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Effective Knowledge Transfer during Biopharmaceutical Technology Transfer - How Well Do We Do It?

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Effective Knowledge Transfer during Biopharmaceutical Technology Transfer

How well do we do it?

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ABSTRACT

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While knowledge management (KM) has been widely applied in other sectors, the international biopharmaceutical sector has struggled with the meaningful and sustained application of effective KM practices. This is evident even though KM has been highlighted in regulatory guidance for over 10 years, and the positive business impact of KM is well recognized in other sectors. This paper focuses on the topic of KM as applied to biopharmaceutical technology transfer, introducing new research that explores the importance and effectiveness of knowledge transfer as an integral component of a biopharmaceutical product technology transfer. Results from multiple sources explored in this paper are well aligned in recognizing that knowledge transfer is very important to enable technology transfer, yet the biopharmaceutical sector is not very effective at this knowledge transfer. This is especially true of tacit knowledge transfer which is often reported to be ineffective. Additional research will further define the barriers to improve knowledge transfer effectiveness and how the biopharmaceutical sector might improve in this area.

1) Introduction

This paper presents a case for the need to improve knowledge transfer (more broadly knowledge management) as part the technology transfer stage in the pharmaceutical product lifecycle. The

importance of effective knowledge transfer to enabling successful technology transfer is established and the current effectiveness is characterized using multiple inputs which are assessed, reported, and discussed.

While knowledge management (KM) approaches have been widely applied in other sectors, the international biopharmaceutical sector has struggled with meaningful and sustained application of effective KM practices. Furthermore, recent research carried out by the TU Dublin Pharmaceutical Regulatory Science Team [1] has identified that technology transfer occurs over many phases of the product lifecycle and that knowledge transfer is underappreciated and undervalued during such transfers. This paper seeks to further understand the barriers to improve knowledge transfer for enabling successful technology transfer and knowledge management application for the biopharmaceutical sector.

2) Background

a) Pharmaceutical Regulatory Context

In 2008 The International Council for Harmonisation (ICH) published a guideline on Pharmaceutical Quality System Q10 [2], commonly referred to as “ICH Q10.” The objectives of ICH Q10 are:

- a. to achieve product realization
- b. to establish and maintain a state of control
- c. to facilitate continual improvement.

ICH Q10 positioned knowledge management (KM) as an enabler to the Pharmaceutical Quality System (PQS) (Figure 1) suggesting that effective knowledge management is required to realize an effective PQS, and therefore to achieve the objectives of ICH Q10. This regulatory guidance marked the first time that knowledge management was identified as an expectation for the sector. However, minimal guidance on what is required or how this might be achieved is provided

in ICH Q10. Although the sector has struggled with KM adoption, no further regulatory guidance has been published beyond the Q&A document [3] since the release of ICH Q10. However, the Q&A document also discusses what KM is *not* to be. In particular, it is not viewed as an information technology (IT) system. Rather, the ‘what’ and ‘how’ for KM were left up to individual organizations. The absence of further guidance, such as models for best practices, guiding principles, or measures of progress or realization is a contributory factor as to why progress in KM has been slow and elusive in the sector.

