

Knowledge Management *(the other enabler)*

PIA
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About Me

Joined Eli Lilly and Company in 2008
Clinical Trial Quality Assurance



Global Serialization Program in 2015
Change Management, Knowledge
Management, & Training Strategy



Competitive Continuous Improvement
(Lean) Coach IPM 2022



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Eli Lilly and Company

- Our Mission: We make medicines that help people live longer, healthier, more active lives.
- Our Vision: We will make a significant contribution to humanity by improving global health in the 21st century.
- Our Values: Integrity, excellence, respect for people

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KM BACKGROUND

- Definitions
- Regulatory History
- Activity in Pharma

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Wait...there's two?

Per ICH Q10¹:

1.6 Enablers: Knowledge Management and Quality Risk Management

Use of *knowledge management* and quality risk management will enable a company to implement ICH Q10 effectively and successfully. These enablers will facilitate achievement of the objectives described in Section 1.5 above by providing the means for science and risk based decisions related to product quality.

...it takes **both** QRM & KM across a product's lifecycle to:

- Achieve product realization
- Establish and maintain a state of control, and
- Facilitate continual improvement

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What exactly is KM? Well, it depends...

"Systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components." – **ICH Q10, June 2008**¹

"Knowledge Management is the process of capturing, developing, sharing and effectively using knowledge (such as patient, product, and process knowledge) to drive a business." – **BPOG Technology Roadmap, Knowledge Management, 2017**²

"Management with regard to knowledge; it uses a systemic and holistic approach to improve results and learning; it includes optimizing the identification, creation, analysis, representation, distribution and application of knowledge to create organizational value." **ISO 30400:2016, ISO 30401:2018**³

"The application of a structured process to help information and knowledge flow to the right people at the right time so they can act more efficiently and effectively to find, understand, share, and use knowledge to create value." – **APQC, KM Glossary 2022**⁴

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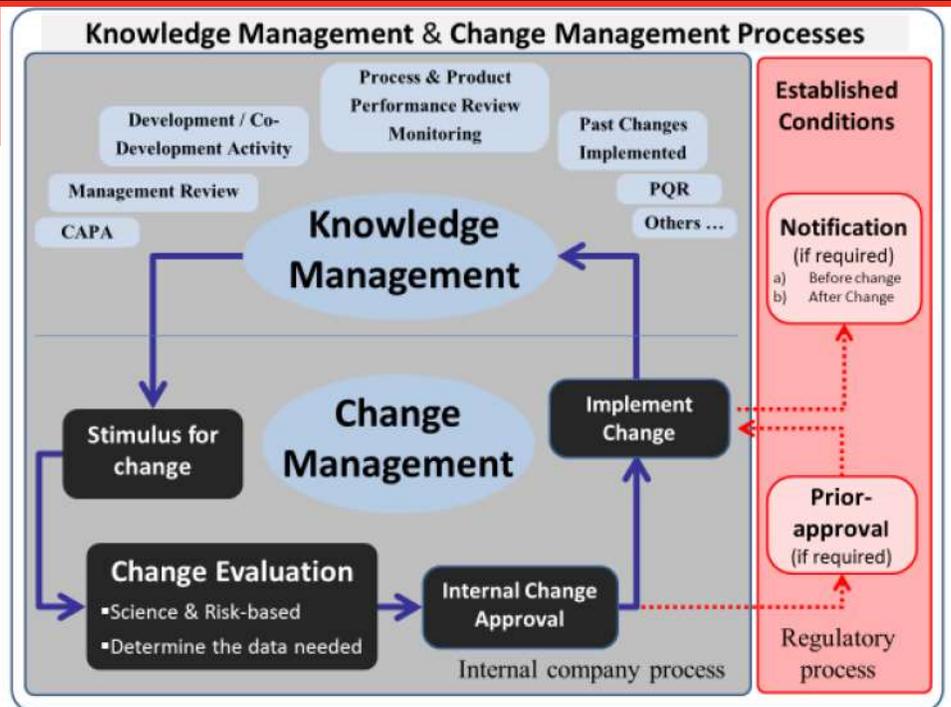
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ICH Q12

“An effective change management system includes active knowledge management, in which information from multiple sources is integrated to identify stimuli for changes needed to improve product and/or product robustness.”⁵



