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Managing Knowledge and Risk:a Literature Review on the Interdependency of QRM and KM as ICH Q10 Enablers

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Managing Knowledge and Risk:a Literature Review on the Interdependency of QRM and KM as ICH Q10 Enablers

Cover Page Footnote

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Simple Practices to Facilitate the Flow of Valuable Tacit Knowledge during Biopharmaceutical Technology Transfer: *A Case Study*

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Abstract
The biopharmaceutical industry is regarded as a knowledge industry. However, in general, the industry is not effective at managing its knowledge as an asset across the product lifecycle, including during fundamental processes such as technology transfer. This is true in particular for *tacit knowledge* (e.g., *know-how*), where tacit knowledge it considered critical to the success of technology transfer, yet tacit knowledge transfer is *somewhat ineffective*. This can lead to the introduction of risk and other undesirable outcomes. This paper profiles a case study in tacit knowledge flow where a series of pragmatic practices were deployed during a complex vaccine drug substance technology transfer. These practices demonstrated improvements in tacit knowledge flow as evidenced by learning, process improvements and gaps in knowledge identified, which were subsequently addressed to reduce risk, increase product and process understanding, improve robustness, and define future development needs. Common success factors for these simple practices are explored through the case study. A key takeaway is that such knowledge transfer processes do not need to be complex nor onerous in order to achieve tangible improvements in knowledge transfer effectiveness.

1. Introduction
The biopharmaceutical industry is a *knowledge industry* with its intensive use of technology and human capital [1]. Indeed a biopharmaceutical company's long-term viability flows from its ability to develop, apply and grow knowledge about products and processes while ensuring sufficient supply of safe, efficacious and cost-effective products to the marketplace. Thus, knowledge is an asset to the company and as such, there is value in managing knowledge assets in the same way as physical assets [2].

Standard Knowledge Management (KM) practices[1] can be used as a means to improve the effectiveness of how knowledge is managed as an asset and how knowledge *flows* through an organization [3]. Ideally, for a biopharmaceutical product, knowledge must flow across the entire lifecycle from product development through to product discontinuation [4]. Yet research has shown that the current effectiveness of knowledge management in the biopharmaceutical industry is lacking [2]. Knowledge is not managed as an asset, does not flow freely, and 'leaks' from the organization through a variety of means, including [5], [6]:

[1] The term 'practice' refers to the collective approach or methodology used, typically consisting of considerations for people (e.g., roles and mindsets), process, technology and governance

- employee turnover
- inconsistent expectations and processes for knowledge capture
- sub-optimal capture and use of lessons learned
- organizational 'silos'
- ineffective knowledge transfer between people and/or functional groups)

This 'leakage' is especially true given the long cycle times associated with the biopharmaceutical product lifecycle, large number of people involved, highly complex processes, and typically global distributed nature of research, manufacturing, and supply chain organizations.

A recent study by the authors on the importance of knowledge transfer for the sustained success of technology transfer found that the transfer of *explicit* knowledge (e.g. documents) and *tacit* knowledge (e.g. 'know-how') were both extremely important to successful technology transfer. However in gauging knowledge transfer effectiveness, the transfer of *explicit* knowledge was found to be only **marginally effective**. The transfer of *tacit* knowledge fared worse, as it was considered **somewhat ineffective** [5].

This paper presents a brief introduction to tacit knowledge as related to the biopharmaceutical industry and its importance to technology transfer. This is followed by a case study profiling a series of practices to facilitate tacit knowledge transfer during a new product introduction technology transfer, along with the results achieved.

2. 'Tacit knowledge' and its importance

Some definitions of tacit knowledge refer to philosophical or abstract concepts. A common example is the knowledge of how to ride a bike. How do you know this, and how would you describe this to someone else? Polanyi is credited with the term *tacit knowledge* in his 1966 book, the *Tacit Dimension*, and the related observation that "we know more than we can tell." [7]

Tacit knowledge can be defined as skills, ideas and experiences that people have but are not codified and may not necessarily be easily expressed [8]. With tacit knowledge, people are not often aware of the knowledge they possess or how it can be valuable to others. Effective transfer of tacit knowledge generally requires extensive personal contact, regular interaction, and trust [9]. A tangible example of this is the journeyman and apprentice, where the apprentice is coached over an extended period by the highly skilled and experienced journeyman. In fact, 70% to 80% of the collective knowledge in biopharmaceutical companies is tacit knowledge [10], [11] yet these assets are not managed well.

In contrast to explicit knowledge, which is commonly regarded as *know-what* (i.e., facts), tacit knowledge can be described as *know-how*. In the limited references to tacit knowledge currently embedded in biopharmaceutical literature, *know-how* is the most common expression representing tacit knowledge, along with related concepts of *experienced* and *expert* [4], [12]–[15].

