sites

3. **Commercial Manufacturing**
    - Achieving product realisation, establishing and maintaining a state of control and facilitating continual improvement

4. **Product Discontinuation**
    - Manage the terminal stage of the product lifecycle effectively

2.1.3 KM and QRM as dual enablers of the PQS

A depicted in Figure 1, Knowledge Management and Quality Risk Management are positioned as enablers to the PQS. ICH Q10 states [4]:

> *'Use of knowledge management and quality risk management will enable a company to implement ICH Q10 effectively and successfully. These enablers will facilitate achievement of the objectives [previously described] by providing the means for science and risk-based decisions related to product quality.'*

Research by the PRST has highlighted the importance of both QRM [5]–[8] and KM [9], [10], and more recently has explored their interdependency [11].

The identification of QRM and KM as enablers of an effective PQS recognises that the pharmaceutical industry is based on highly complex sciences – indeed a knowledge industry [12], [13] – and high stakes are involved given the direct impact on patient well-being, and possibly society at large as the COVID-19 pandemic has demonstrated. As such, the industry is highly dependent on acquiring knowledge to minimize uncertainty and maximize understanding, and in turn to use this knowledge and understanding to minimize risk and inform decision making [14], [15].

Furthermore, while paramount, ensuring high quality products is not the *only* reason the industry is dependent on effective management of knowledge. As a knowledge industry, knowledge underpins many things, including operational effectiveness and even employee engagement [16].

Lipa *et al.* [17], [18] presented the case that risk and knowledge are connected – and therefore risk management and knowledge management are also connected. Lipa proposed a framework, the *Risk-Knowledge Infinity Cycle* (*RKI Cycle*), as a means to intentionally connect

QRM and KM. The *RKI Cycle* is depicted in Figure 2 and presented in more detail in a subsequent paper in this special edition.

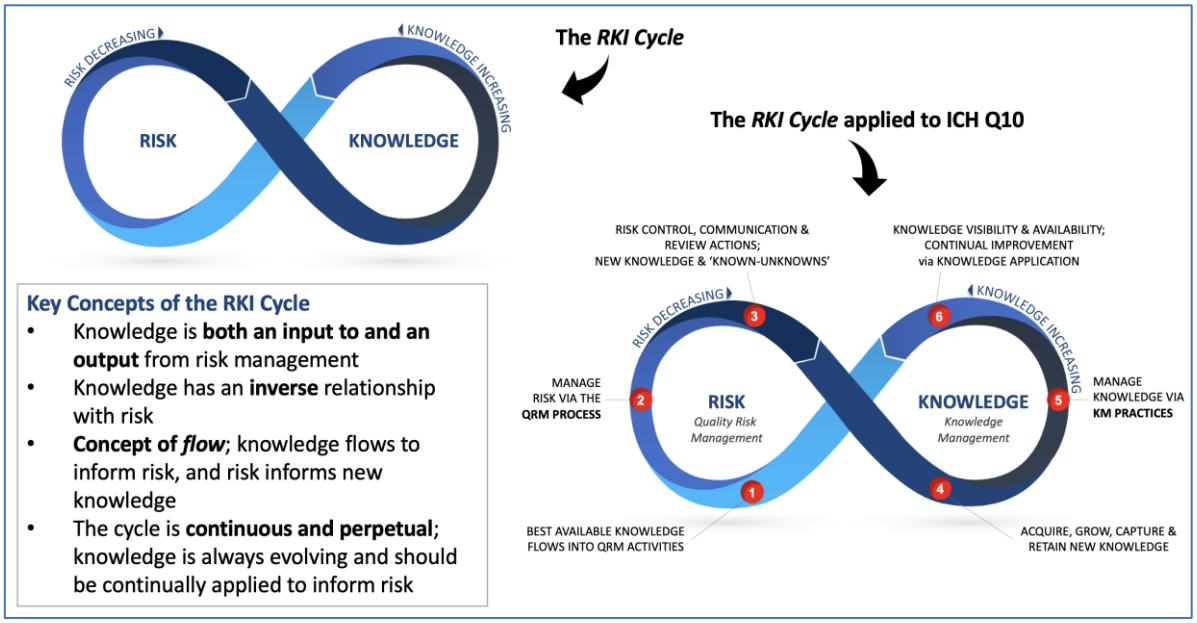

Figure 2 - The RKI Cycle

Lipa *et al*. further proposed a re-imagined PQS image as depicted in Figure 3, one where the enablers of KM and QRM are united, and together enable all elements of the PQS across the entire pharmaceutical product lifecycle.