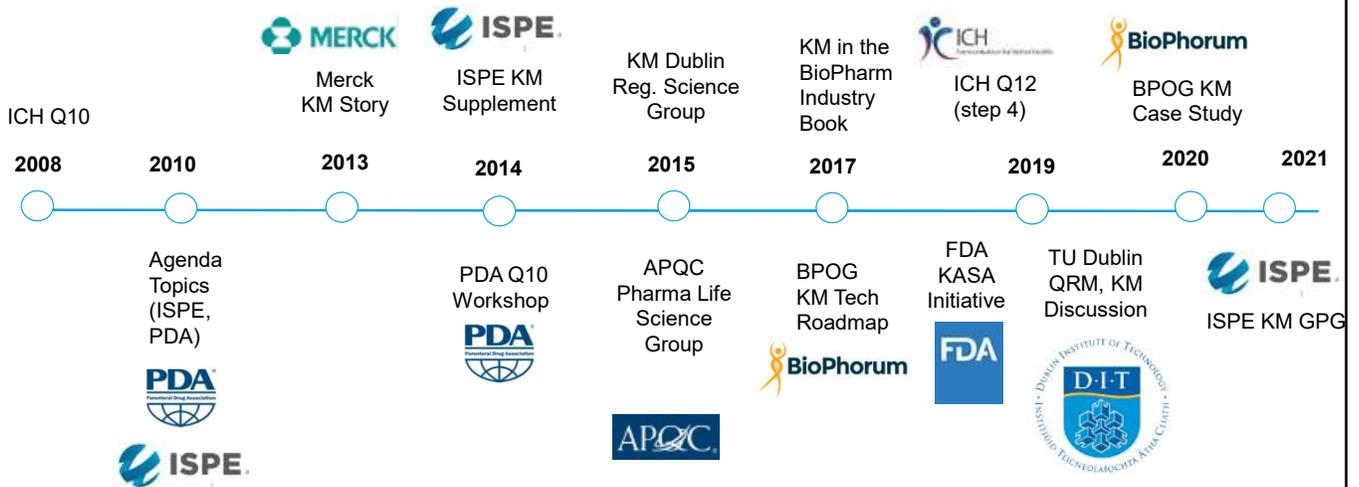
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KM in Pharma Timeline



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Observed KM Activity in Pharma

- External workgroups & engagement are growing (BPOG, APQC, ISPE, PDA, Knowledge & Collaboration Council)

As of 2020:

- 15/29 - # of pharmaceutical companies, engaged in/ # of times assessments ran measuring/evaluating their current KM programs through APQC (since 2010).
- 1-6 – Average # of years formal KM programs have been in place in pharma (with a few over a decade!)
- No** pharma company has achieved KM at an enterprise level (commonly focused in manufacturing)

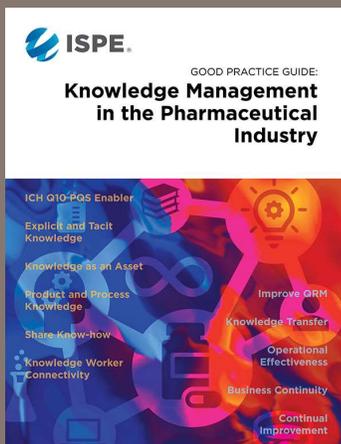
26+ Pharma Manufacturers observed with activity and/or connection to Knowledge Management (industry working groups, associations, conferences, LinkedIn, etc).

