

Knowledge Management: An Iterative Process

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- Outline
 - The role of Knowledge Management as an enabler for ICH Q10 – Pharmaceutical Quality System (PQS)
 - *Knowledge Management*, an enhanced perspective
 - Knowledge across the lifecycle
 - Case Study & Key Learnings
 - Additional Considerations
 - ICH IWG – *Q10 Q&A* on KM
 - Closing thoughts

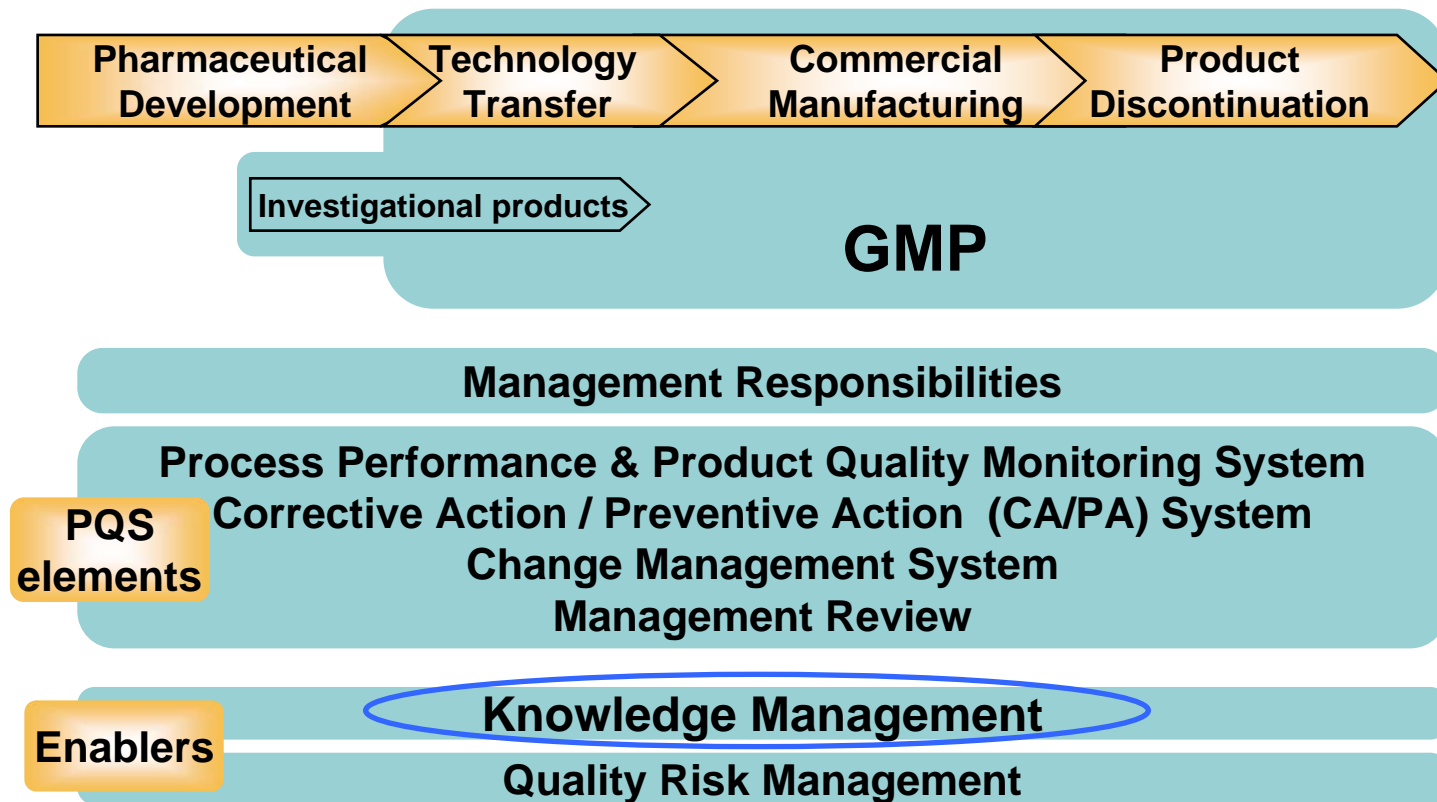
“Knowledge Management”

Definition, per ICH Q10 § 1.6.1

- Knowledge Management:
 - ... is a **systematic approach to acquiring, analysing, storing, and disseminating information** related to products, manufacturing processes and components.
 - **Sources of knowledge** include, but are not limited to:
 - prior knowledge
 - pharmaceutical development studies
 - technology transfer activities
 - process validation studies over the product lifecycle
 - manufacturing experience
 - innovation
 - continual improvement
 - change management activities