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In addition, the concepts of *know-why* and *know-who* can also be considered tacit knowledge [16], and the authors find the illustration in Figure 1 by shared Brinson [17] useful to depict this visually by linking knowledge to actions. In particular, the inner relationships of **insight** (*know-what* + *know-why*), **reaction** (*know-why* + *know-how*) and **method** (*know-what* + *know-how*) are of clear and inherent value to knowledge work of the biopharmaceutical industry in pursuit of **meaningful action** as found in the centre of the figure.

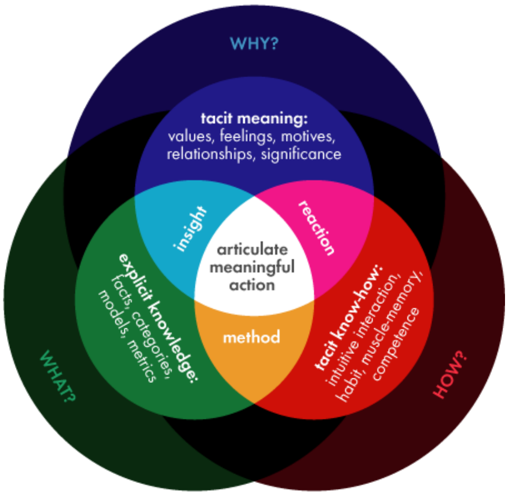

Figure 1 – Know-What, Know-Why and Know-How **[17]**

Knowing *what*, *why* and *how* empowers the decision maker with the best available knowledge on hand, to take the most meaningful actions to manage risk to both the patient and the business. Ensuring this knowledge is available and is applied is key as demonstrated in the *Risk-Knowledge Infinity Cycle* described in 2020 by Lipa et al [18]. This framework (Figure 2) highlights the relationship between knowledge and risk: As knowledge *increases*, risk *decreases*. This is accomplished in part by ensuring the effective flow of knowledge in-to and out-of risk management and other business processes.

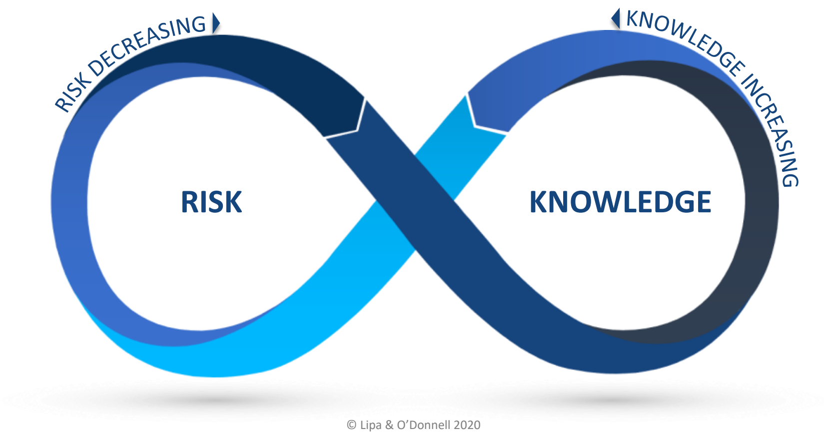

Figure 2 - The Risk-Knowledge Infinity Cycle **[18]**

3. Tacit knowledge and technology transfer

This paper focuses on a biopharmaceutical product technology transfer and describes pragmatic practices to enable the capture and transfer of tacit knowledge (i.e., technical *know-how* and *know-why*, and to a lesser extent *know-who*). This case study demonstrates how relatively simple practices can have a strong impact on how knowledge is managed as an asset and in turn reduces risk to the patient.

The bias toward explicit knowledge and general neglect of tacit knowledge is perhaps not surprising in an industry with the informal mantra "if it isn't written down, it didn't happen", as often reinforced by GMP (Good Manufacturing Practice) training. Yet, critical tacit knowledge is expected to be transferred during technology transfer by industry experts and regulatory agencies alike, including key development activities, learnings from failures, pilot scale knowledge, how to run a process in a particular piece of equipment, how risk is communicated, etc. [5].

According to APQC, "knowledge is sticky, and without a process it will not flow" [11]. There are a variety of common knowledge management practices which can facilitate the structured transfer of tacit knowledge, including:

- social networks
- storytelling
- shadowing of experts
- lessons learned / after action review
- communities of practice
- and others

However, these practices are not commonly employed during technology transfer within the biopharmaceutical sector. Instead, typically there are unstructured practices used to transfer tacit knowledge in a highly ad hoc manner. For example, where a receiving site representative may observe a batch being manufactured at the sending site prior to transfer. Facility fits, process walkthroughs and risk assessments are other means where some tacit knowledge is transferred, although typically in an ad hoc manner.