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KM CORE CONCEPTS

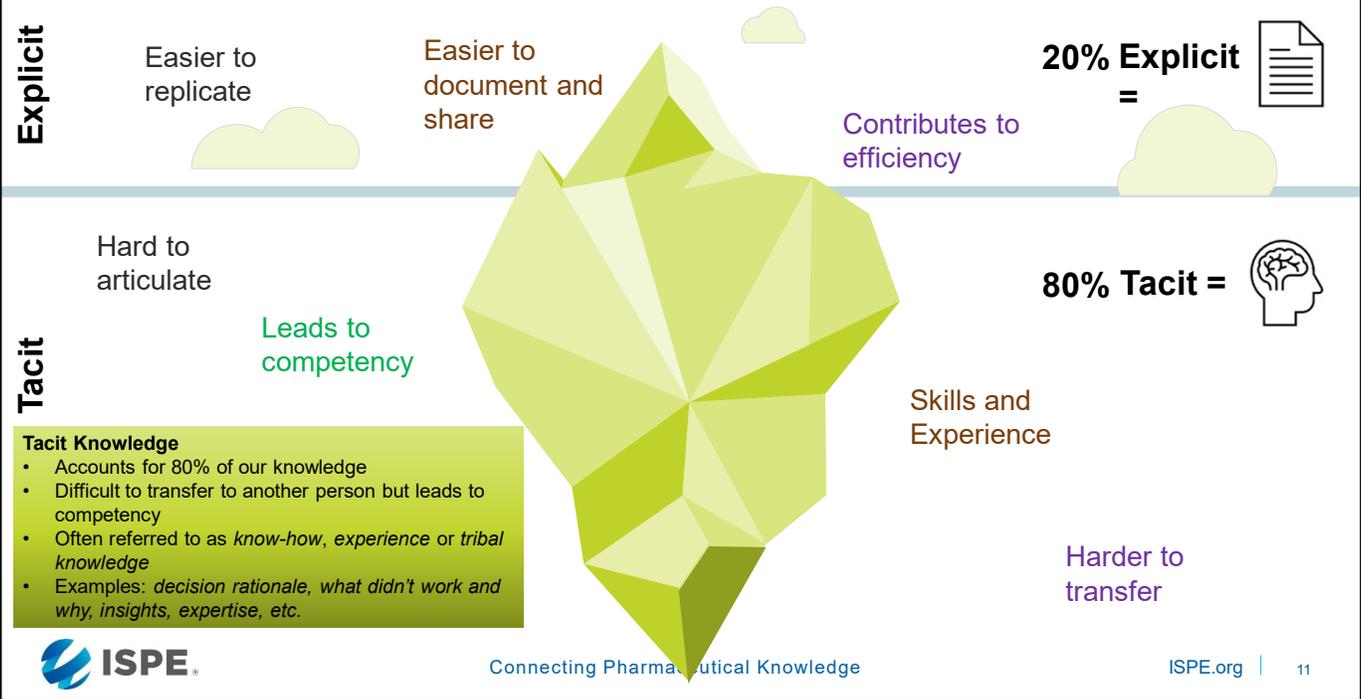
- Types of Knowledge
- Data vs. Knowledge
- KM as a “How” vs. a “What”

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The Iceberg: Tacit and Explicit Knowledge⁷



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Data, Information, Knowledge and Insights^{7,8}

Data: Discrete, objective facts, lacking context

Information: Data with context and relationships

Knowledge: Contextualized information leading to understanding

Insight⁸: Deep intuitive understanding / advanced contextualization that leads to predictive understanding – human or machine

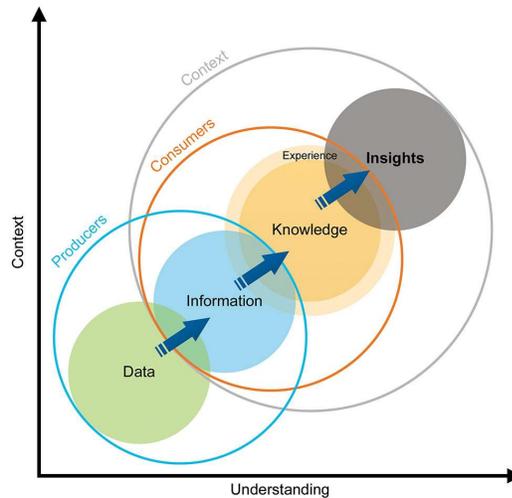


Figure 3.2: The Journey to Insights: Relationship between the Producers and Consumers of Data, Information, and Knowledge⁹

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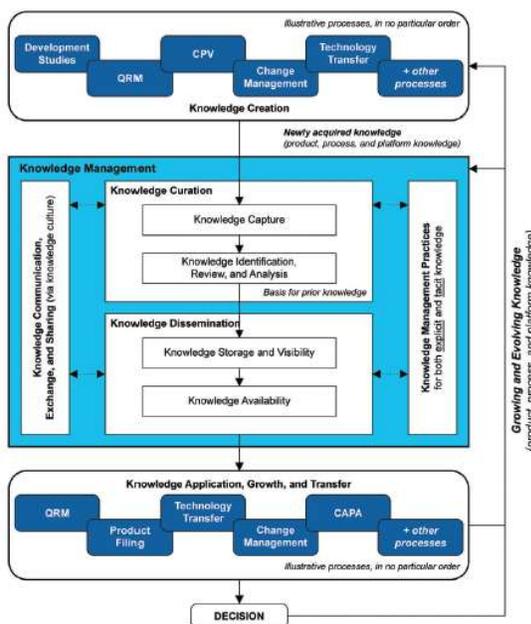
KM Process Model⁷