KM as an Enabler

How KM enables PQS, per ICH Q10 Annex 2

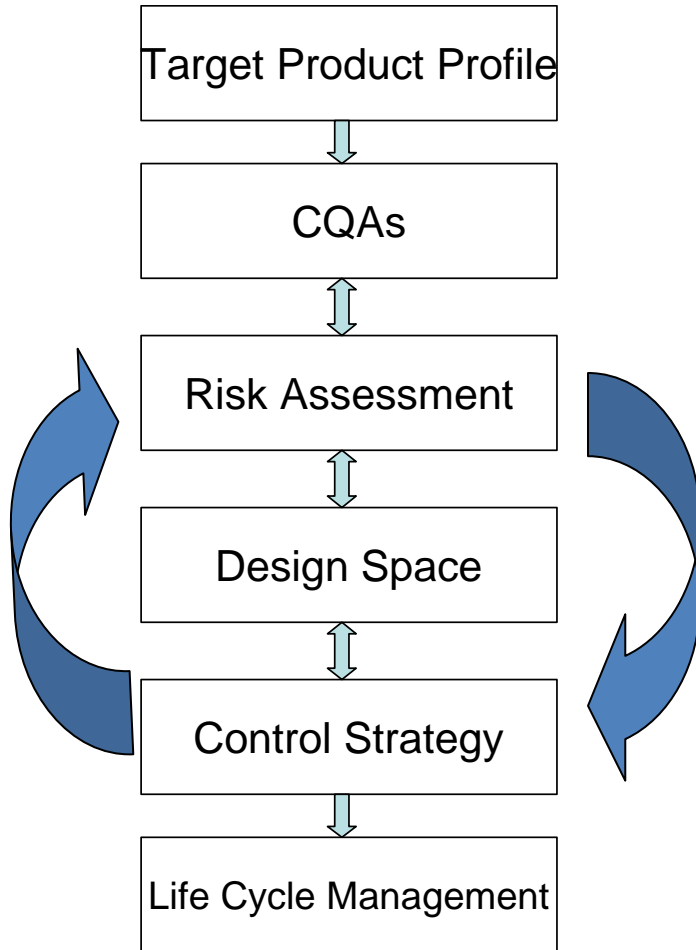


*[KM is an enabler applicable throughout the lifecycle stages, and supports] the PQS goals of achieving **product realisation**, establishing and maintaining a **state of control**, and facilitating **continual improvement**.*

QbD Approach

ICH Q8, Q9 & Q10

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Development of a control strategy for a product is an **iterative activity as knowledge about the product and manufacturing process evolves**