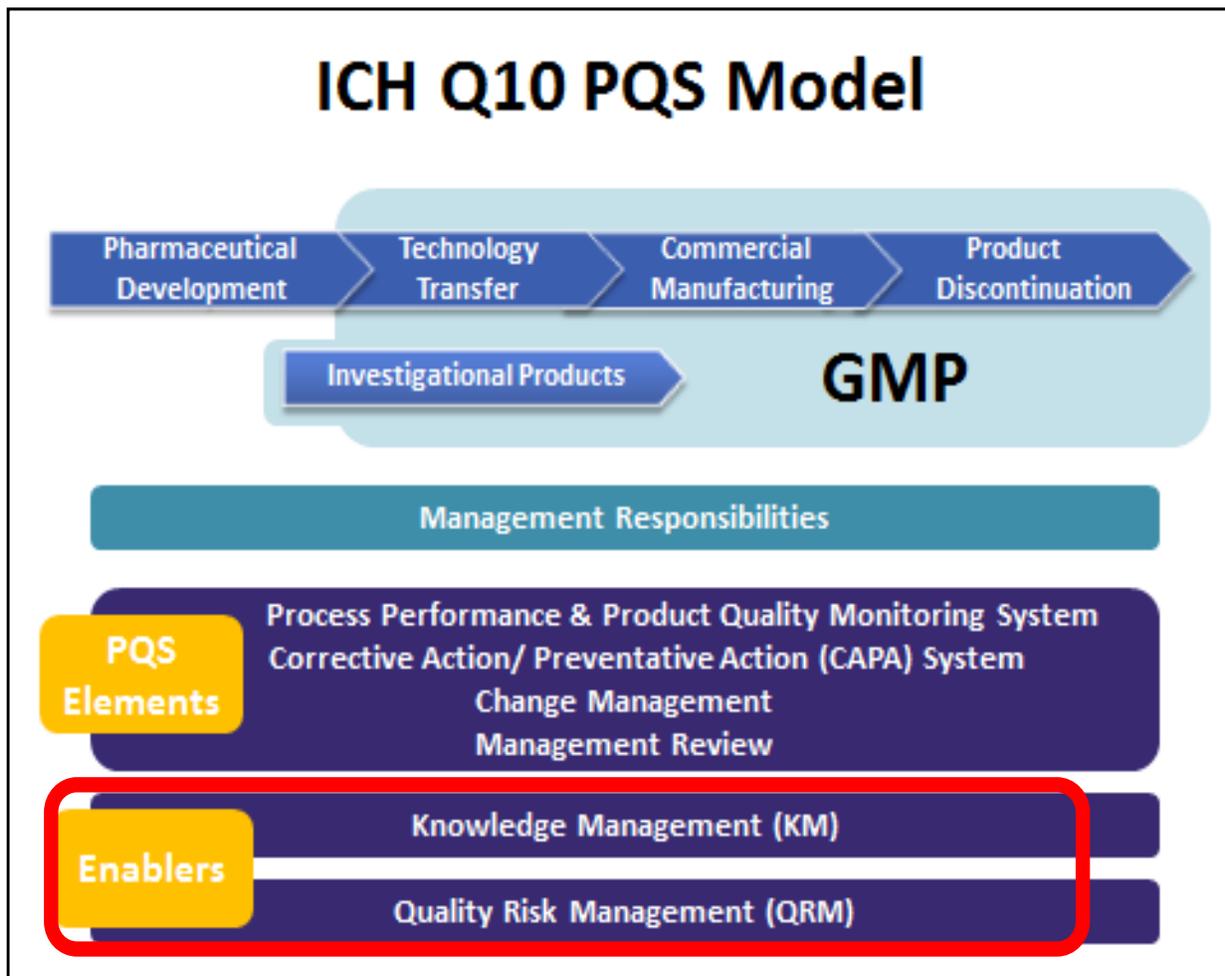


Figure 1 - ICH Q10 Pharmaceutical Quality System

Formal research on knowledge management in the biopharmaceutical sector was undertaken by Kane in 2014 [1]. At that time, little guidance existed to describe how KM might actually enable a more effective pharmaceutical quality system. Kane’s research has led to the establishment of

a model, known as the *Pharma KM Blueprint* [1] which consists of four key elements one of which is the premise of this paper: The Pharmaceutical Product Knowledge Lifecycle (PPKL) Model. The PPKL addresses the challenge of enabling knowledge flow in order to increase visibility, access and use of product and process knowledge assets across the product lifecycle. Specifically, this model asserts the pharmaceutical product lifecycle diagram depicted in ICH Q10 [2] does not account for the multiple instances of technology transfer that would typically occur over the lifecycle of a product, nor the generation and capture of tacit knowledge generated during technology transfer or continual improvement activities. Kane’s model presented in Figure 2 substitutes the ICHQ10 Technology Transfer lifecycle stage with an enhanced lifecycle stage entitled New Product Introduction and highlights the need for technology and knowledge transfer along the full lifecycle of the product.