The following case study presents examples of three structured KM practices which were shown to be effective in enabling tacit knowledge flow during a new product introduction.

4. Case Study: Three (3) practices to improve tacit knowledge flow during technology transfer

Recognizing the importance of tacit knowledge and the general ineffectiveness of tacit knowledge transfer, an effort was undertaken during a technology transfer at a major multi-national biopharmaceutical company to improve tacit knowledge transfer in support of on-time filing and commercial launch of a new therapy. It is important to note the case study example is a highly complex vaccine drug substance product which resulted in a large number of process performance qualification (PPQ) batches (i.e., there were a large number of validation batches, many more than the typical 3). The transfer was a new product introduction from a late-stage development organization to the full-scale commercial manufacturing facility within the innovator company. Due to typical aggressive technology

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transfer timescales and resource constraints, the tactics for tacit knowledge capture and transfer had to be as pragmatic as possible for the technology transfer team.

Drawing on best practices in knowledge management, each of the tacit knowledge transfer practices reviewed in this case study share common elements, including:

- Standardized business process for knowledge capture and transfer (and codification to explicit knowledge, where appropriate)
- Basic governance to ensure prioritization and follow through on important actions
- Enabling mindsets for sending and receiving site personnel, including 'safe to share' and a sense of inquisitiveness. This included active engagement and participation from people, including experts from the sending site and members from the receiving site

In addition, each practice featured a targeted set of open-ended questions to foster dialogue, tailored to the context at hand.

The three practices developed and utilized in this case study were:

1. What if…?
2. Technology Transfer Batch Execution Review
3. Tacit Knowledge Turnover Assessment

4.1. What If…?

Process overview

The *What if…?* practice for knowledge transfer is a form of a risk assessment [19].

In this case study using *What if…?*, the technology transfer team took a stepwise approach to interrogate the process in a structured manner by asking the sending site subject matter expert (SME):

"What if <operating parameter x> exceeds it's typical range?"

This was followed by a discussion on what evidence existed to support this knowledge. This process explored what would happen at the typical high and low range limits and was repeated for each operating parameter.

This practice was not intended to replace a formal quality risk assessment, but rather to enhance dialogue amongst a broader team through a lens of discovering *"what is known"* and *"how do we know it?"*. Figure 3 provides a process overview, including illustrative questions asked as part of this process.

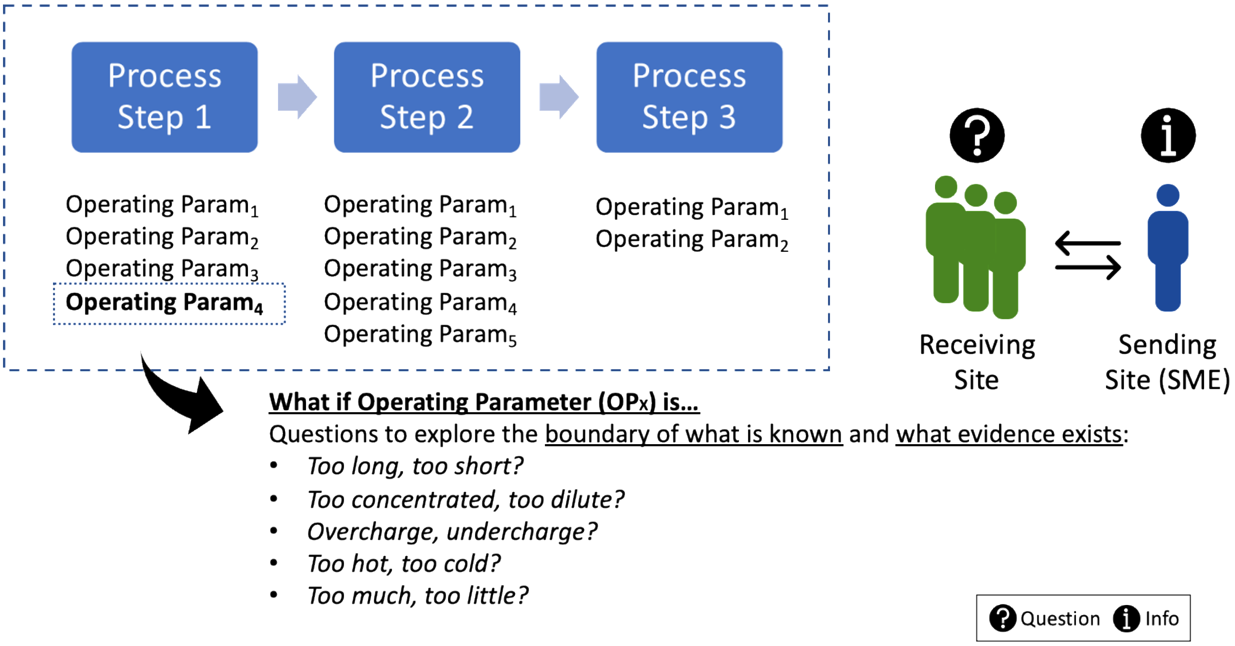

Figure 3 – "What If…?" Process Overview

How the process helped with tacit knowledge transfer ("learn before")