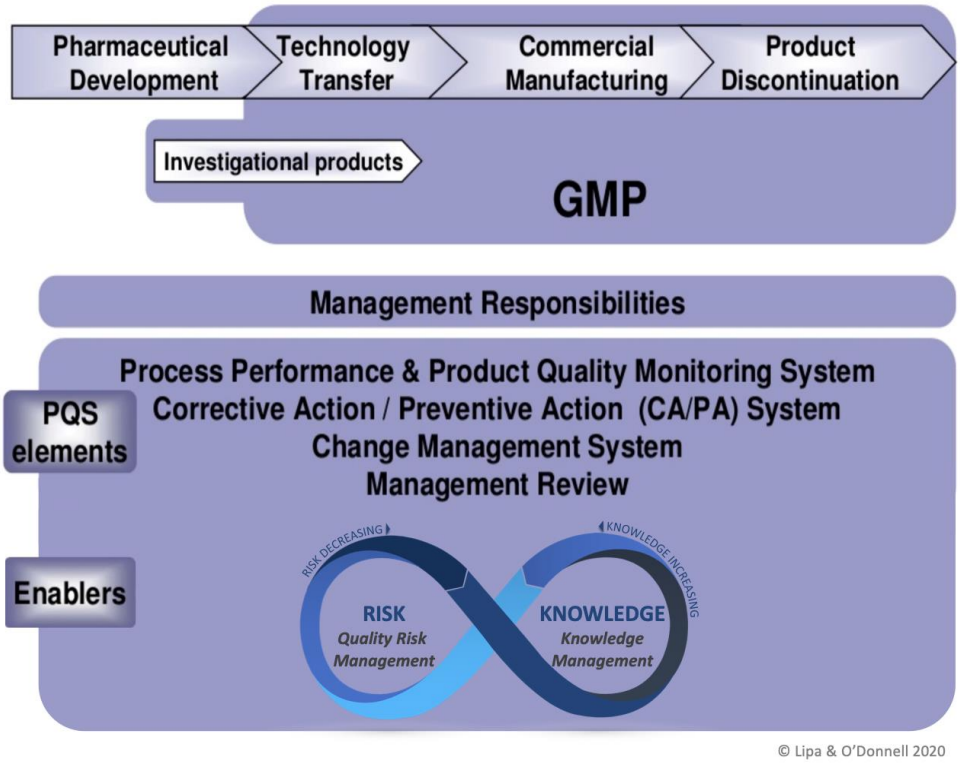

Figure 3 - A Re-imaged PQS Foundation

2.1.4 The PQS as a mechanism for continual improvement

Two of the high-level objectives of the PQS described in ICH Q10 are to 'establish and maintain a state of control' and to 'facilitate continual improvement'. Ramnarine *et al*. [19] explored this challenge in a paper entitled *'Continual improvement while maintaining a state of control: A concealed paradox or a mutual interdependence?'* In this study they suggested that:

> '*Proactive quality management, including the use of enhanced science and risk-based approaches, offers a solution … in that it facilitates an increase in smart and calculated (but responsible) risk-taking, to achieve continual improvement and innovation, as envisioned by the leading quality thinkers, QMS concepts, and the ICH guidelines'*.

Continual improvement is thus a requirement of an effective PQS. The commercial life of a product can span from 15 to 30+ years, during which time much can happen with a product, making the product lifecycle dynamic. Product and process understanding increases with experience over time, operational performance potentially improves, patient use information grows, issues occur, technologies advance, regulations and industry practices evolve, new trends emerge – all of which leads to a need for changes and continual improvement throughout the life of a product, while maintaining product quality and a state of control.

Ramnarine *et al.* propose that the ICH PQS model provides a framework for enabling continued improvement and innovation while maintaining a state of control, using enhanced science and risk-based approaches. Knowledge is the key to this, as described by Ramnarine *et al.:*

> *'As new knowledge is gained, regulations (and their interpretations) evolve, technologies emerge, new risks surface, and processes need to become less variable and more reliable - changes become inevitable. Therefore, demonstrating a state of control requires demonstrating continual improvement. If continual improvement is absent within the framework of a quality system, a loss of control may be the result. The Q10 PQS model is an excellent framework that can guide product lifecycle management, change management and continual improvement in a systematic, transparent, and structured manner that maintains state of control'.*

ICH Q10's objectives of a Pharmaceutical Quality System for companies to achieve product realisation, establish and maintain a state of control, and facilitate continuous improvement are indeed aspirational, and well founded. The role of QRM and KM in supporting these goals has been well documented in recent research papers by PRST members, and other industry and academic colleagues. While the focus of this journal is on the technology transfer stage of the lifecycle, it must be acknowledged that continual improvement transcends all lifecycle phases. The current focus on digital transformation in the industry presents many opportunities to enable innovation and continual improvement. The digital product profile solution discussed in the paper 3 of this journal entitled *'Building Excellence in Knowledge Transfer: Leveraging a digital backbone for Technology Transfer*' shows how the aggregation of data and linking of systems can be used as a mechanism for making knowledge available to support improvement across the product lifecycle.