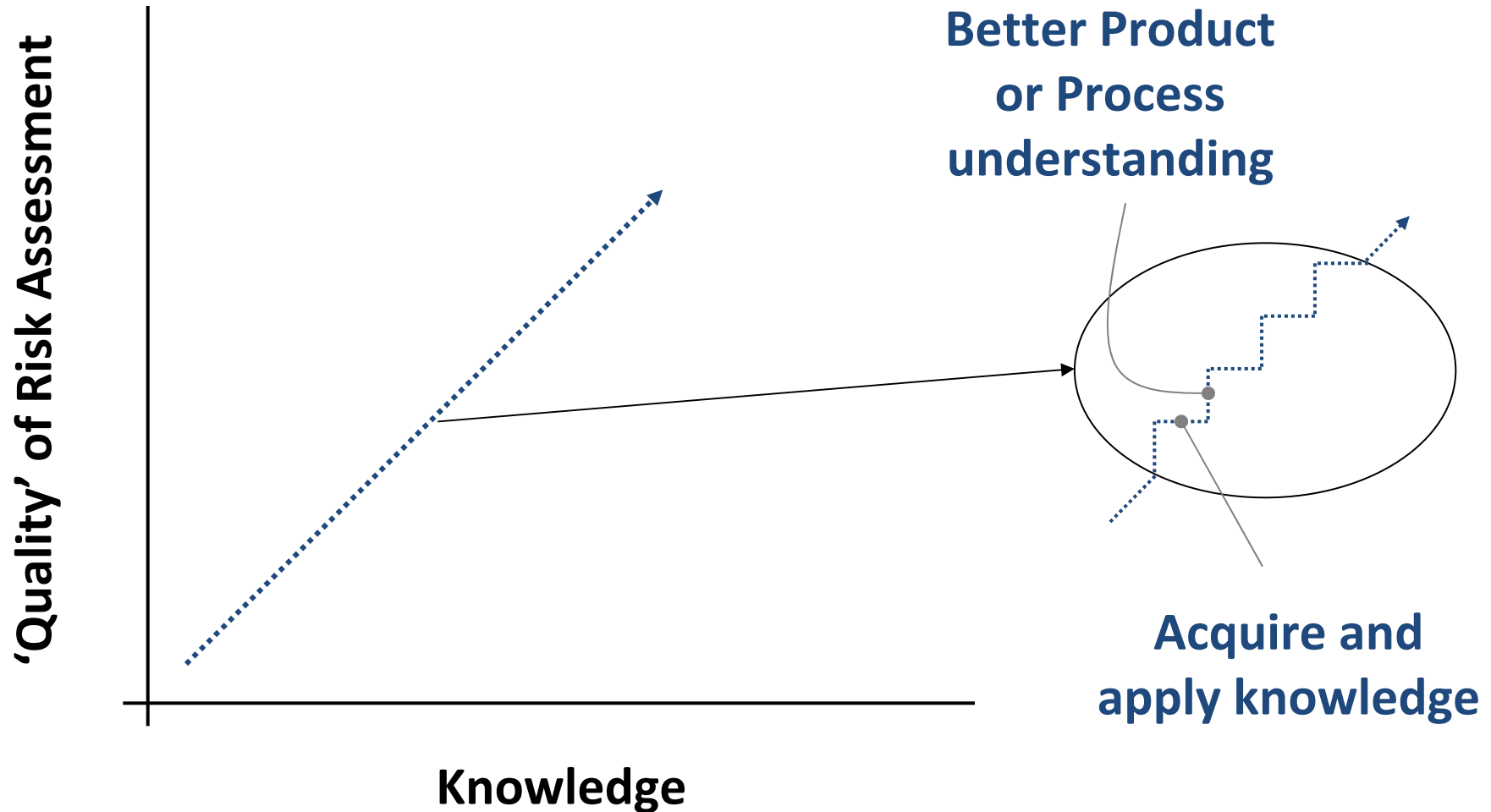
Knowledge is also shared between development and supply over the product lifecycle to enable continual improvement

An iterative process, *enabled by knowledge*

Knowledge at work

Knowledge drives better understanding

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What is KM?

Knowledge Management is labeled as many things...

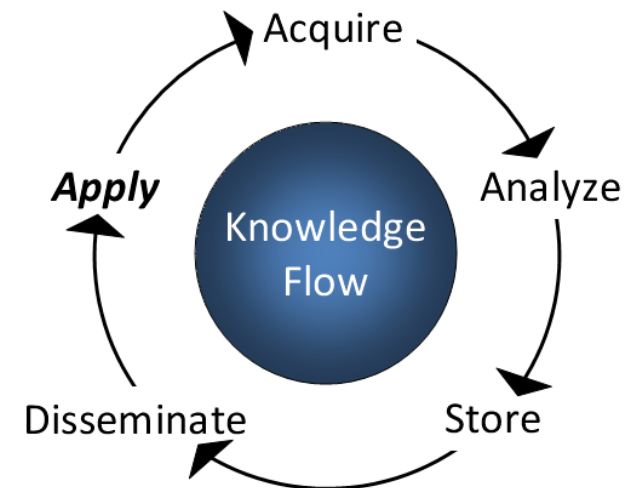
...an iterative
process

...a systematic
approach

...an enabler

Propose an enhanced perspective:

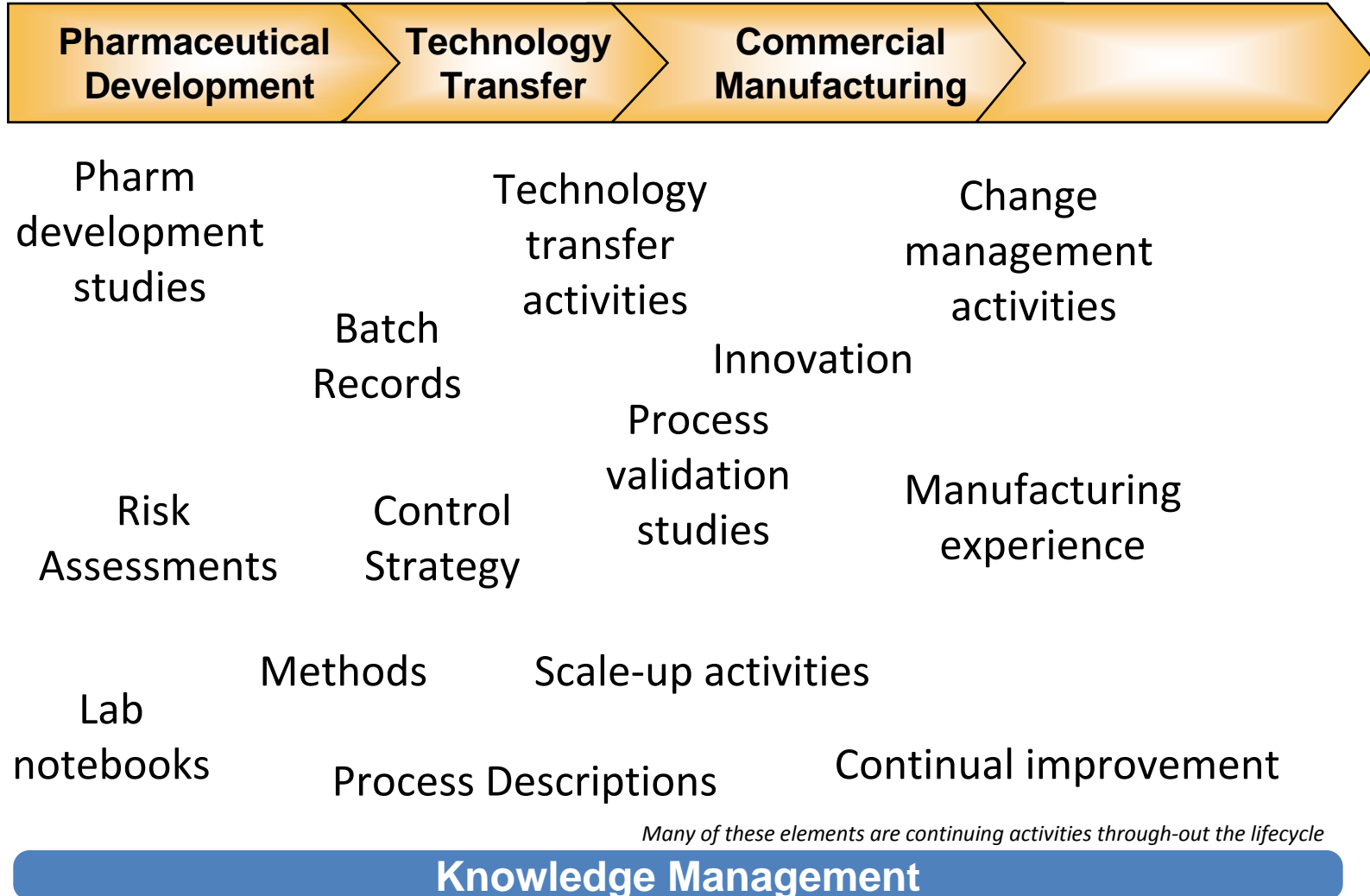
Knowledge Management (KM) is a set of *enabling capabilities* and associated *behaviors*; that supports how knowledge is *acquired, analyzed, stored, disseminated and applied*; so that knowledge will *flow, grow and evolve* over time