The *What if…?* practice, deployed by the receiving site-based technology transfer team, created important dialogue between the SMEs of the sending site and the new process team at the receiving site in exploring what is known about the performance of each operating parameter at the boundary of its limits. This included the identification and transfer of relevant supporting evidence (knowledge) which may not have been otherwise transferred.

This line of questioning also allowed the team to engage in rich discussion about 'known unknowns.' In other words – known gaps in knowledge – such as areas not previously studied. This enabled the receiving site to better understand **risks, areas of uncertainty, process sensitives, and inform future process development opportunities**. The dialogue that emerged created a powerful learning opportunity for the receiving site, enabling the team to "learn before" process execution.

Results

In this case study, the *What if…* practice identified over 100 potential actions which were grouped into key categories of:

- Process knowledge (67%)
- No data exists (16%)
- Equipment knowledge (11%)
- Other (6%)

Of these, a vast majority (84%) were actioned, indicating the site recognized the value in addressing the gaps and closing them. A tracking mechanism with basic metrics and regular review with the technology transfer leadership team (a governance body) were key enablers to ensure this knowledge was acted upon and built back into the flow of the work.

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4.2. Technology Transfer Batch Execution Review

<u>*Process overview*</u>

For this technology transfer, the authors developed a new practice, named by the authors as the *Technology Transfer Batch Execution Review (TT-BER)*. *TT-BER* consists of two parts:

1. A *pre-batch review*, based on concepts found in a pre-job brief. A pre-job brief is a practice often used in safety management processes involving high hazard and/or complex work activities [20], [21]
2. A tailored *After Action Review* (AAR) [22], serving as a post-batch review

This pairing of reviews both before and after batch execution create a closed loop cycle supporting risk mitigation, learning and continuous improvement.

In this case study, the technology transfer team huddled prior to execution of each PPQ batch to conduct a *pre-batch review*. As part of this *pre-batch review*, the team reviewed key questions including:

- "*What does good look like for our planned activity?*"
- *"What changed since last time?"*
- *"What is new, unique or difficult?"*

An illustrative set of questions is included in Figure 4.

The back end of the *TT-BER* practice was the post-batch review. Practically speaking, this was an *after-action review* tailored to the context of a batch execution. The technology transfer team paused to reflect, drawing on after-action review best practices to explore a series of key questions culminating with

- *"What can we learn?"*
- *"Who needs to know?"*

An illustrative set of *after-action review* questions is included in Figure 4.

