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Mapping KM Methods and Tools across the Pharmaceutical Product Lifecycle

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Abstract

Knowledge management is positioned as an enabler of ICH Q10, and the visibility and availability of product and process knowledge across the entire pharmaceutical product lifecycle is vital to the sustained success of an organization and to the effectiveness of an organization's pharmaceutical quality system as defined by ICH Q10. This paper illustrates where knowledge management has a role to play within each product lifecycle phase. This paper goes on to further define phase-appropriate KM methods and tools to help address these needs and create end-to-end product and process knowledge visibility and availability.

Introduction

Developing and manufacturing medicines is a deeply scientific endeavor, and an organization's ability to find, apply and grow knowledge is fundamental to its sustained success. When considering the purpose of *knowledge management* (KM) in the biopharmaceutical industry, the goal should be to prospectively manage knowledge as an asset *so that* the best possible knowledge is available when and where it is needed to enable patient optimal outcomes. Knowledge management can support this ambition through enabling a highly effective pharmaceutical quality system, inclusive of risk-based decision making powered by knowledge. Knowledge management indeed is positioned as an enabler to the pharmaceutical quality system as established in ICH Q10 [1]. The Pharmaceutical Product Knowledge Lifecycle (PPKL) Model [2] highlights this by identifying the need for product and process knowledge to be visible and available across the entire pharmaceutical product lifecycle.
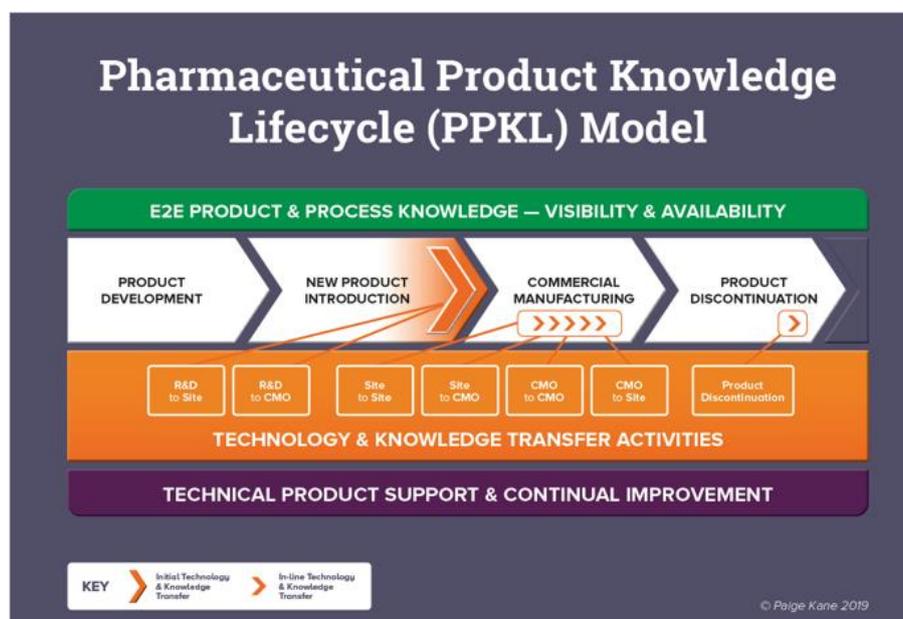

Figure 1: The Pharmaceutical Product Knowledge Lifecycle (PPKL) Model [2]

The need for KM during each phase of the pharmaceutical product lifecycle

To accomplish this, there are a variety of effective KM methods and tools[1] available to manage knowledge across the pharmaceutical product lifecycle [3]. Understanding the key focus of each lifecycle phase provides an opportunity to select phase-appropriate KM methods and tools. The intent is not to create 'silos' by having distinct KM methods and tools per phase, but rather to understand the end-to-end needs to manage knowledge and to deploy relevant, fit-for-purpose KM methods and tools embedded in the flow of work. A best-practice principle to enable effective knowledge management is to deploy standardized KM methods and tools [3]. With standardized approaches and thoughtful consideration of the end-to-end needs, knowledge can be managed in a very intentional, consistent and visible manner across the product lifecycle *and* across products. This improved visibility and availability of product knowledge will better enable the goals of ICH Q10 (i.e., (i) product realization, (ii) establishing a state of control and (iii) a basis for continual improvement [1]) and form the basis for 'prior knowledge' to be available in the future.

Following for each lifecycle phase in sequence is a list of illustrative knowledge-related activities and associated description of the central role KM can play in enabling each phase.