2.2 A Closer Look at the Concepts of 'Knowledge' and 'Knowledge Management'

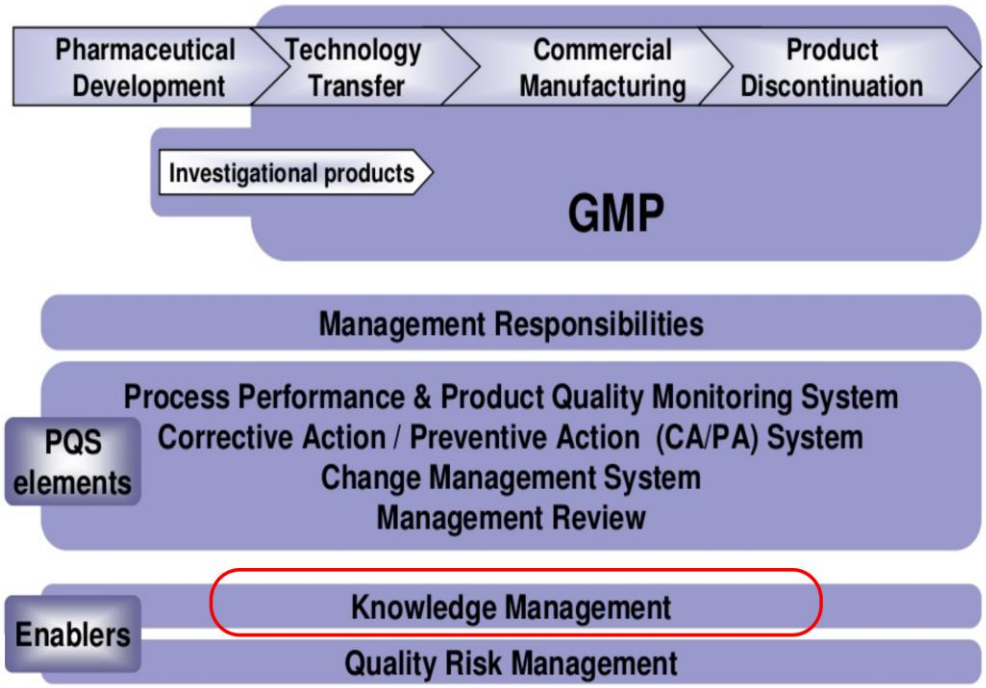

Figure 4 - KM as an enabler to the PQS

As one of the twin enablers to a PQS identified in ICH Q10 it is useful to take a close look at knowledge, types of knowledge and knowledge management, as often there is confusion around them. Then once 'knowledge' has been addressed, the linkage between knowledge and data is work considering.

2.2.1 Definitions of knowledge and knowledge management

Knowledge

An important starting point is to understand what these terms of 'knowledge' and 'knowledge management' mean. Interestingly, the definitions are highly variable which perhaps suggests why knowledge management is often an elusive topic. In the experience of the authors, people tend to have inherent pre-conceptions of what knowledge and knowledge management is (or isn't). One of the most common misperceptions is on the difference between data and knowledge, which is explored later in this section.

Considering formal definitions of *knowledge*, ICH Q10 which introduces KM has not expressly defined the term. The international standard on knowledge management issued by ISO does define KM, as follows [20]:

Human or organizational asset enabling effective decisions and action in context

- *Note 1: Knowledge can be individual, collective or organizational.*

- *Note 2: There are diverse views on the scope covered within knowledge, based on context and purpose. The definition above is general as to the various perspectives. Examples of knowledge include insights and know-how.*
- *Note 3: Knowledge is acquired through learning or experience.*

APQC, a leading organization in industry-agnostic KM research and training, defines KM as *'Information in action'* [21]

And while ICH Q10 does not expressly defined the term 'knowledge' a closer look at the ICH guidelines and industry guidance suggest several synonyms invoking the concept of knowledge. Such terms include *prior knowledge*, *scientific knowledge, science, product and [or] process knowledge, experience, product development history, expertise, know-how, product and [or] process understanding, 'lessons learned'*, etc.

In fact, definitions of science invoke the concept quite clearly. Greene and O'Donnell [22], suggested that the inherent relationship between *science* and *knowledge* cannot be disputed. Evidence of this was proven by various definitions of *science* as shown in Table 1.

Table 1 - Definitions of Science

Definition of 'Science'	Source
Knowledge about or study of the natural world based on facts learned through experiments and observation	Merriam Webster Dictionary
A systematically organized body of knowledge on a particular subject	Oxford English Dictionary
Archaic knowledge of any kind	Oxford English Dictionary
A branch of knowledge or study dealing with a body of facts or truths systematically arranged and showing the operation of general laws	Dictionary.com
Systematic knowledge of physical or material world gained through observation and experimentation	Dictionary.com
Knowledge, as of facts or principles; knowledge gained by systematic study	Dictionary.com

Knowledge Management

While ICH Q10 did not define the term knowledge, it did define the term knowledge management as follows [4]:

> *'Systematic approach to acquiring, analysing, storing, and disseminating information related to products, manufacturing processes and components.'*

Notably, the ICH Q10 guideline did not cite any other literature in proposing this definition. Other definitions exist in cross-industry guidance, including the ISO standard on knowledge management and APQC

ISO 30401 [20]:

'Management with regard to knowledge.