Translating KM – QRM (ICH Q9) ‘like’ Model

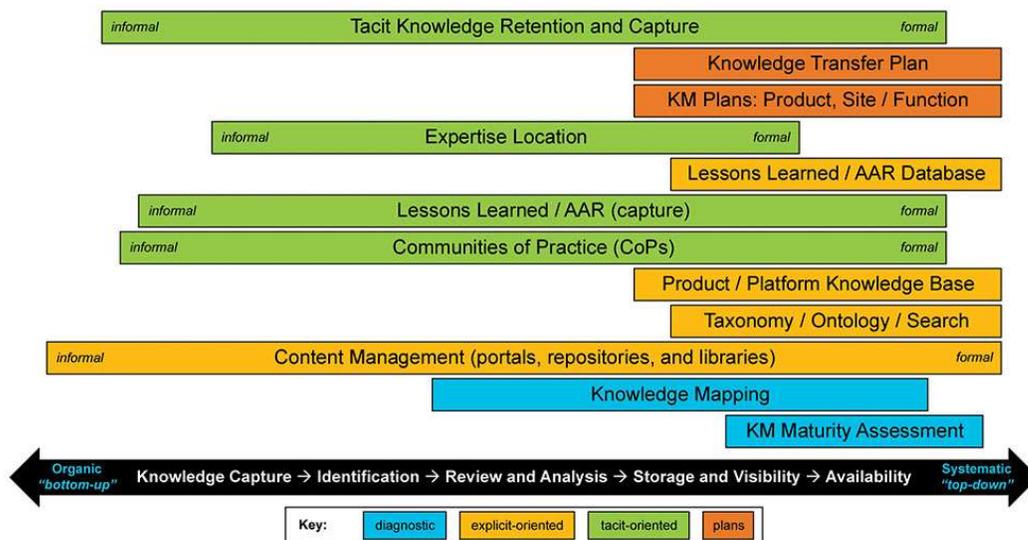
Model speaks to:

- Knowledge Curation (Capture & Analysis)
- Knowledge Dissemination (Storage & Availability)
- Knowledge Application Growth & Transfer
- Use of KM Methods and Tools
- Inputs and outputs of knowledge

Figure 4.1: Knowledge Management Process Model (Adapted from Lipa, O'Donnell, and Greene 2020, 4 [31])
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KM Methods & Tools, cont. ⁷



KM Concepts, Cont.

PQS Enabler⁶

- Process performance/quality monitoring,
- CAPAs,
- change management,
- management review, and monitoring, and
- the overall lifecycle of knowledge for a product
- Hand in Hand with QRM. As patient, product, and process knowledge increase risk decreases. Reuse of prior knowledge should inform risk for new products

OpEx⁶

- Improved business performance through systematic transfer and retention of knowledge.
- Reduction of knowledge leak
- Like Lean Six Sigma, is easily linked to forms of waste:
 - re-creating existing knowledge,
 - search time to connect with knowledge,
 - repeating mistakes because we aren't using prior knowledge, etc).

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KM CASE STUDY

- Retrospective Review: Serialization Knowledge Mapping through the KM Process Model

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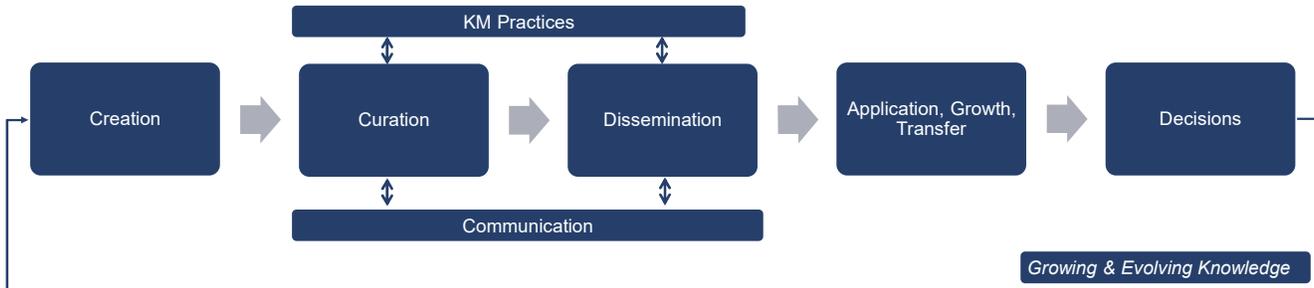
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Serialization: KM Process Model & Knowledge Mapping

Throughout the case study, we'll recall the major Components of the KM Process Model¹⁰:



Serialization: In Pharmaceutical Manufacturing, the addition of a unique identifier (serial number) to the finished pack. This unique identifier is used throughout the supply chain to track or verify product authenticity.