Product Development

Considering *Product Development*, illustrative knowledge-related activities include:

- Application of prior knowledge for risk assessments to determine areas of study
- Development work to capture new knowledge
- Ongoing risk assessment and risk control

Knowledge Management should be a key enabler to *Product Development* through standardized methods and tools delivering the following:

- **Access to prior knowledge** (platform technologies, other products, expertise in the company (individuals & CoEs[2]), external scientific literature, prior learnings & lessons, et al.)
- **Capture of new knowledge** during early development work (both what worked and what did not)
- **The record of product development**, including scientific knowledge and supporting design choices and other decision rationale

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New Product Introduction / Technology Transfer

Considering *New Product Introduction / Technology Transfer*, illustrative knowledge-related activities include:

- Application of knowledge for risk assessments
- Comprehensive knowledge transfer
- Opportunity to learn more about the product/process

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[1] Methods and tools are also commonly referred to as KM practices, approaches or capabilities
[2] CoE = Center of Excellence

- Supporting the goal to ensure a right-first time transfer, robust process and capable receiving site

Knowledge Management should be a key enabler to *New Product Introduction / Technology Transfer* through standardized methods and tools delivering the following:

- **Access to comprehensive product and process knowledge**, including development and manufacturing history, including key decisions, learnings from failures, changes, etc.
- **Access to subject matter experts / personnel** with process experience
- **Capture of new learnings** including increased knowledge and understanding of product/process, lessons learned, etc.

Commercial Manufacturing / Continuous Improvement

Considering *Commercial Manufacturing / Continuous Improvement*, illustrative knowledge-related activities include:

- Ongoing knowledge build through accumulated manufacturing experience
- Lifecycle management, including planned and unplanned changes
- Seek to minimize disruptions to product availability by rapid problem solving and solving problems at root cause

Knowledge Management should be a key enabler to *Commercial Manufacturing / Continuous Improvement* through standardized methods and tools delivering the following:

- **Capture of new learnings** including increased knowledge and understanding of product/process, lessons learned, etc.
- **Knowledge visibility and availability** across the full product lifecycle (including development) to ensure broad access to knowledge to support process monitoring, continual improvement, change management, investigations, et al
- **Support for problem solving and sharing of best practices and improvements** across the supply chain and back to development organization

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Product Discontinuation

Considering *Product Discontinuation*, illustrative knowledge-related activities include:

- Knowledge transfer for archival and future access on demand
- Harvesting learnings to inform 'prior knowledge'

Knowledge Management should be a key enabler to *Product Discontinuation* through standardized methods and tools delivering the following:

- **Capture of knowledge in a complete and structured manner** to allow for future access (e.g. stability, complaints, etc.)
- **Capture of learnings** including insights for platform knowledge and other potential 'prior knowledge'

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Phase-appropriate KM methods & tools

Table 1, *Phase-appropriate KM methods & tools across the pharmaceutical product lifecycle*, provides a summary of the above considerations and corresponding KM methods and tools which can be deployed to fulfill the needs of each lifecycle phase. These methods and tools are organized by those required for *Planning & Requirements Definition*, *Mostly Explicit (knowledge)-based methods and tools*, *Mostly Tacit (knowledge)-based methods and tools*, and *Enabling Elements*. Table 2, *Description of KM Methods and Tools,* provides a brief description for each of these methods and tools.

Table 1: Phase-appropriate KM methods & tools across the pharmaceutical product lifecycle

Lifecycle Phase	Areas of emphasis where knowledge is required	How Knowledge Management can provide benefit...	KM Maturity Assessment	Knowledge Mapping	Product KM Plan	Knowledge Transfer Plan	Site / Functional Area KM Plan	Content Management	Taxonomy & Search	Platform Knowledge Base	Product Knowledge Base	Communities of Practice	After Action Review / Lessons Learned	Expertise Location	Decision Rationale Capture	Tacit Knowledge Retention & Transfer Practices	KM Roles	KM Training	Knowledge-valuing culture	Sponsorship, Governance, Metrics & Other enablers
		Note 1: Illustrative concepts, not an exhaustive listing *Note 2: References below to knowledge refer to both explicit and tacit knowledge* *Note 3: Additional concepts or complexity may be introduced when when multiple entities are involved*																			
Product Development	- Application of prior knowledge for risk assessments to determine areas of study - Development work to capture new knowledge - Ongoing risk assessment and risk control	Common KM elements for *Product Development* phase	X	X													X	X	X	X
		Access to prior knowledge (platform technologies, other products, expertise in the company (individuals & CoEs), external scientific literature, prior learnings & lessons, et al)						X	X	X	X	X	X	X						
		Capture of new knowledge during early development work (both what worked and what didn't)			X		X	X	X	X	X		X		X					
		The record of product development, including scientific knowledge and supporting design choices and other decision rationale			X	X		X	X	X	X		X		X	X				
New Product Introduction / Technology Transfer	- Application of knowledge for risk assessments - Comprehensive knowledge transfer - Opportunity to learn more about the product/process - Supporting the goal to ensure a right-first time transfer, robust process and capable receiving site	Common KM elements for *Technology Transfer* phase		X													X	X	X	X
		Access to comprehensive product and process knowledge, including development and manufacturing history, including key decisions, learnings from failures, changes, etc.			X	X	X	X	X	X	X	X	X	X	X	X				
		Access to subject matter experts / personnel with process experience				X			X			X		X		X				
		Capture of new learnings including increased knowledge and understanding of product/process, lessons learned, etc.			X	X	X	X		X	X	X	X		X	X				
Commercial Manufacturing / Continuous Improvement	- Ongoing knowledge build through accumulated manufacturing experience - Lifecycle management, including planned and unplanned changes - Seek to minimize disruptions to product availability by rapid problem solving and solving problems at root cause	Common KM elements for *Commercial Manufacturing* phase	X	X													X	X	X	X
		Capture of new learnings including increased knowledge and understanding of product/process, lessons learned, etc.			X		X	X	X	X	X	X	X		X	X				
		Knowledge visibility and availability across the full product lifecycle (including development) to ensure broad access to knowledge to support process monitoring, continual improvement, change management, investigations, et al			X		X	X	X	X	X	X	X	X	X	X				
		Support for problem solving and sharing of best practices and improvements across the supply chain and back to development organization			X		X	X	X	X	X	X	X	X	X	X				
Product Discontinuation	- Knowledge transfer for archival and future access on demand - Harvesting learnings to inform 'prior knowledge'	Common KM elements for *Product Discontinuation* phase		X													X		X	X
		Capture of knowledge in a complete and structured manner to allow for future access (e.g. stability, complaints, etc.)			X			X	X		X		X	X	X	X				
		Capture of learnings including insights for platform knowledge and other potential 'prior knowledge'				X				X		X	X	X	X	X				