- *Note 1: It uses a systemic and holistic approach to improve results and learning.*
- *Note 2: It includes optimizing the identification, creation, analysis, representation, distribution and application of knowledge to create organizational value.*

APQC [21]:

'A collection of systematic approaches to help knowledge flow to and between the right people at the right time (in the right format at the right cost) so they can act more efficiently and effectively to create value for the organization.'

Indeed, these definitions of both *knowledge* and *knowledge management* present some inherent variability in how the terms are described, and hence perhaps pose a risk to understanding by the industry.

2.2.2 Types of knowledge

It is important to recognize there are multiple types of knowledge. While explicit knowledge is likely top of mind for many, tacit knowledge is also an important source of knowledge for the biopharmaceutical industry. In fact, the literature suggests 70-80% [21], [23] of what organizations collective knowledge is held as tacit knowledge. Useful definitions of tacit and explicit knowledge, with examples of both are provided in Table 2.

Table 2 - Explicit & Tacit Knowledge: Definitions and Examples

	Explicit Knowledge	Tacit Knowledge
Definition	Explicit knowledge is codified knowledge – knowledge that is written down [24] Knowledge that can be expressed in words, numbers, and symbols and stored in books, computers, etc. Explicit knowledge can be articulated and easily communicated between individuals and organizations[3]	Tacit knowledge refers to knowledge that resides in the minds of individuals and is surfaced in response to a situation or action. [24] Tacit knowledge is often referred to as 'know-how', 'know-why', or 'know-who'
Examples	• Documents • Pictures • Videos • Processes • Templates • Business rules • Standard operating procedures	• Decision rationale • Knowledge gained through experience • Mental models • Details of the order of operations • The unusual operation of items of equipment • The actual way an operation is carried out • Interventions • Use of work arounds

[3] Cambridge Dictionary: https://dictionary.cambridge.org/us/dictionary/english/explicit-knowledge

2.2.3 Exploring the relationship between data and knowledge

Any discussion on Knowledge would not be complete without a focus on data and the relationship between knowledge and data. Adams *et al.* in their paper entitled; 'Exploring pathways from data to knowledge to insights in the pharmaceutical industry: Introducing the Pharmaceutical Knowledge Ecosystem' [25], discussed this topic in detail. In that paper they introduced a long-standing framework in the discipline of information science is the Data, Information, Knowledge, Wisdom (DIKW) hierarchy shown in Figure 5 [26].

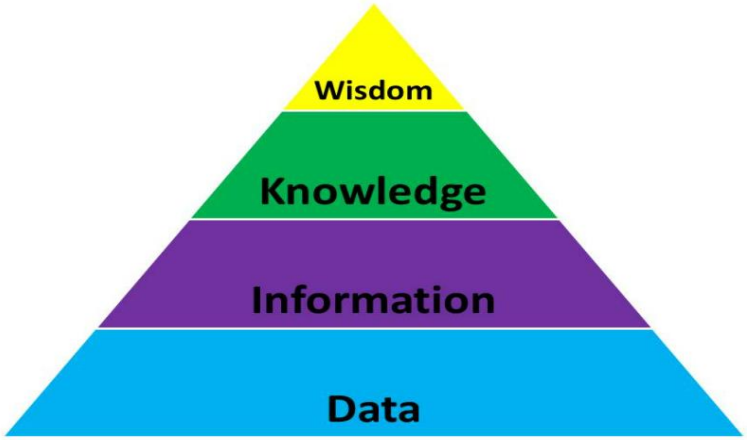

Figure 5 - DIKW Hierarchy

While the DIKW hierarchy is helpful, it is not necessarily pragmatic in application in the current pharmaceutical technology environment. Kane, as part of her PhD research, proposed an alternative to the above DIKW hierarchy, replacing *wisdom* with *insights*, shown in Figure 6 [10] .

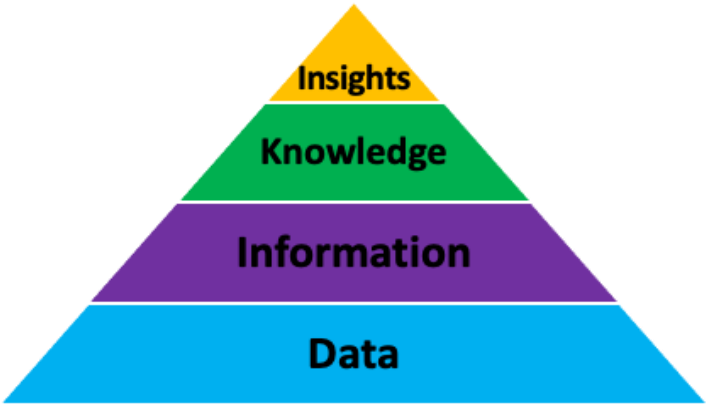

Figure 6 - Data-Information-Knowledge-Insights (as adapted by Kane)

Wisdom is widely agreed to be a "uniquely human" characteristic, whereas insights take account of current technological advances where data transformation can lead to insights. While insights may be derived by people with knowledge and experience, they may also be derived from computing or machine learning models that identify trends and correlations previously not possible to see with experience alone.