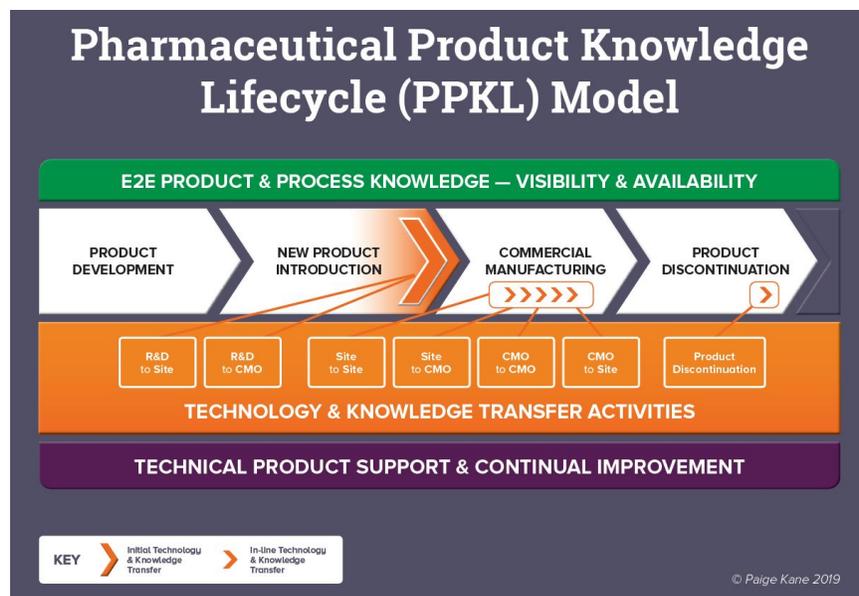


Figure 2 - Pharmaceutical Product Knowledge Lifecycle (PPKL) highlighting technology and knowledge transfer in multiple points along the product lifecycle [1]

While the PPKL model develops the concept of Technology and Knowledge Transfer (as highlighted in the orange bar in Figure 2), it is acknowledged that future research opportunities are warranted in the area of new product introduction and technology transfer. This paper outlines the first of a series of research to address this.

Currently ICH Q12, Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management, Q12 [4], is in draft. Q12 is intended to further advance the expectation that improved product and process knowledge can contribute to a reduction in the number post-approval change submissions, as the accumulated knowledge gained during development and implementation of changes will manage risks to product quality. These regulatory expectations should further increase the importance and urgency for the sector to be more effective at the practice of knowledge management.

b) Technology Transfer's Dependency on Knowledge Transfer

A scan of current literature suggests the importance of successful technology transfer, and of knowledge to the success of technology transfer. The PDA Technical Report No. 65 on Technology Transfer [5] states "technology transfer can affect drugs and patients", clearly highlighting the importance of an effective technology transfer to ensure product outcomes and protect patients. And Millili [6] outlines examples where insufficient process knowledge result in a poorly scaled-up process, along with other undesirable outcomes including:

- Non-robust processes (decreased process capability, i.e. Cpk)
- Decreased reliability
- Reduced production rates
- Increased number of atypical events (e.g. defects, elegance issues, etc.)
- Difficulty handling variations (raw materials, process controls, ...)
- Inefficient validation.

Further examples in the literature refer to other areas where the sector struggles with transferring knowledge during technology transfer, such as contamination control and sterilization technology risks [7]. Consider the following issues and shortcomings cited on knowledge transfer effectiveness during technology transfer:

- "...assays were transferred but the sending party did not provide complete information and some of the information was out-of-date..." [8]

- “...poor process understanding, coupled with incomplete documentation (i.e. codification) of all the required process parameters...” [9]
- “The third mistake is not arranging for scientist-to-scientist interaction during the transfer process. Scientists from similar departments at both the transferring company and the receiving company need to get acquainted, understand the transfer process, and then work side by side at the bench or in the plant. Without that personal interaction, your transfer is risky” [10]
- “...incomplete knowledge transfer...is a consistent problem...” [11]
- “...there was no master document to track all the information and it was sent out piecemeal to different points of contact...” [8]
- “...providing incomplete information about the nature of the biopharmaceutical or protein molecule such as its properties, its activities, and its stability under different conditions. Often, companies know this information, but don’t pass it on...” [10]

There is a clear opportunity to improve the effectiveness of knowledge transfer during technology transfer, which in turn will improve technology transfer outcomes and associated patient outcomes. In better leveraging the knowledge of the organizations involved – and ensuring that knowledge is available and accessible, such improvements will also address, at least in part, the regulatory expectations emerging from ICH Q12.