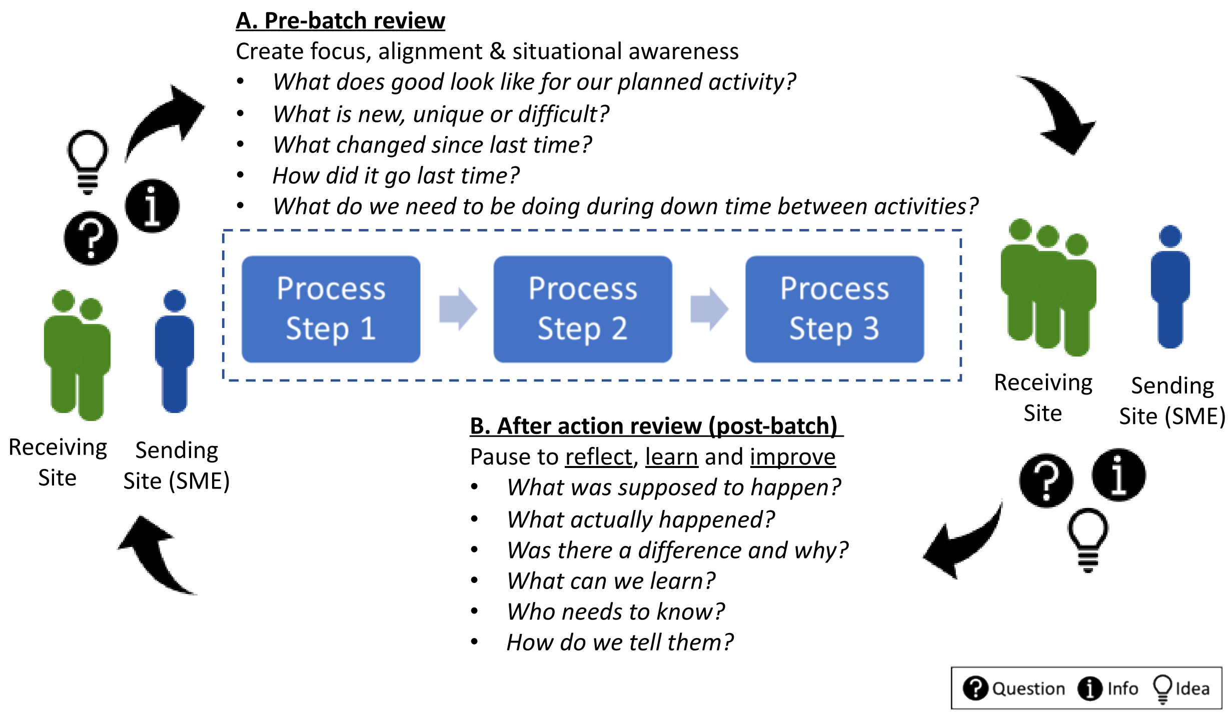

Figure 4 – Technology Transfer Batch Execution Review (TT-BER) Process

How the process helped with tacit knowledge transfer ("learn during")

As discussed above, the *TT-BER* practice with *pre-batch review* and *after action review* activities was newly conceived for this technology transfer project. The *TT-BER* ˆ provided a powerful opportunity for the technology transfer team to come together and surface assumptions, changes, areas of concern and other tacit knowledge held by the team members in anticipating batch execution. Given this case study involved a new product introduction, significant learning occurred involving the equipment and the process. In particular, the context of the upcoming batch execution and what was known from the prior batch created strong situational awareness for the team, enabling the team to better focus on successful execution of the task at hand.

The *TT-BER AAR* (post-batch review) similarly provided a structured opportunity for the team to pause and reflect on what actually happened versus what was intended to happen. The open-ended questions on understanding *why* the actual outcome were not the same as intended (whether for better or worse) and transforming this insight into an actionable lesson. These insights drove tangible learning and improvement actions which were tracked via the governance process. Through these reviews with associated dialogue, the *TT-BER* process enabled the receiving site to "learn during" process execution in a very agile and adaptive manner through the enhanced knowledge transfer.

Results

The metrics associated with the *TT-BER* practice are telling. The process produced 82 potential actions. Of these:

- 52 were implemented (63%)

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- 16 were tagged as future continuous improvement opportunities (20%)
- 11 were not applicable (e.g. duplicates, once-off, etc.) (13%)
- 3 were managed through the formal quality system (4%)

A qualitative review of the 52 actions implemented revealed that **43 of the 52 could have potentially led to a deviation in the quality system** had they not been proactively addressed. For example, to conduct additional studies to extend hold times and thus mitigate future deviations once the process execution cycle time and other logistics were better understood.

This demonstrated a powerful example of proactive risk mitigation and associated positive impact to right-first-time execution, improved quality, reduced cost, and reduced lead time. Furthermore, testimonials from the technology transfer team enthusiastically supported these outcomes. The production area lead noted:

> *"the process enabled process improvement on a near real-time basis for items that may have lingered for years. While items that were necessary to ensure 'ready for launch' would have been captured, 'ready for supply' items may have been missed."*

This was a clear testament to the impact of *TT-BER* on the process robustness and future manufacturability.

A further endorsement from the technology organization was as follows:

> *"After action review provided the required environment to generate an ambitious continuous improvement recommendation to run small scale studies to extend the proven acceptable range…not restricted by timeline & system. After action review allowed time to 'fix' [potential issues]."*

A tracking mechanism with basic metrics and regular review with the technology transfer leadership team who provided appropriate governance were key enablers. This practice was further recognized at the corporate manufacturing division by being awarded the winner of a highly competitive award for innovation.

4.3. Tacit Knowledge Turnover Assessment

<u>*Process overview*</u>

For this technology transfer, the authors developed a second new practice, named by the authors as the *Tacit Knowledge Turnover Assessment (TKTA)*. The authors intent was to conceive a means to create further dialogue to reflect on understanding, uncertainty and risk to augment the standardized post-campaign after action review. While the after action review would focus on learning from the technology transfer and associated business process, *TKTA* was intended to focus on product and process insights.

TKTA is a simple reflection process to evaluate the 'big picture' *after* PPQ batches were complete *but prior to* attrition of the sending site subject matter experts (or their memories). The sending site and receiving site selected their top 5 to 10 questions from a list of about 25 potential questions. Each group reflected on the questions independently and then met together to review as a team and agree on actions. Figure 5 provides a process overview and illustrative questions used to prompt dialogue amongst the team.