Indeed, taking this a step further, Kane [10] proposes that while it is useful to replace wisdom with insights in the DIKW hierarchy, on reflection, the successive goal is to achieve understanding. Whereas insights could be regarded as discrete, understanding represents a holistic comprehension – a state of mastery for a given domain or topic. Having mastered this progression of data to information to knowledge to insights and understanding – it presents the opportunity that one will be able to make informed and effective decisions, based on accumulated evidence, as provided by the underlying structure, as depicted in the proposed model below [27].

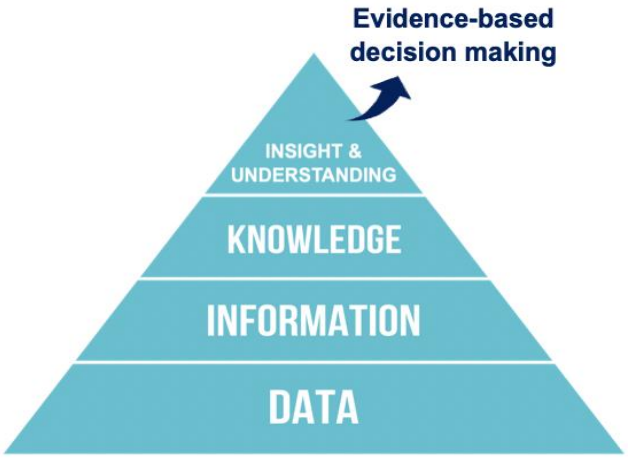

Figure 7 - Data-Information-Knowledge-Insight & Understanding (as adapted by Lipa)

From above discussion and figures, it is clear that understanding the relationship between knowledge and data, and how they transition into insights and understanding, is key to an effective PQS and enhanced decision-making. The existence of technology solutions such as the digital product profile (as discussed in paper 3 of this special edition) provides a mechanism which enables the digital data of a product be accessed through out the product lifecycle, and also a mechanism to connect the discrete digital data that may exist in discrete software platforms and make it available to decision-makers as needed.

While knowledge management was identified as an enabler to the PQS, in order to fully act as an enabler, the different types of knowledge and digital data that exist must understood and also 'managed' to ensure they are available and flow to support decisions and continued improvement throughout the pharmaceutical product lifecycle.

2.3 The Importance of Technology Transfer to the Objectives of the PQS

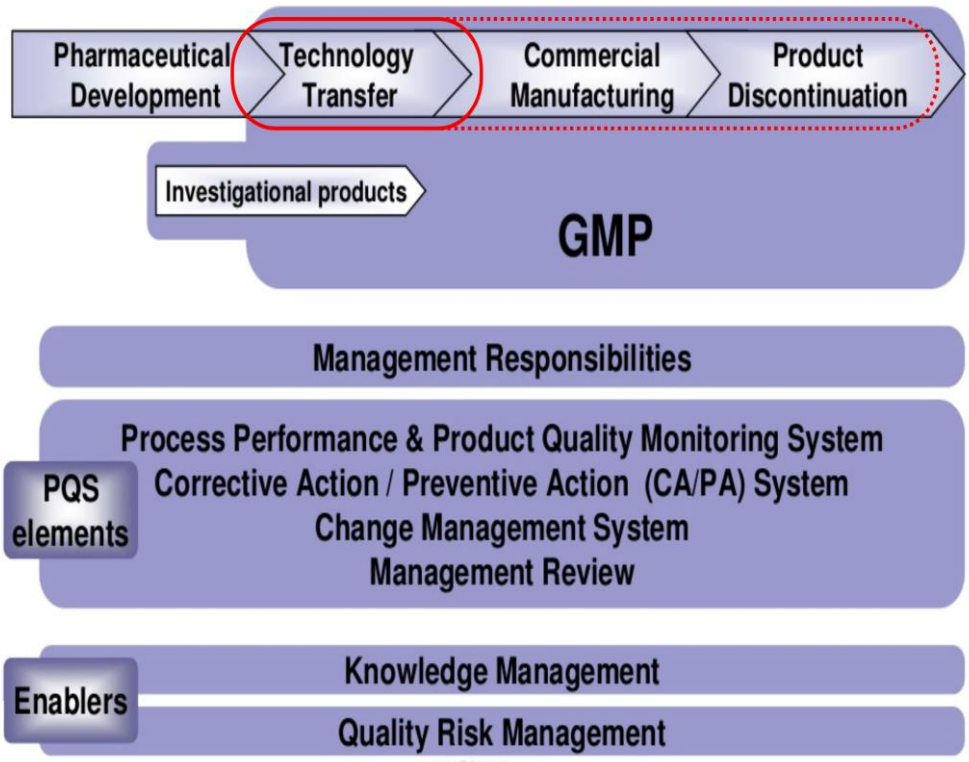

Figure 8 - Technology Transfer within the PQS

Reflecting on the PQS objectives of product realisation, establishing and maintaining a state of control, and facilitating continual improvement, the interface between the key lifecycle phases and the transfer of knowledge between them is critical in achieving these objectives.