3) New Research to Advance Knowledge Transfer Understanding and Effectiveness

Building on the foundational research by Kane, and the advancing expectation to better manage product and process knowledge highlighted in Q12 [4] and other business contexts [12], further research on knowledge management during at technology transfer has commenced by Lipa. The research will explore elements of both explicit and tacit knowledge management during technology transfer. Lipa’s preliminary research hypothesis is as follows:

- a. The sector **does not have a holistic end-to-end view of what it knows about its products** across the product lifecycle, **nor how to best ensure this knowledge ‘flows’** to ensure the best possible product outcomes. These outcomes include product realization through a readily available, cost effective and high-quality product to patients, as well as additional outcomes of operational efficiency and a workforce that has the knowledge it needs to do its best work.
- b. Further, **tacit knowledge is critical but is not effectively managed or transferred** during key activities in the product lifecycle, including key processes such as technology transfer.

In order to raise awareness and to provide guidance on how to improve knowledge transfer associated with technology transfer, and to ultimately improve technology transfer outcomes, this research commences by characterizing the current state of how KM enables technology transfer, including perceived importance and effectiveness for explicit and tacit knowledge. The research approach is to gather input from multiple sources to establish a baseline on knowledge transfer effectiveness within technology transfer.

Three distinct research activities were undertaken to gather input as follows:

- a. Literature review of industry guidance on technology transfer.
- b. Survey, from an audience survey conducted in April 2019, on the importance and effectiveness of knowledge transfer as part of technology transfer
- c. Expert interviews from international industry and health authorities

Further additional research may include:

- a. Benchmark other industries on processes and proven effectiveness of knowledge transfer.
- b. Develop a model to describe the maturity of knowledge transfer.
- c. Develop recommendations for enhancing knowledge transfer during technology transfer, including any supporting tools, assessments or models to accelerate post-research uptake.

4) Results – Characterization of Current State Knowledge Transfer

a) Literature Review: Industry Guidance on Technology Transfer

Initial research included a review of common industry guidance on technology transfer, to assess the extent to which **knowledge transfer**, **knowledge management** and **tacit** knowledge concepts are presented and explained, along with the extent of illustrative examples and guidance or tips on the 'how'. The following technology transfer guidance was reviewed, and the frequency of these concepts was tabulated and summarized in Table 1.

- WHO Guidelines on Transfer of Technology in Pharmaceutical Manufacturing [13]
- ISPE Good Practice: Technology Transfer, 2nd Edition [14]
- ISPE Good Practice: Technology Transfer, 3rd Edition [15]
- PDA Technical Report, No. 65, Technology Transfer [5]
- PDA Tech Transfer Interest Group Report Out, PDA 2019 Annual Meeting (presentation) [16]

A qualitative assessment was conducted on how well these guidance documents introduced the knowledge transfer concepts above, including how well they are collectively **explained**, whether they **provided illustrative examples**, and whether they **provided guidance / tips on 'how'**. These results are also provided along with author commentary in Table 1.

Table 1 - Summary of Guidance citing Knowledge Transfer as an Enabler to Technology Transfer

Organization	Technology Transfer Guidance Document	Year of Issue	Length in Pages	Frequency of Terms			How well these terms are collectively...			Observations by Author
				Knowledge Transfer	Knowledge Management	Tacit (Knowledge)	Explained	Illustrative Examples Provided	Guidance / Tips on How provided	
WHO	WHO Guidelines on Transfer of Technology in Pharmaceutical Manufacturing	2011	25	1	1	0	Little to None	Little to None	Little to None	Single reference, brief introduction to concepts.
ISPE	Good Practice Guide: Technology Transfer (Second Edition, <i>superseded</i>)	2014	81	12	4	5	Limited	Limited	Little to None	Solid references to the importance of KT and KM, and how successful TT is dependent. Tacit concept introduced.
ISPE	Good Practice Guide: Technology Transfer (Third Edition)	2018	152	21	13	14	Good	Good	Limited	KM cited as a driver for the update, strong guidance on the importance of underlying knowledge. Solid examples for tacit knowledge. Some simple examples of how but examples are high level or conceptual only.
PDA	Technical Report No. 65, Technology Transfer	2014	61	0	3	0	Little to None	Limited	Little to None	Brief introduction to concept of KM, but little beyond high level concepts linked to ICH Q10.
PDA	PDA Tech Transfer Interest Group Report Out, 2019 Annual Meeting (presentation)	2019	n/a	yes	yes	no	Limited	Limited	Little to None	Included as this was a recent development and may lead to a revision to PDA TT Technical Report, and/or a Technical Report on KM. KM focus appears exclusively document centric, no mention of tacit knowledge or related concepts. Inventories provided by type but concepts of KT / KM not well explained.