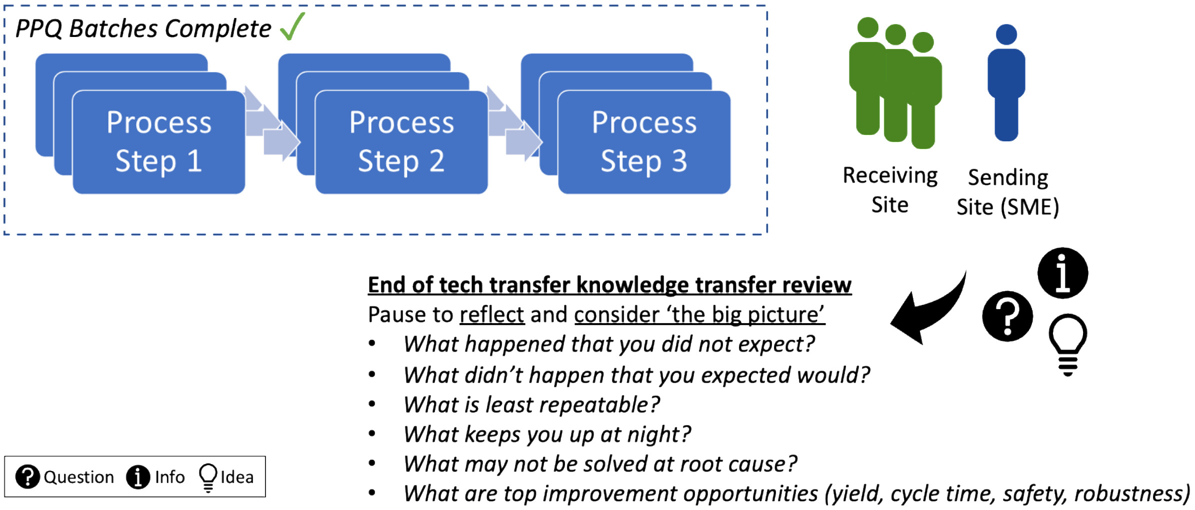

Figure 5 – The Tacit Knowledge Turnover Assessment (TKTA) Process

How the process helped with tacit knowledge transfer ("learn after")

As discussed above, the *TKTA* practice to capture tacit knowledge was newly conceived for this technology transfer project. Similar to the other practices deployed prior, this practice also facilitated rich dialogue amongst the team members, providing a process, a time and a context to explore and exchange tacit knowledge. The perspective of this process was prompting the team to 'zoom out' to the big picture with the PPQ batches completed. As the questions in Figure 5 illustrate, they are intended to explore un-met expectations, sources of uncertainty, concerns, and future opportunities. This practice enabled the receiving site to engage in candid, transparent dialogue and to "learn after" completion of the technology transfer activities.

Results

Similar to the *What if…?* process, the dialogue that emerged provided rich insights to inform risk, training of staff and future process development opportunities. In this case, the team identified 70 "answers" to the questions posed as part of the process. These 70 answers resulted in 39 actions taken to close gaps. These gaps were grouped into key categories of:

- Unexpected from PPQ (20%)
- What keeps you up at night (20%)
- Process improvement opportunities (17%)
- Learnings to share from key failed experiments (12%)
- Items that are least repeatable (8%)
- 'Rules of thumb' to capture (7%)
- Other (areas to study more, things not understood from PPQ, rationale from past decisions)

This *TKTA* process was conducted in addition to a formal after-action review and generated additional valuable insights and opportunities as it provided a different line of questioning than a traditional AAR. A tracking mechanism with basic metrics and regular review with the

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technology transfer leadership team who provided appropriate governance were key enablers.

5. Additional practices to facilitate tacit knowledge flow during technology transfer

While this case study presents three practices focused exclusively on tacit knowledge for technology transfer, the authors acknowledge there are several additional KM practices which can be highly beneficial in facilitating tacit knowledge transfer. For each, a standard process, supporting tools and templates, a mindset to manage knowledge as an asset and appropriate governance are critical success factors. **Table I** below outlines a series of additional KM practices which may be beneficial.