2.3.1 Technology transfer: Not a one-time event

Technology transfer is a pivotal stage in the lifecycle of a product as it presents a risk to the goals of ICH Q10 in the form of a discontinuity of knowledge. It is also very common for technology transfer to introduce changes to the process and/or equipment – whether intentional (e.g., process changes to improve yield, batch size, cycle time, etc.) or required for the transfer (e.g., use of similar but slightly different equipment, etc.) – and as such introduces further risk which must be assessed and controlled. Other categories of risk may include transfer scope, inherent complexity, maturity of process technology, maturity of receiving site, cultural issues or contractual agreements [28].

While ICH Q10 positions technology transfer as a discrete lifecycle stage in a product lifecycle, some have argued this underappreciates the reality of technology transfer for the biopharmaceutical industry, as while technology transfer does occur for new product introduction as positioned by ICH Q10, it can also occur at many times and in many contexts throughout the lifecycle. The model shown below in figure 9 developed by Kane illustrates this concept [10].

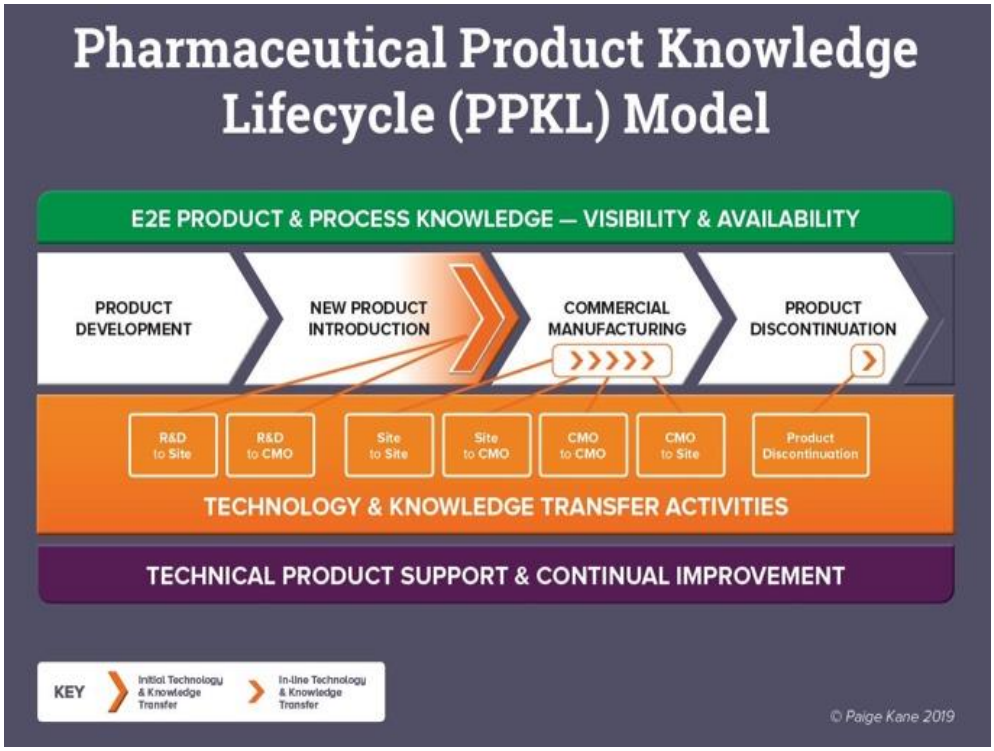

Figure 9 - The PPKL Model

Technology transfer involves the transfer of technology to manufacture a product effectively and reliably in a different location. However, technology transfer is also highly dependent on knowledge availability and knowledge transfer to complete the transfer project successfully, and also for sustained and robust manufacturing at the receiving site. Indeed, ICH Q10 recognizes the centrality of knowledge in how it defines technology transfer [4]:

> *"The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach and on-going continual improvement."*

The fact that the goal of technology transfer is to transfer '*product and process knowledge*' between sites if often missed in practice, with the focus on transferring the technology rather than the knowledge. A starting point to change this practice is to understand the importance of knowledge and how it supports the PQS.