Korea Cialis (Alcobendas)



Argentina Gemzar (Indianapolis)

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KM in Serialization



2016 GSP Objective:
 “Aggressively increase personnel serialization capabilities (global team and site).”

Change Management

Regulatory Req's/ Activation

Serialization Basics

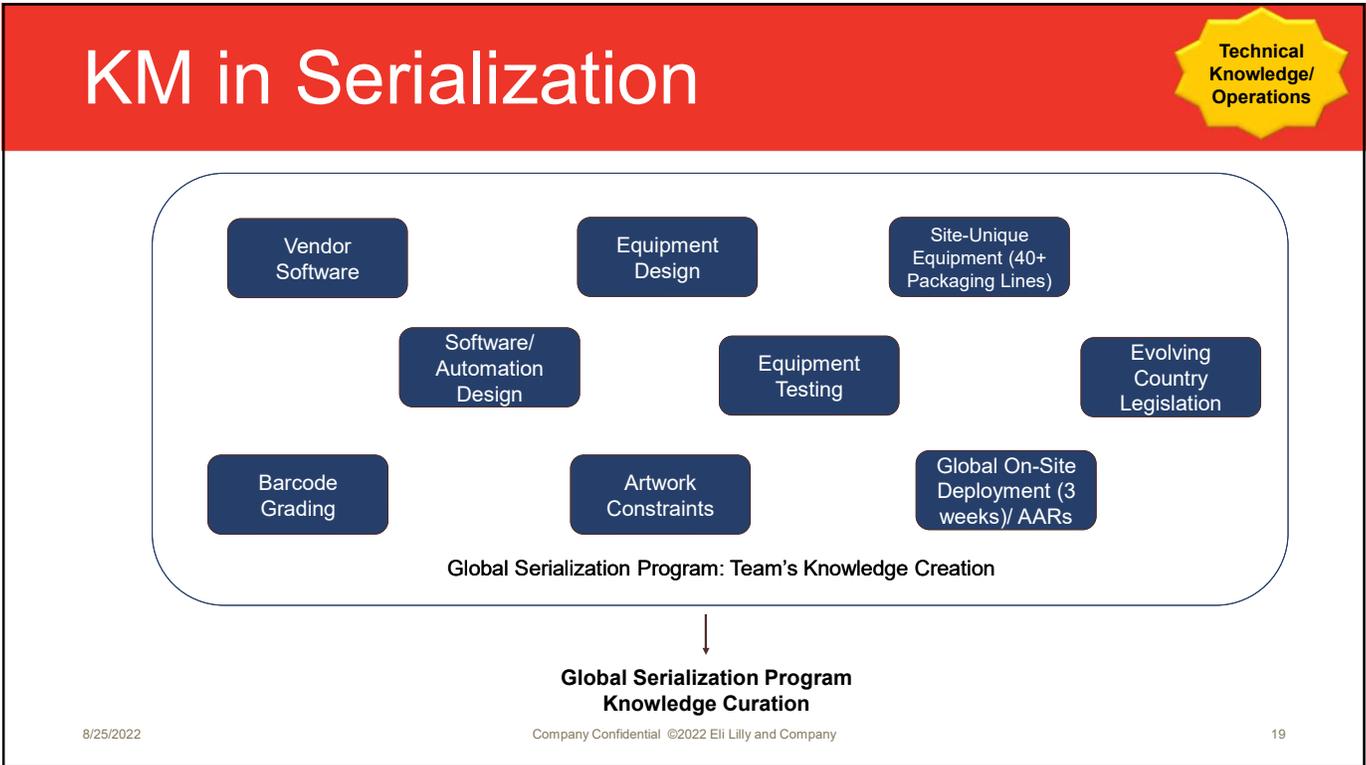
Technical Knowledge/ Operations

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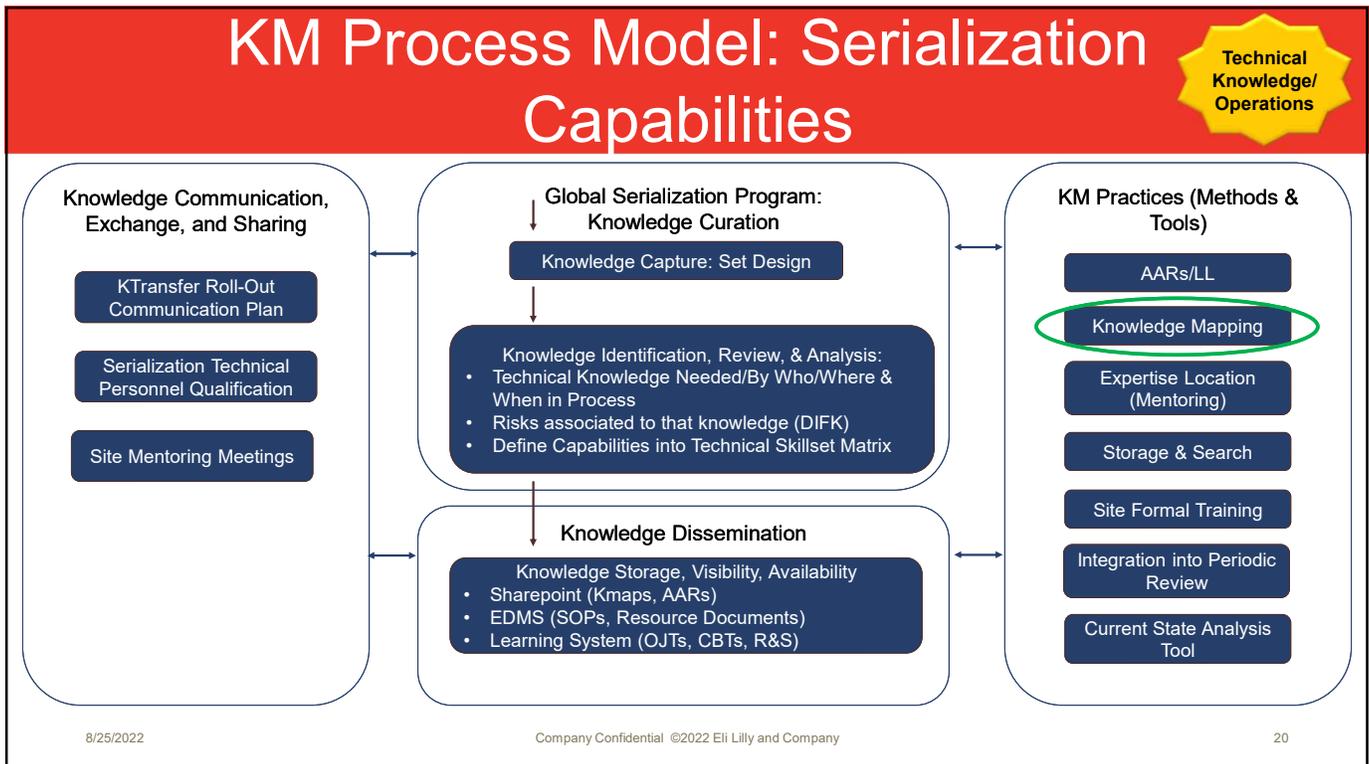
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Knowledge Map Deep Dive

What is a knowledge map?

- A diagnostic tool^{4,6} that can identify critical knowledge in a business process or in an organization and surface gaps in knowledge quality or availability
- Helps identify disruptions in knowledge flow, risks, and connects who needs what knowledge & when
- Excellent at identification/extraction of Tacit Knowledge

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Keys to Knowledge Discovery

- Process step
- Activity
- Who needs this knowledge?
- What knowledge is needed?
- Who owns this knowledge?
- Tacit/Explicit?
- Where is this knowledge?
- Current Training?
- How big the knowledge gap?
- Additional Details



