1. Introduction and Research Context

This paper provides a brief overview of my four-year PhD journey exploring Knowledge Management (KM) across the product lifecycle in the Biopharmaceutical sector. When embarking on my research I was keen to bridge knowledge management theory to practice in, and for, the biopharmaceutical sector. So here I present a brief overview of the context of my research and a summary of my outputs.

Prior experience working across multiple phases of the biopharmaceutical product lifecycle uniquely positioned me to explore the challenges of managing biopharmaceutical lifecycle knowledge. In my 25 years in the sector, I have had the opportunity to provide quality oversight for toxicology studies in good laboratory practices (GLP), good clinical practice trials in animals and humans (GCP), and have held several operational roles in the good manufacturing environment (GMP). As a result, I have had first-hand experience of the challenges arising due to the difficulty, and sometimes inability, to find the knowledge we should know. This results in business and compliances challenges when we cannot effectively use that knowledge. These points are also made by Kevin O’Donnell earlier in this monograph e.g. product defects, drug shortages, inability to deliver medicines to patients in a timely manner because of rework or relearning.

As an industry, we are not learning from how others effectively manage knowledge. My study focuses on how we take those learnings from others, apply them to the sector and enable knowledge to flow to where it is needed.

2. Research Drivers, Methodology and Research Questions

A key research driver for me was the realisation that despite being a highly regulated industry, the Pharmaceutical Industry is not unique. To quote from Cindy Hubert (Trees & Hubert, 2017, p. 48):

> ‘The Pharmaceutical Industry has a very strong belief in its own uniqueness’.

Investigating further we find that aerospace and nuclear industries are also highly regulated and have a keen focus on KM and Risk Management. Reflecting on knowledge management for our sector, it is discussed by six sentences in ICH Q10. Since the publication of Q10 in 2008 we haven’t seen a lot of conversation on KM.
I think that is because it is a bit ambiguous: while everyone agrees that we must manage our knowledge, it is very difficult to understand what exactly that means, and what it looks like to implement KM.

At the commencement of my research in 2014 very little guidance existed on how to manage product and process knowledge. My literature review was challenging as I pondered ‘Why can I not find relevant literature?’ After countless hours of research, I concluded that it did not exist. Conversely, ICH Q10 twin enabler of Quality Risk Management (QRM) has a dedicated ICH Guidance document (Q9) since 2005 and is the topic of many publications and industry discussions. This realisation further fuelled my desire to pursue this research.

The aims of my research were to explore how best to utilise existing new and emerging pharmaceutical knowledge to enhance the quality of medicinal products, by examining approaches to facilitate flows of knowledge in order to reduce the risk of failures affecting the business or the patient.

In order to address these aims I developed the following research questions to focus my study:

- **Q1** — What are the current levels of adoption of Knowledge Management in the Biopharmaceutical Sector?
- **Q2** — What is ‘Critical Knowledge’ and ‘Prior Knowledge’ in relation to the product realisation and continuous improvement vision of ICH Q10?
- **Q3** — What would a Pharma KM Blueprint look like to help the industry start moving along the curve to implement Knowledge Management?

3. Research Outputs

In the course of my study I contributed to the body of industry knowledge by leading focus groups, chairing conference sessions on the topic, and presenting widely, building the momentum for Knowledge Management within the sector.

In addition, I was part of the editorial team and key author of a book entitled: ‘A lifecycle approach to knowledge management in the biopharmaceutical industry’ (Calnan, Kane, Lipa, & Menezes, 2018). This book is unique in that it is a book on Knowledge Management specifically written for the sector. It includes perspectives from Regulators, Patients, Academics and Industry case studies from clinical, manufacturing and commercialisation areas.

As my work matured, I developed a range of tools and assets to support knowledge management, using insights gathered from over 230 focus group participants over three years. These informed the major output of my research - the Pharma KM Blueprint - which is designed as a methodology to start bridging the gap from KM theory to practice, and is shown in **Figure 4.1**:
3.1 The Pharma KM Blueprint

The Pharma KM Blueprint is composed of four elements:

i. Managing Knowledge as an Asset

ii. The Pharmaceutical Product Knowledge Lifecycle (PPKL) Model

iii. The House of Knowledge Excellence Framework (HoKE)

iv. Knowledge Management Effectiveness Evaluation (KMEE).
i. Managing Knowledge as an Asset

The first component of the blueprint addresses the need to value and maintain *knowledge assets* in the same way as physical assets within an organisation.

*Example – A Bioreactor*

*If we treated our knowledge like we do a bioreactor, what would that look like?*

*We would do considerable research on our equipment before spending money to design/purchase or a bioreactor. We give a lot of thought to how we use it, where it fits in the facility - the more we use the bioreactor the more value it brings. Empty equipment that is not making product doesn’t bring us value.*

So, thinking of Knowledge as an asset: like the bioreactor, the more the asset is used the more value it creates. That can be said for knowledge also: the more we use it the more value it creates.

Assets can appreciate or depreciate. Not all knowledge has the same value over time. There is some knowledge that we just don’t need anymore, and that’s ok. We have record retention policies to deal with explicit knowledge past its useful life.

Both physical and knowledge assets have a value: they can be traded. When I think back to my time working in the start-up of a manufacturing facility, we had subject-matter experts (SMEs) coming in from all over the world to bring their knowledge to help us start up the facility. You can buy some knowledge. The industry spends a lot of money on consultants for good reason: because they have knowledge we don’t.