Terms: TT = Technology Transfer; KT = Knowledge Transfer; KM = Knowledge Management

On review of these guidance documents and the summary depicted in Table 1, the following are observations shared by Lipa. In general:

- a. Technology Transfer guidance is often very **'document-centric'** (i.e. focused on explicit knowledge)
- b. Knowledge management, mostly around explicit knowledge, is called out in guidance but is **vague** in what it means:
 - Little for supporting principles or guidance on how to do it effectively
 - Starting to change in places...but perhaps still not enough or fast enough.
- c. **'Tacit' knowledge is not often well recognized** as a source of knowledge, nor is there guidance on how to do it effectively.

- d. Technology Transfer risks of failure **do not acknowledge** concepts of **insufficient knowledge transfer or availability**.

For ISPE guidance, the second edition of the Good Practice Guide was included as a baseline to compare against the third edition, to evaluate any changes over time. The third edition [15] lists five areas of highlight for the revision, one of which is “Recognition that knowledge management is a critical component of effective technology transfer...”. It is clear in the results summarized in Table 1 the presence of KM and related concepts has been significantly strengthened beyond a starting baseline from the second edition.

For PDA guidance, the PDA Tech Transfer Interest Group at the 2019 PDA Annual Meeting in March 2019 in San Diego, California, shared the results of a recent survey on Technology Transfer [16]. Lipa attended the session where the PDA Tech Transfer survey results were shared. The survey was intended to assess the current practices and future needs for improving the Technology Transfer process. The survey covered:

- Demographics
- Types of Technology Transfer Performed
- The Technology Transfer Process
- Use of Multi-Disciplinary Teams
- Technology Transfer Tools
- Challenges.

The results indicated that KM would be an area where additional PDA guidance would be helpful. The subsequent discussion on KM in session focused heavily on a ‘*master plan*’ for knowledge management which primarily focused on documents and information. Also, a set of KM “soft skills” was identified as required, although in the opinion of Lipa, these are primarily good business communication and team leadership skills, rather than traditional KM skills as described elsewhere [17].

In general, across any of the guidance documents, there does not appear to be a measure for the effectiveness or completeness of knowledge transfer associated with technology transfer, with

the exception of document turnover lists. This will be further investigated during subsequent research.

b) Survey: Audience Survey on *Knowledge Transfer Enabling Successful Technology Transfer*

Once the literature review was complete and based on the review findings and the researcher's own experiences, a survey was developed to further support the hypothesis problem statement by testing the opinion of a naïve audience. The survey was designed to solicit their perspectives on the importance and effectiveness of knowledge transfer to enable an effective and efficient technology transfer. This survey was deployed at a recent seminar, *An Audience with Regulatory, Academia and Industry on The Role of Effective QRM & KM in Product Realization for Patients in the 21st Century* on 04-April-2019 at Technological University Dublin.

The survey was distributed to the audience of approximately 120 attendees, and 56 responses were received. It is important to note results from this survey are considered directional in nature due to the qualitative nature of the questions provided, although useful comparisons can be made within the response data. A detailed review of the complete survey results can be found in the monograph of the proceeding from the seminar [18].

A key focus of the survey was to evaluate the perceived **importance** of both explicit and tacit knowledge to an effective and efficient technology transfer.

Explicit knowledge was defined as:

Documents and other 'codified' knowledge that takes no explanation or dialog to fully understand.

Tacit knowledge was defined as:

Knowledge associated with experience, subject matter expertise, decision rationale, observation, undocumented history and other knowledge "in people's heads."

The survey also solicited opinions on the corresponding **effectiveness** for each explicit and tacit knowledge transfer. The results are summarized in Figure 3.