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Knowledge Map Example

Process	Activity	Who needs this knowledge?	What knowledge is needed?	Who owns this knowledge?	Tacit or Explicit?	Where is this knowledge?	Current Training	How big is the knowledge gap?	Additional Details
List the process for which knowledge is being mapped	List the specific activities within that process	Who applies this knowledge to accomplish this task	List the types of knowledge required to perform this activity	List the sources of record or experts who own this knowledge	Mark as T, E, or T/E	List repositories or people who have the knowledge	What training is available today? Is it informal (e.g., pptx slides, lunch and learns,) or formal (in success factors)?	Rate as 3, 6, or 9 (3 = small, 6 = medium, 9 = large)	Provide any notes or further c
3.0 Add a New Line	Issue Change Request to GSP CRB for Adding a Line	Site	GSP CRB Business Process GSP Change Management Process	GSP KM/Training Consultant (Steph)	T/E	Central 19 - GSP CRB Charter Change Management SOP Drafted	informal slide deck for roll out to sites (Steph)	6	Gap: Need to formalize SOP & determining training assignments assigned due to CRB process being out writes through deployment documented CRB charter.
	SES CCB performs impact assessments for new line	SES CCB Members	Impact Analysis Questions: Is it a new line at a new site or existing? Confirm line needs to be serialized?	GSP Software SME SES CCB Coordinator	T/E	GSP Software SMEs, SES CCB Coordinator SES CCB Charter	None	3	Gap: Need a standardized impact assessment tool for SES CCB use, as a 3 as it only requires confirm line needs to be serialized.
	Agree on GSP (R&R matrix, SES Cost Estimate, SES integration approach, GSP Resourcing needs)	Site PM GSP SES PM/Management GSP Process Engineers	GSP cost estimating GSP Roles and Resourcing Integration of SES approach (testing SES at OEM or only at site)	GSP SES PM and SES Process Engineer	T/E	SES Roles and Responsibilities Matrix on GSP Collab Space, Cost Estimate templates on GSP Collab space	informal review of R&R and cost estimates for SES with site	3	Gap: Create an SOW template that and GSP can use to agree on who resourcing sites will require from new line deploy. Rated as 3 as the business process.
	GSP CRB Approves request and assigns resources to support work	GSP CRB	Input/recommendation from SES CCB Resource Availability (Budget, People, Timing) CLASS C&Q needs to know what information related to SES belongs in the separate SES CQVMP or integrated equipment/SES CQVMP	GSP CRB	E	SES CCB Meeting Minutes/Impact Assessments Budget/Resources/Tracking (GSP Management, Tyler) Serialized CQVMP template	None	3	3 due to this being a business process

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Defining Capabilities

Pulled "knowledge needed" from 8 Kmaps



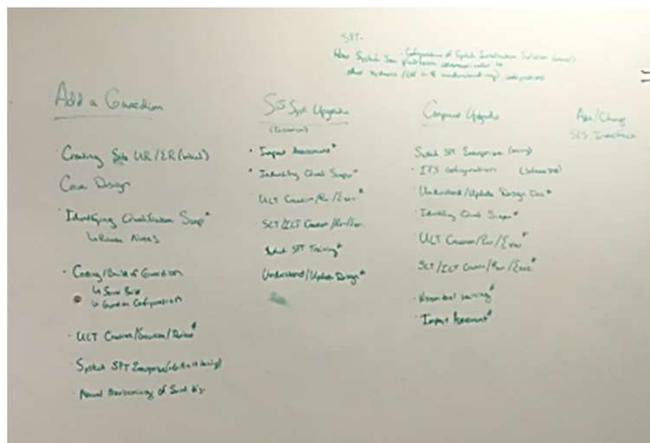
"Nextperts" summarized knowledge into skillsets for each sub-process