Table I - Additional KM practices for tacit knowledge

KM Practice	Description relative to technology transfer
Retention of critical knowledge	The *retention of critical knowledge* process is a risk assessment and risk management process to mitigate the impact of employee turnover, especially highly experienced staff with unique, 'mission critical' knowledge. This process can be applied during technology transfer (e.g. if experts leave the project or the organization) and/or selectively at the end of the technology transfer before experts move on to new assignments. The *retention of critical knowledge* process starts with a risk assessment of the individual's knowledge to help objectively define and prioritize areas of highest risk (what knowledge is critical or unique to this individual). Once prioritized topics are identified, the process guides the manager and expert through a series of facets of expertise to evaluate including *know-what*, *know-how*, *know-who*, and *know-why*. Knowledge transfer happens primarily during dialogue between expert and (ideally) successor or other expert, and through new knowledge assets created in response to the prioritized risks (e.g., white papers, training modules, product histories or other critical knowledge).
After-action review (AAR)	*After action review*, and closely related KM practice of lessons learned, are well-characterized processes [22] which focuses on extracting lessons from projects or events (what went well, in addition to what did not go well) and to ensure better performance on future project through targeted process improvements.
Decision Trackers	Simple lists of key decisions with supporting rationale (e.g. assumptions, choices evaluated, selection criteria and reasoning) can be beneficial to the receiving unit, who would not typically have understanding or visibility to these details 'looking back' in the future. This tacit knowledge can help with investigations, risk management, and development opportunities at a minimum
Subject Matter Expert (SME) Listing	Simple lists of who the subject matter experts are for a given product and process can be a valuable resource for future reference.
Communities of Practice (CoPs)	Communities of practice are powerful venues to connect diverse sets of people with areas of common interest. For technology transfer, a community focused on the process of technology transfer itself can help support the effective execution of the business process for technology transfer. Further, topic-specific communities (e.g. platform technologies) can also be invaluable to support technology transfer, especially when problems arise.

6. Discussion

The three knowledge transfer practices described in the case study, taken in aggregate, **allowed the receiving site to "learn before, learn during and learn after"** the technology transfer project, benefiting both the technology transfer at hand, the future of the product at the site, and future technology transfer projects. The *sending* site is also likely to benefit in understanding their effectiveness at capturing and transferring knowledge, creating a learning opportunity for future projects. This rich tacit knowledge sharing also enables the receiving site to go beyond the routine "minimal viable knowledge" typically shared as part of a technology transfer project. Currently, this knowledge sharing tends to be heavily biased to explicit knowledge – and is especially so when faced with the schedule, cost, and resource pressures of technology transfer projects. When an organization realizes the potential impact of these tacit knowledge transfer practices on the overall technology transfer and long-term manufacturability of the product, the benefit becomes obvious.

These processes share common success factors, including a standard process, open ended questions to foster dialogue, basic governance, supporting mindsets and active engagement. Exhibiting the mindsets and active engagement to share important tacit knowledge during technology transfer also demonstrates a fundamental behaviour of 'a culture of knowledge excellence.' A 'culture of knowledge excellence' (i.e. '*knowledge culture*') emphasizes "A way of organizational life that enables and motivates people to create, share and utilize knowledge for the benefit and enduring success of the organization." [23] This *knowledge culture* is further characterized by the boundaryless flow of knowledge, a culture of inclusion, a sense of curiosity, a growth mindset and a desire to capture, share and grow knowledge across the organization [24]. As an example of the potential impact, a study in *Harvard Business Review* reported that workers who take time to reflect perform more than 20% better than those who do not pause to reflect [25].

There are limitations to these processes. These processes by no means guarantee a perfect technology transfer and they do impact on the time of key staff to execute. Therefore, they must be appropriately sponsored by management and applied in a "fit for purpose" manner and at the right time. Resulting actions must be prioritized. The critical success factors discussed cannot be overlooked (including governance). In addition, while these practices focus on tacit knowledge transfer, one must not forget there are other activities required for explicit knowledge transfer (and the need for further enhancement).

7. Conclusion

Significant strides can be made in tacit knowledge transfer during technology transfer as described in this case study and participant feedback. These processes aren't overly complex, onerous, or mysterious. Rather they are about a basic commitment and discipline to create a time, space, and context for people to engage in dialogue, facilitated by open-ended, probative questions to surface knowledge.

This tacit knowledge also includes assumptions, insights, decision rationale or other knowledge which may well be obvious to the experienced sending site or SME but are likely not so obvious to the receiving site staff. As the saying goes, "You don't know what you know until you are asked a question." These simple processes when embedded in routine work do

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just that: **They provide a process for knowledge to flow, and through the case study presented above, have demonstrated clear benefits** to proactive risk mitigation, improved quality and higher right first time PPQ batches. In addition, there are long term benefits anticipated, including improved process robustness and increased knowledge available to inform risk-based decision making. And while this case study indeed focused on a highly complex scenario, there is likely no lack of opportunity on the horizon given the growth of technology transfers and more complex products (including advanced therapies).

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References

[1] S. Gera and K. Mang, "The knowledge-based economy: Shifts in industrial output," *Canadian Public Policy*, vol. 24, no. 2, 1998, doi: 10.2307/3551772.

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

[3] P. E. Kane and M. J. Lipa, "The House of Knowledge Excellence— A Framework for Success," in *A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry*, 1st ed., N. Calnan, M. J. Lipa, P. Kane, and J. C. Menezes, Eds. Boca Raton, FL: Taylor & Francis, 2017, pp. 181–224.