2.3.2 Knowledge transfer during technology transfer

As further evidence of the recognition knowledge plays during technology transfer, the third edition of the *ISPE Good Practice Guide for Technology Transfer* [29] highlights five areas of importance, one of which is "Recognition that knowledge management is a critical component of effective technology transfer…". Furthermore, the ISPE guide introduces the concept of tacit knowledge, describing tacit knowledge in multiple ways, including "knowledge from experience rather than explicit knowledge," "practical information that may

or may not be initially documented", and "nuances or hands-on information which are note detailed in manufacturing instructions."

In the authors' experiences, tacit knowledge transfer during technology transfer can be highly variable in practice. Recent research by the authors exploring the importance and effectiveness of both explicit and tacit knowledge transfer, summarized in Figure 10, shows a gap in knowledge transfer effectiveness [30]. While explicit knowledge transfer and tacit knowledge transfer were both considered highly important (blue bars), the *effectiveness* of explicit knowledge transfer was reported as *marginally effective*, and tacit knowledge transfer was reported as *somewhat ineffective* (orange bars).

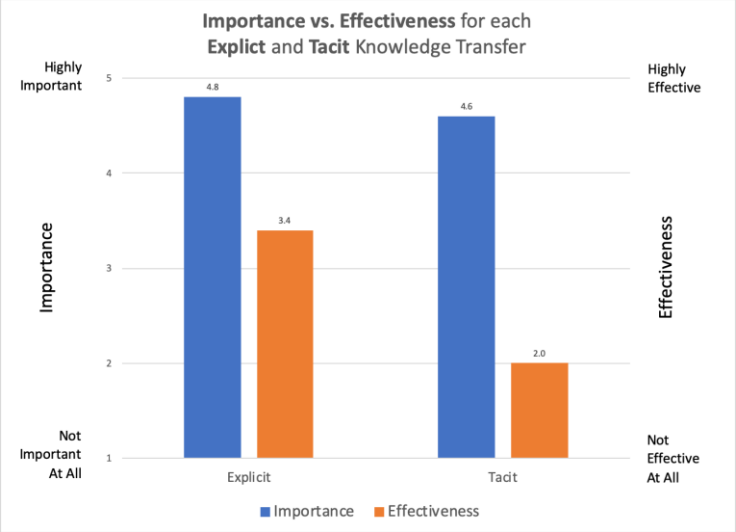

Figure 10 - The importance and effectiveness of explicit and tacit knowledge transfer

In addition, the research identified a positive correlation between knowledge transfer effectiveness and product cost, quality and availability.

Research by Lipa *et al*. explored many of the challenges with knowledge transfer during technology transfer, and identified six specific knowledge transfer challenges as follows [31]:

1. Narrow focus on transferring the minimum knowledge required to manufacture the 'golden batch' (i.e., when things go to plan)
2. Knowledge transfer is heavily biased towards documents, whereas tacit knowledge (know-how) is not methodically transferred
3. Knowledge leakage when valuable experience and learnings are not captured, recognised or considered relevant
4. Knowledge leakage because of the lack of structured and standardized KM approaches
5. Knowledge leakage through the loss of staff experience as people move or turnover
6. The context of the technology transfer project poses a risk to knowledge transfer (e.g., language differences, time zone differences, complexity of technology, maturity of receiving site, etc.).

These challenges are depicted visually in Figure 11 below [11], across the flow of technology transfer. While Figure 11 is representative of a new product introduction, the same challenges apply for site-to-site transfers during commercial manufacturing.