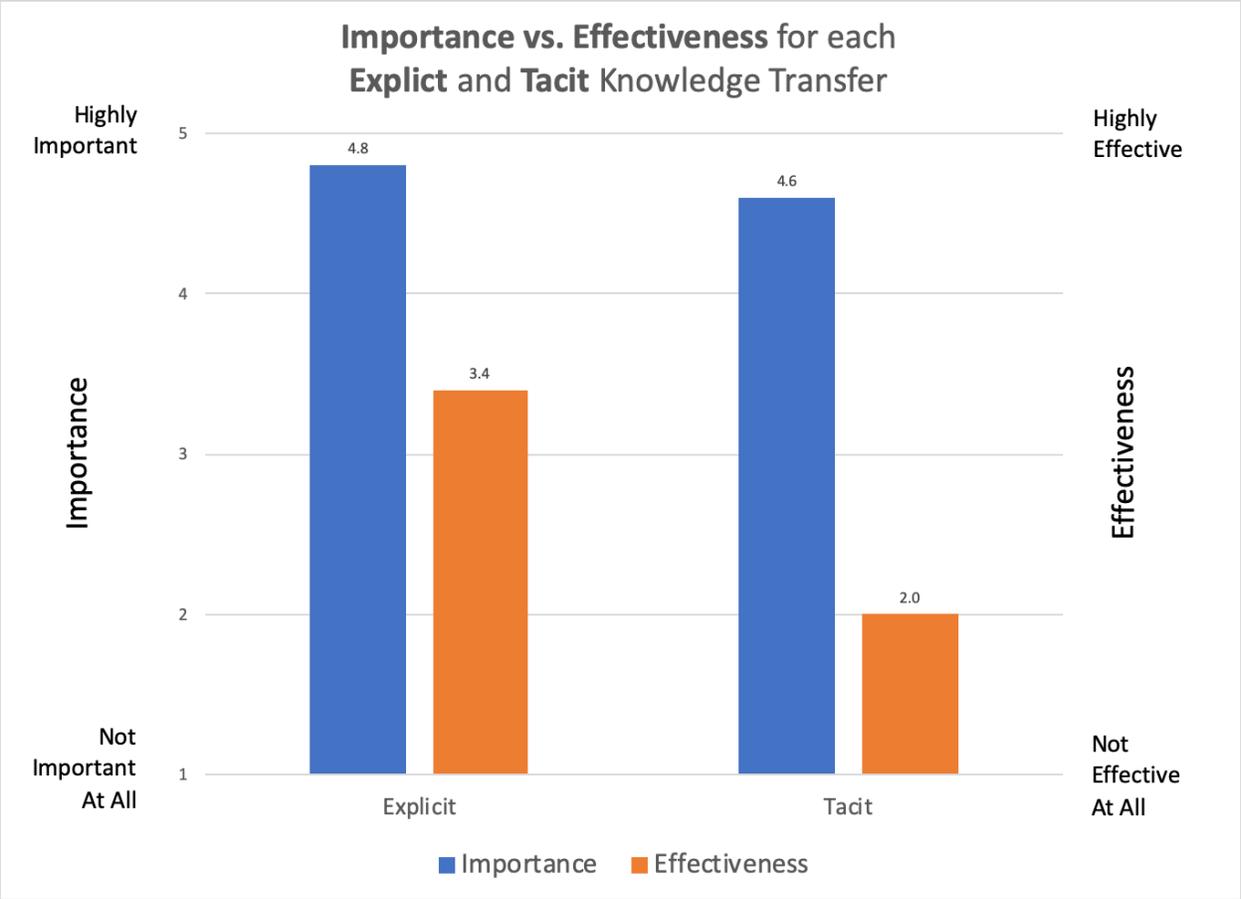


Figure 3 - Importance vs. Effectiveness for each Explicit and Tacit Knowledge Transfer

The results indicate strong agreement that **both explicit and tacit knowledge are critical** to an effective and efficient technology transfer, with the relative criticality being generally similar (4.8 and 4.6 respectively on Figure 3). When explicit knowledge transfer effectiveness is evaluated, the effectiveness of explicit knowledge transfer is only **marginally effective** (3.4). When tacit knowledge transfer effectiveness is evaluated, effectiveness of tacit knowledge transfer is **somewhat ineffective** (2.0).

Although only directional in nature, these survey results support the importance of knowledge transfer to technology transfer outcomes. Clearly, there is a gap between the reality of how

well we transfer (effectiveness) versus the importance of having the knowledge transferred. This gap exists for both explicit knowledge and tacit knowledge but is more prominent for tacit knowledge. Advances to improve knowledge transfer effectiveness will benefit technology transfer outcomes, and ultimately benefit patients.

c) Expert Interviews: International Industry and Regulatory Authority experts

Four experts were interviewed in Q2 2019 to explore their perspectives on the importance of knowledge transfer as a part of technology transfer, on the effectiveness of each explicit and tacit knowledge transfer, and expectations for tacit knowledge transfer. The interview participants are blinded but represent the following perspectives, noting their input is their own opinion and does not represent the position of their affiliated organization:

- Participant A: Senior inspector & compliance manager, EU pharmaceutical regulatory authority. Frequent international speaker, committee member and panelist with 18+ years’ experience.
- Participant B: Director, United States pharmaceutical regulatory authority. Frequent international speaker, committee member and panelist with 25+ years’ experience.
- Participant C: Senior Director in Technology, United States, multinational biopharmaceutical company. Experience of 25+ years’ in multiple roles and companies.
- Participant D: Senior Director, EU, multinational pharmaceutical company. Experience of 30+ years’ in multiple roles and companies, including health authority and academic experience in the biopharmaceutical sector.

The interviews followed a structured set of questions and were typically an hour long. The interviews were transcribed, coded and responses summarized in Table 2.

Table 2 - Summary of Expert Interviews

Considering the end-to-end (E2E) product lifecycle depicted in ICH Q10 [2], To what extent do you agree that knowledge transfer could be improved for technology transfer, leading to better outcomes?	
<i>Regulatory Authority Perspectives</i>	<i>Industry Perspectives</i>
<i>The ‘Big Picture’</i>	<i>The ‘Big Picture’</i>

<ul style="list-style-type: none"> • Lots of opportunity to improve • A number of companies do a good job • Initial technology transfer is critical • Starts with taking learning from development • Need honesty and transparency • Understand how much variability • Residual latent risk remains <p><i>Business Process Challenges</i></p> <ul style="list-style-type: none"> • Ceremonial writing of report • Many companies capture only part • Knowledge gets lost between development and commercial manufacturing • Deep investigations were eventually uncovered still in place at the old facility • Don't lose in translation <p><i>Document Challenges</i></p> <ul style="list-style-type: none"> • Knowledge gets lost or buried in documents • Documents may not be in usable format • Documents may be long 	<ul style="list-style-type: none"> • Knowledge transfer is essential • Tech transfer as opportunity to give another group of people the ability and skill to do what you have been doing adequately • Could be improved deeper understanding and benefits would accrue, including cost, quality and availability • Technology transfer sometimes driven by a compliance need, not a knowledge need • Technology transfer sometimes seen as a tedious task that must be done <p><i>Business Process Challenges</i></p> <ul style="list-style-type: none"> • Many functions work in a vacuum • Not everyone knows what everyone else is doing • Delays due to needing to purchase or modify equipment not planned ahead • Ensure quality systems can handle new process • Approval delay for insufficient quality systems • Know how may not be transferred
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On a scale of 1 to 10 (10 = exceptional)
How would you rate the range and average effectiveness of knowledge transfer of explicit knowledge during technology transfer?

<i>Regulatory Authority Perspectives</i>	<i>Industry Perspectives</i>
Participant A: Average: 6 out of 10 Range: 3 to 8 Participant B: Average: 7 out of 10 Range: 3 to 9	Participant C: Average: 6 out of 10 Range: 3 to 10 Participant D: Average/ Range: "in the upper half, with wide standard deviation"

On a scale of 1 to 10 (10 = exceptional)
How would you rate the range and average effectiveness of knowledge transfer of tacit knowledge during technology transfer?

<i>Regulatory Authority Perspectives</i>	<i>Industry Perspectives</i>
Participant A: Average: 3 out of 10 Range: 1 to 5 Participant B: Average: 5 out of 10 Range: 1 to 7	Participant C: Average: 7 out of 10 Range: n/a Participant D: Average / Range: "Not as effective as explicit knowledge, in the lower half, with wide standard deviation"