[4] ICH, *Quality Guideline Q10: Pharmaceutical Quality System*. Geneva, 2008.

[5] M. Lipa, P. E. Kane, and A. Greene, "Effective Knowledge Transfer During Biopharmaceutical Technology Transfer - How Well Do We Do It ?," *IVT Network*, vol. 25, no. 4, 2019, [Online]. Available: https://www.ivtnetwork.com/article/effective-knowledge-transfer-during-biopharmaceutical-technology-transfer-0.

[6] M. Lipa, A. Greene, and N. Calnan, "Knowledge Management as a Pharmaceutical Quality System Enabler: How Enhanced Knowledge Transfer can help close the Q10 to Q12 Gap," *PDA Journal of Pharmaceutical Science and Technology*, p. pdajpst.2020.011825, 2020, doi: 10.5731/pdajpst.2020.011825.

[7] M. Polanyi, *The Tacit Dimension*. Chicago: The University of Chicago Press, 2009.

[8] R. Chugh, "Do Australian universities encourage tacit knowledge transfer?," in *IC3K 2015 - Proceedings of the 7th International Joint Conference on Knowledge Discovery, Knowledge Engineering and Knowledge Management*, 2015, pp. 128–135, doi: 10.5220/0005585901280135.

[9] H. M. Collins, "Tacit Knowledge, Trust and the Q of Sapphire," *Social Studies of Science*, pp. 71–85, 2001, doi: 10.1177/030631201031001004.

[10] S. C. Beardsley, B. C. Johnson, and J. M. Manyika, "Competitive advantage from better interactions," *McKinsey Quarterly*, no. 2, pp. 52–63, 2006.

[11] APQC, "Introduction to Knowledge Management (KM)," Houston, TX, 2018. [Online]. Available: https://www.apqc.org/resource-library/resource-listing/introduction-knowledge-management-km-essentials-0.

[12] ISPE, "Good Practice Guide: Technology Transfer," ISPE, Tampa, 2018. [Online]. Available: https://ispe.org/publications/guidance-documents/good-practice-guide-technology-transfer-3rd-edition.

[13] M. Gibson and S. Schmitt, *Technology and Knowledge Transfer - Keys to Successful Implementation and Management*. River Grove, IL: PDA-Davis Healthcare International Publishing, 2014.

[14] ICH, *Quality Guideline Q9: Quality Risk Management*. Geneva, 2005.

[15] ICH, *Pharmaceutical Development Q8 (R2)*. Geneva, 2009.

[16] B. Johnson, E. Lorenz, and B. Å. Lundvall, "Why all this fuss about codified and tacit knowledge?," *Industrial and Corporate Change*, vol. 11, no. 2, 2002, doi: 10.1093/icc/11.2.245.

[17] S. Brinson, "A Quick Guide to Knowledge and Intelligence." https://www.sambrinson.com/a-quick-guide-to-knowledge-and-intelligence/ (accessed Dec. 29, 2020).

[18] M. J. Lipa, K. O'Donnell, and A. Greene, "Knowledge as the Currency of Managing Risk: A Novel Framework to Unite Quality Risk Management and Knowledge Management," *Journal of Validation Technology (JVT)*, vol. 26, no. 5, 2020.

[19] American Chemical Society, "What-if Analysis - American Chemical Society." https://www.acs.org/content/acs/en/chemical-safety/hazard-assessment/ways-to-conduct/what-if-analysis.html (accessed Dec. 29, 2020).

[20] Occupational Safety and Health Administration, "1926.952 - Job briefing," 2014. https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.952 (accessed Jan. 02, 2021).

[21] Los Alamos National Lab, "Pre-Job brief Guide," LA-UR-10-04321, 2010. [Online]. Available: https://www.lanl.gov/safety/videos/ism/docs/pre_job_guide.pdf.

[22] M. Darling, C. Parry, and J. Moore, "Learning in the thick of it," *Harvard Business Review*. 2005.

[23] S. Oliver and K. Reddy Kandadi, "How to develop knowledge culture in organizations? A multiple case study of large distributed organizations," *Journal of Knowledge Management*, vol. 10, no. 4, pp. 6–24, 2006, doi: 10.1108/13673270610679336.

[24] M. J. Lipa, "Enhancing Knowledge Flow to Protect Patients: Frameworks for Effective Biopharmaceutical Knowledge Management (Ph.D. Confirmation Report)," Dublin, Ireland, 2020.

[25] F. Gino and B. Staats, "Why Organizations Don't Learn," *Harvard Business Review*. 2015.

https://arrow.tudublin.ie/level3/vol15/iss2/3
DOI: https://doi.org/10.21427/2jdq-jq09