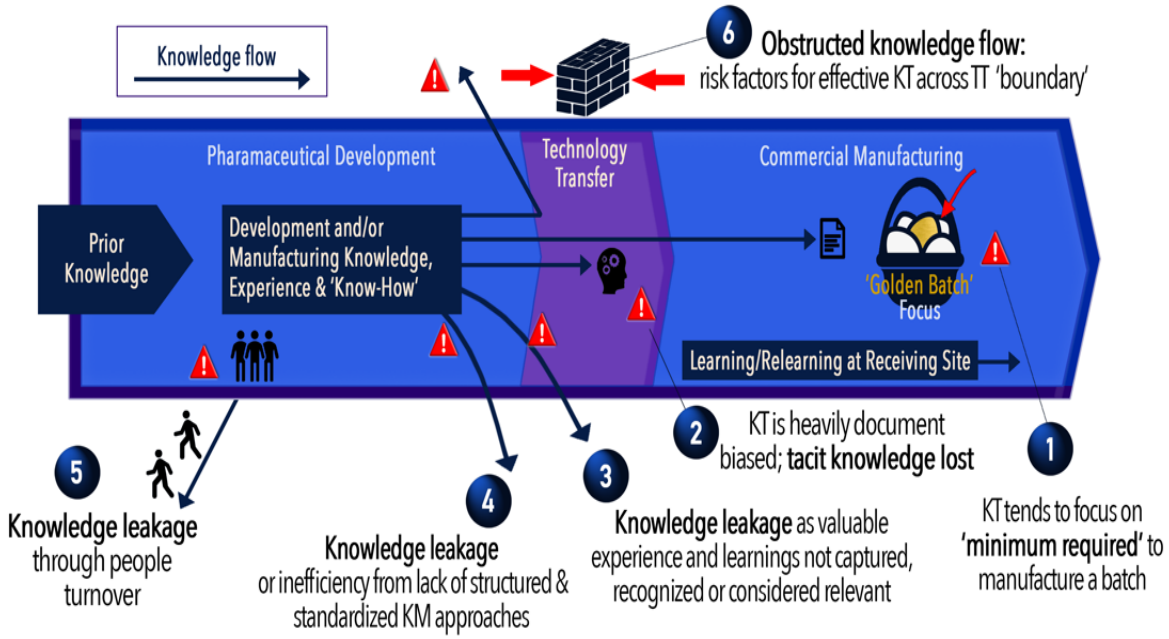

Figure 11 - Knowledge transfer challenges during technology transfer (adapted)

The research study proposed five high level requirements for effective knowledge transfer during technology transfer as follows [31]:

1. Knowledge transfer is guided by an intentional and robust plan
2. Knowledge transfer is best enabled by a culture which values knowledge as an asset
3. Standardized approaches for KM are established for both explicit and tacit knowledge
4. Tacit knowledge is uncovered and transferred during technology transfer
5. Knowledge transfer is measured, and an action plan is created to address gaps and opportunities (feed forward and feedback).

When one reflects on the challenges discussed above on effective knowledge transfer during technical transfer, it is apparent why this is a timely opportunity to bundle frameworks and digital solutions available to enhance knowledge transfer at technology transfer and present them collectively in this special issue of Level 3.

3 Steps toward digital transformation: the knowledge-enabled technology transfer cycle

To summarise and tie together the key concepts presented in the previous section:

- The PQS is intended to ensure availability of high-quality products to patients, and depends on managing knowledge and risk to do so effectively…

- …knowledge, knowledge management, and the evolution of data to insights and understanding are crucial to the PQS, and the biopharma industry success at large...

- …without effective technology transfer (inclusive of knowledge transfer), the goals of the PQS are at risk (including innovation and continual improvement), and it has been shown that substantial deficiencies exist for knowledge transfer during technology transfer.

Figure 11 above provides a helpful summary of the knowledge transfer challenges to be addressed to enable a knowledge-enabled TT. In response, this special edition of Level 3, is based on the theme of **advancing knowledge enabled technology transfer**, and featuring an emphasis on **steps towards digital transformation** coupled with the recognition of the importance of **people and their tacit knowledge**. Figure 12 concisely summarizes the topics presented in this special edition, and following, **Table 3** provides further description on each topic, and a mapping to the knowledge transfer challenge each helps address.

Figure 12 - Level 3 Special Issue topics

Table 3 - Outline of topics in this special issue and the knowledge transfer challenges they each help address

Topic	Description	KT Challenges addressed (Figure 11)
Explicit & Tacit Knowledge	A fundamental understanding of these concepts, including a recognition of the concept of tacit knowledge and its role in the biopharmaceutical industry are critical for effective knowledge management and technology transfer. These concepts have been previously defined in this paper (see section 2.2.2) and are explored further in papers 2, 3 and 4 of this special issue.	1 – 5
Managing Knowledge & Risk	The paper entitled '*Managing Risk and Knowledge: Frameworks to Guide Knowledge-Enabled Technology Transfer'* (paper 1 in this special issue) focuses on a novel framework to improve the integration between risk management and knowledge management. This framework, the *RKI Cycle*, can be co-deployed with additional frameworks to improve knowledge transfer and knowledge management resulting in tangible improvements in managing risk and knowledge during technology transfer.	All (1 – 6)
Digital Product Profile	The paper entitled *'The Implications of Tacit and Explicit Knowledge for Technology Transfer: When it goes well and when it goes wrong & what can digital do to help'* (paper 3 in this special issue), look as solutions such as the Digital Product Profile can address the challenges presented in this paper.	1 – 4
Interoperability & Digital Siloes	Digital Product Profile (paper 3 in this special issue) represents a business contextualised framework that manages all associated product and process data across the digital silos. It does this by availing of eco-system technologies to define and manage materials, equipment, process design, critical quality attributes, quality control specifications and process parameters to create a single source of truth.	1 - 4
Emerging Technology	The paper entitled *'Emerging Technologies: Empowering people to capture, share and transfer tacit knowledge'* (paper 3 in this special issue) focuses on the potential that emerging technologies has to harness tacit knowledge	2, 3, 5

Topic	Description	KT Challenges addressed (Figure 11)
 **Data Analytics**	The paper entitled '*People Perspectives in the Deployment of Data Analytics for New Knowledge generation in Pharmaceutical Manufacturing'* (paper 4 in this special issue) explores the role of people in the deployment of data analytics tools. Case studies in technology transfer and across manufacturing are presented.	1 & 6

We hope you enjoy reading this special issue of Level 3. We would welcome your comments and feedback – please send to anne.greene@tudublin.ie

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