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Table 2: Description of KM Methods and Tools

KM Method or Tool	Description
Planning & Requirements Definition	
KM Maturity Assessment	A means to objectively measure maturity of KM effectiveness based on various attributes such as process, culture, technology, etc.
Knowledge Mapping	A structured means to document the knowledge needed for a business process, a functional group, a role, etc. Used to understand knowledge requirements and identify gaps.
Product KM Plan	A strategy document to define the plan for how the knowledge associated with a product will be managed.
Knowledge Transfer Plan	A strategy document to define the plan for how the knowledge transfer will be managed.
Site / Functional Area KM Plan	A strategy document to define the plan for how the knowledge associated with a site or functional group will be managed.
Mostly Explicit-based	
Content Management	A structured[3] means to manage documents and other explicit knowledge (e.g., videos, pictures, etc.). Typically includes the end-to-end lifecycle of content (e.g., creation, tagging, storage, delivery). Applies to both GMP and non-GMP content which may be managed in separate systems.
Taxonomy & Search	Taxonomy is a structured means to describe and tag content (and potentially other features such as synonyms, semantics, etc.), and a means to deliver results through a robust, integrated search enabled by such a taxonomy.
Platform Knowledge Base	A structured means to define the scope of platform knowledge (explicit and tacit) and corresponding approaches to manage this in a consistent way to ensure knowledge visibility and availability across the product lifecycle.
Product Knowledge Base	A structured means to define the scope of product knowledge (explicit and tacit) and corresponding approaches to manage this in a consistent way to ensure knowledge visibility and availability across the product lifecycle.
Mostly Tacit-based	
Communities of Practice	A structured means to connect groups of people with a shared need or interest
After Action Review / Lessons Learned	A structured means to surface learnings from the experiences of people, often associated with a project or other business process, and subsequently capture and implement these learnings to support continual improvement.
Expertise Location	A structured means to identify important expertise and/or experience in the organization and connect to it on demand.
Decision Rationale Capture	A structured means to capture decision rationale and ensure it is available in the future when needed.

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[3] Structured = Standardized and inclusive of people, process, technology and governance

KM Method or Tool	Description
Tacit Knowledge Retention & Transfer Practices	A variety of structured means to identify, prioritize, transfer and retain tacit knowledge (i.e., know-how and other knowledge "in people's heads")
Enabling Elements	
KM Roles	Standardized roles for managing knowledge consistently, such as community stewards.
KM Training	Training on appropriate KM topics to build awareness and competency of individuals in the organization.
Knowledge-valuing culture	Mindsets and behaviors which value the knowledge of the organization as an asset (e.g., capturing and sharing lessons, seeking to leverage prior knowledge)
Sponsorship, Governance, Metrics & Other enablers	Best practices to enable effective and sustainable KM. [ref]

Conclusion

While there is no "one right answer" on how to best manage knowledge across the pharmaceutical product lifecycle, a pragmatic approach to understand the intent and focus of each phase can provide valuable insights on how knowledge might be utilized and how KM can address these needs. This paper provides a high-level outline to illustrate this, and subsequent effort can be undertaken to further define the specific requirements (what processes, what knowledge, what users, etc.). In fact, the *Planning & Requirements Definition* section provides the impetus to do just this – to leverage such approaches to create an intentional plan (e.g., product, site or knowledge transfer plans) supported by a clear definition of the knowledge needed (provided by a knowledge map). The authors hope that while this is described at a high-level in this paper, the concepts will be useful to further "demystify" what can be done to make progress in knowledge management in support of ICH Q10 and overall operational effectiveness.

References

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

[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.