My founding premise is that there is a market value for knowledge, so it must be treated as an asset, and we must manage it as an asset. Linking back to the bioreactor example, there is a process to manage, maintain and decommission a bioreactor. Do we have such processes and roles to manage our knowledge? Reflecting on this notion may mean we need some new roles in our companies that don’t already exist.

ii. The Pharmaceutical Product Knowledge Lifecycle (PPKL) Model

The second component of the Pharma KM Blueprint addresses the challenge of enabling knowledge flow in order to increase visibility, access and use of the product and process knowledge assets across the product lifecycle. To encourage this, I reimagined the pharmaceutical lifecycle as depicted in Figure 4.2:
In practice, who owns the product knowledge across the lifecycle? In my experience it is fluid and typically changes (if even acknowledged) as the product moves along the lifecycle. Sometimes it is a team of people: we know the saying “when it is everybody’s job, it is nobody’s job!”

We need to think differently about how we manage product and process knowledge. This is reflected in the Product lifecycle model which is adapted from the diagram in ICH Q10 (Figure 4.2). The ICH Q10 diagram is very important as it is one of the few places where the lifecycle model is articulated. It depicts ‘technology transfer’ as one stage in the lifecycle. However, I believe technology transfer is not a once-off activity, nor is it a linear activity. It is an activity that for many products will happen multiple times in its life. Technology Transfer is a knowledge-rich step where a tremendous amount of knowledge is generated. Much of this knowledge is tacit knowledge, which is in somebody’s head: it is *what we know*. Do we have a way to really capture that tacit knowledge? In particular, when we look ahead to ICH Q12 and the promise of regulatory relief, there is a tremendous expectation that we understand our products. In order to demonstrate that we understand our product and process knowledge, I would suggest that it is more than risk assessments that we need.

So, in my research I present a different way to look at the product lifecycle to enable us think differently about how we manage our knowledge. In the PPKL model shown above ‘Technology Transfer’ is depicted by blue arrow symbols, and in fact, I prefer to call it ‘Technology and Knowledge Transfer’ as it is the knowledge that we are transferring. In the model the Technology Transfer activities occur throughout the entire lifecycle. The emphasis on them may be different at different stages, hence the different sizes of the blue arrows. In addition, we should think about what business processes we need to enable knowledge flow throughout the lifecycle of the product. Whether we are doing a technical transfer or not, there are always technical...
support and continuous improvement activities. Thinking about continuous improvement activities, when you capture that knowledge is that available to all? Often it is stored somewhere different than with the rest of the knowledge of that product, making it challenging to get a holistic view of what we know about a product.

Another topic we don’t reflect much on is product discontinuation, a key lifecycle phase identified by ICH Q10. When we discontinue a product, do we think about what knowledge we need to keep? I suggest we typically focus on record retention, but if we have other products on similar platforms we may be losing valuable knowledge about them if we don’t consider this as a knowledge sharing opportunity.

The focus on this reimagined Pharmaceutical Product Lifecycle (PPKL) model is on End-to-End process knowledge. Removing the silos, which can be generated by roles in the lifecycle, and focusing on what we need to do to make the knowledge visible to everyone along the lifecycle. In addition, in the course of my research it became apparent that it is difficult for product development teams to get knowledge and learnings back from commercial manufacturing activities. We need to ensure knowledge is not just flowing from left to right in the diagram.

### iii. The House of Knowledge Excellence (HoKE) Framework

The third component of the Pharma KM Blueprint is a framework for 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.

This Framework, entitled ‘The House of Knowledge Excellence Framework’, is published by Kane and Lipa, 2018, and is depicted in Figure 4.3 (opposite).

The House of Knowledge Excellence is a high-level overview of what a knowledge management programme would look like. To enable the flow of knowledge (not the management of knowledge) this programme suggests looking at the four pillars of people, process, technology and governance. Where there are very specific practices, most not unique to the pharmaceutical industry, which should be adopted to enable flow, the systematic approach to Knowledge Excellence must reflect the direction of the organisation. It has to deliver value and there has to be some catalysis for success.
iv. Knowledge Management Effectiveness Evaluation (KMEE)

The final component of the Pharma KM blueprint is 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 is an on-the-ground practitioner diagnostic which can be used by teams to pose two important questions:

- **Q1** — Are teams/organisations availing of knowledge tools and best practices they have?
- **Q2** — Do they understand what knowledge they need and their knowledge flow problems?

This evaluation diagnostic evaluation includes examples of how identified gaps can be closed.
4. Conclusion and further information

In conclusion, the main output of my research is the **Pharma KM Blueprint** which presents the principle of managing knowledge as an asset, the reimagined lifecycle of a pharmaceutical product model depicting how knowledge can flow, the holistic programme for KM, and the diagnostic tool. The items can be used separately or in conjunction to lay the foundation for how you can approach knowledge management in your organisation.

For further information on the Pharma KM blueprint and all the elements presented in the paper, I direct you to my PhD thesis entitled ‘A blueprint for Knowledge Management in the Biopharmaceutical Sector’ and is available to download from the DIT repository Arrow, at the following link:

https://arrow.dit.ie/do/search/advanced?q=author:%22Paige%20Kane%22&start=0&context=490738&sort=score&facet=

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References