Repeated skills pulled out to create technical capabilities matrix



Experts endorsed skills sets



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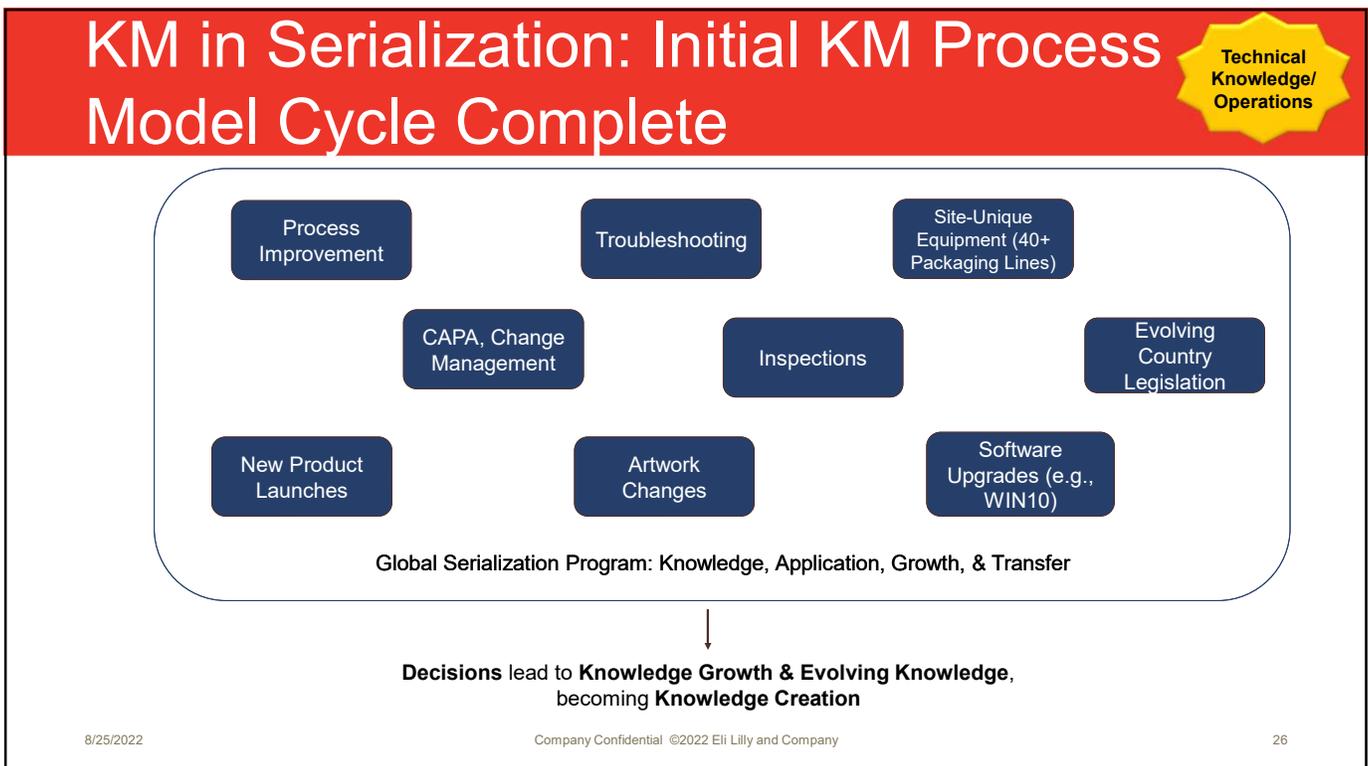
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Serialization Technical Capabilities ¹¹	Site	Service Provider	Global Team	IT
Serialization System (SS) Code Build				
SS Technical Oversight & Coordination				
Creating Initial SS Instance Designs				
New Line: Commissioning & Qualification (C&Q) Activities - Create/Update User Requirements (UR), Validation Master Plans, Planning, Design Reviews & Qualification, Qualification Scope, Traceability Matrices, Code Component Classification, Critical Parameter Assessment, etc.				
SS Unit Level Test Execution (Line and Site Serialization System)				
SS Impact Assessment (includes preliminary analysis of capability of equipment, global software components, design impact, testing impact, schedule impact, vendor needs, etc.)				
Existing line w/Global Team Oversight: C&Q Planning, SS Site Design Review, UR updates, Identify Qualification Scope				
Updating Serialization System Design for Software Components, Equipment Replacement, etc.				
SS System and Integration Level Testing				
C&Q – SS Test Creation/Post Review of Instance Test Cases utilizing approved templates				
Foundation for Serialization – All Technical Personnel				
Core Serialization System Foundation and Troubleshooting				

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The Recap

KM is...

KM is not...

Where do you start?

- Reflect: Where has poor knowledge flow or loss of knowledge hindered us in **reaching our objectives**?
- Tap into KM Industry Resources
- Choose a tool & pilot. Fail fast and iterate.

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Additional Resources (More to Explore!)

- APQC, “Understanding Knowledge Mapping,” American Productivity & Quality Center (APQC), 10 August 2022, www.apqc.org.
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- Guenard, et. al. Biophorum Operations Group, Ltd., Knowledge mapping for the biopharmaceutical industry: A test case in CMC business processes from late-stage development to commercial manufacturing, 25 March 2020, www.biophorum.com.

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QUESTIONS?

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11. ISPE Good Practice Guide: Knowledge Management in the Pharmaceutical Industry Appendix 10 – Process Based Knowledge Mapping: A Serialization Case Study, International Society for Pharmaceutical Engineering (ISPE), May 2021, www.ispe.org.

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