What expectations do you have for tacit knowledge transfer during technology transfer?	
<i>Regulatory Authority Perspectives</i>	<i>Industry Perspectives</i>
<p><i>What to transfer</i></p> <ul style="list-style-type: none"> • Expect much of this is tacit knowledge to do a task • How to run a process in a particular piece of equipment <p><i>Expectations to capture & communicate</i></p> <ul style="list-style-type: none"> • Understand impact of late discoveries or say you don't know • Nothing expressly in marketing authorization requirements about tacit knowledge, but tacit knowledge really important to get transferred • Tacit knowledge should get looked at and written down • How risk is communicated to regulators is a problem • Tension created without transparent sharing of scientific information 	<p><i>What to transfer</i></p> <ul style="list-style-type: none"> • Summarize key development activities • Capture pilot scale knowledge • Capture instabilities • Capture failures • Learn from failures
<p>Consider this statement: “We can do the knowledge transfer associated with a technology transfer via Fed Ex.” Do you agree or disagree? Why?</p>	
<i>Regulatory Authority Perspectives</i>	<i>Industry Perspectives</i>
<ul style="list-style-type: none"> • Disagree <p><i>Human Element</i></p> <ul style="list-style-type: none"> • People need to talk to each other • People need to spend time with each other working through a process 	<ul style="list-style-type: none"> • False! • Fundamentally and profoundly disagree <p><i>Human Element</i></p> <ul style="list-style-type: none"> • There is a human element • Need to talk • Need to walk through process • Need to get experience at sending site <p><i>Sources of Variability</i></p> <ul style="list-style-type: none"> • Levels of experience & understanding • Language translation challenges • Variability due to shift work

These results speak well for themselves; a summary is as follows:

1. Knowledge transfer can be improved and would have meaningful positive impact to technology transfer outcomes, including cost, quality and product availability.
2. Some companies appear to do well but this is the exception, not the norm.

3. Transparency on the level of process understanding is critical to a productive regulatory dialog.
4. Often knowledge gets 'stuck', often based on process or people barriers (e.g. judgement it is not important, buried in long documents, may be in an unusable format).
5. On average, knowledge transfer effectiveness of explicit knowledge is marginal and there is wide variation.
6. On average, knowledge transfer effectiveness of tacit knowledge is ineffective to marginal and there is wide variation.
7. Successful technology transfer required human to human interactions, preferably face to face and time to walk through the details of a process to explore details, sensitivities, what is not known, etc.
8. There is a clear desire that we must get better at this as a sector.

5) Summative Discussion

The three independent research activities and resulting data correlate well and suggest these key findings:

1. Overall, knowledge transfer is critical to a successful and sustainable technology transfer. Ineffective knowledge transfer can have a long-lasting impact on the ability of the receiving site to provide cost-effective, high-quality product with the desired availability.
2. Knowledge to be transferred associated with technology transfer is biased toward explicit knowledge (e.g. documents). This explicit knowledge is critical to the success of the transfer yet we as a sector are only marginally effective at it – it is clearly not a strength. There is some supporting guidance on explicit knowledge that should be transferred, but not prescriptive means on how to do this or how to measure effectiveness.
3. Tacit knowledge associated with technology transfer is not widely recognized as an asset to be transferred, nor is there evidence to suggest we as a sector do it effectively. There is limited understanding on what tacit knowledge is, why it is important and how it can be transferred, including how to measure effectiveness of transfer. There is little

acknowledgement of tacit knowledge in common industry guidance for technology transfer, although there has been an upward trend very recently on calling out tacit knowledge categorically.

4. Regulatory authorities and industry are generally well aligned on these issues and their impact. Both recognize the opportunity – and the need – to improve for the good of patients.

These findings support the problem statements which are being explored, namely, that knowledge does not ‘flow’ readily through technology transfer, and that tacit knowledge is critical but is not effectively managed or transferred. The subsequent research activities to benchmark other industries, develop a knowledge transfer maturity model and associated recommendations to improve knowledge transfer will proceed with the aim to address this opportunity.

6) Conclusion

In conclusion, knowledge management is still a relatively immature practice in the biopharmaceutical sector, especially when compared to Quality Risk Management, Change Management and other practice domains. The need for improved knowledge transfer for technology transfer, as a key focus point of knowledge management in the biopharmaceutical sector, is evident given the findings presented in this paper, supported by the broad alignment and recognition of the issue across different cohorts presented herein. This KM focus first and foremost to protect the patient through availability of a high quality, cost effective product, and present the opportunity pursue other business drivers which ensure the continued competitiveness of the organizations in the sector [12].

The next phases of research by Lipa as introduced in this paper intend to provide practical advice to help the sector apply good KM practices to improve technology transfer outcomes through the following:

- a. Benchmark other industries on processes and proven effectiveness of knowledge transfer.
- b. Develop a model to describe the maturity of knowledge transfer.
- c. Develop recommendations for enhancing knowledge transfer during technology transfer, including any supporting tools, assessments or models to accelerate post-research uptake.

The initial findings presented within this paper well justify the planned efforts in this area.

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