Critical Knowledge

Critical knowledge evolves across the lifecycle

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Knowledge Management

Critical Knowledge

Applying Knowledge Mgmt across the lifecycle

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Pharm development studies

Technology transfer activities

Change management activities

Batch Records

Innovation

Risk Assessments

Control Strategy

Process validation studies

Manufacturing experience

Lab notebooks

Methods

Scale-up activities

Process Descriptions

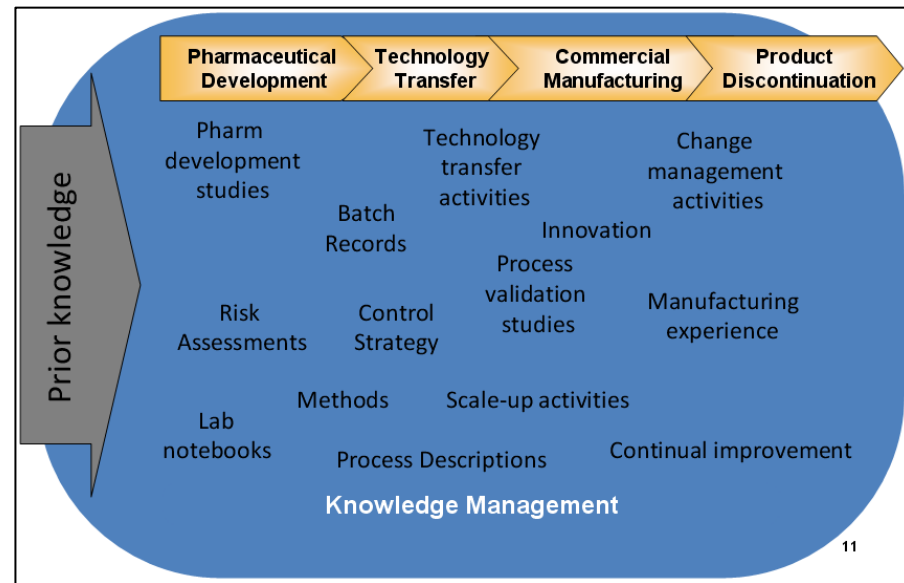
Continual improvement

Knowledge Management

Prior knowledge

Think about it...

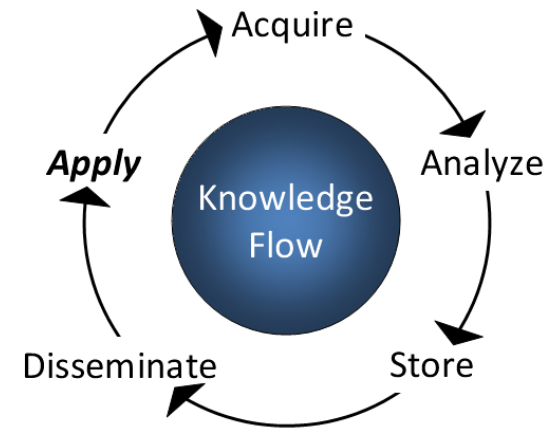
- How can knowledge help you to understand the big picture to make connections
- What about knowledge 'hidden' in the experience and expertise of people and networks?
 - How do you manage this *tacit* knowledge, not just the *explicit* knowledge codified in documents?
- How is all of this knowledge managed across its lifecycle, i.e. *How is the knowledge **acquired, analyzed, stored and disseminated?***



Case Study

This is an example – there is no one ‘right’ way

- Understand business processes for development, tech transfer & manufacturing
 - What knowledge is needed, what is created and how is it used?
- Create a **knowledge map** to understand *knowledge flow*, i.e.
 - How is knowledge *acquired*, *analyzed*, *stored*, *disseminated* and *applied*?
- Identify priority gaps and opportunities
 - For both *explicit* and *tacit* knowledge
- Develop and apply approaches to ensure, standardize and optimize knowledge flow



Case Study

Data is illustrative only

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Using a *Knowledge Map* to characterize knowledge flow

Process Step	Knowledge Needed	Created By	Used By	Explicit or Tacit	Where is it	Flow	Impact	Gap / Opportunity
A	Early Risk Assessment	API Engineering	Pharm Engineering	Explicit	Document Repository	Green	Red	None
				Tacit	Partially captured on RA	Yellow	Red	Rationale not consistently captured
B	Safe operating conditions	Safety Eng	API Engineering	Explicit	Document Repository	Yellow	Red	Not sure which is latest version
C	Summary of lab development	Analytical	Registration Team	Explicit	Local team work space	Red	Red	No standard repository
D	Performance of similar product	Manufacturing	Development	Tacit	Local, at manufacturing sites	Yellow	Yellow	Limited access to SMEs and no standard expectations for reporting
E	Knowledge on powder processing	Pharm Engineering, Manufacturing	Manufacturing	Tacit	Unknown	Red	Yellow	No formal SME listing identified

Case Study

Data & Solutions illustrative only

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Explicit or Tacit	Where is it	Flow	Impact	Gap / Opportunity
Explicit	Document Repository	Green	Red	None
Tacit	Partially captured on RA	Yellow	Red	Rationale not consistently captured

- Standardize **context requirements and how captured** in RA process
- **Identify** and provide access to **SMEs**

Explicit	Local team work space	Red	Red	No standard repository
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- Standardize **Content Mgmt** (e.g. taxonomy, metadata / tagging, version control, access, search, etc.)

Tacit	Unknown	Red	Yellow	No formal SME listing identified
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- Identify key **skills, expertise and experience**
- **Identify SMEs**
- Establish **network** or **COP** and formalize role

RA: Risk Assessment

SME: Subject Matter Expert

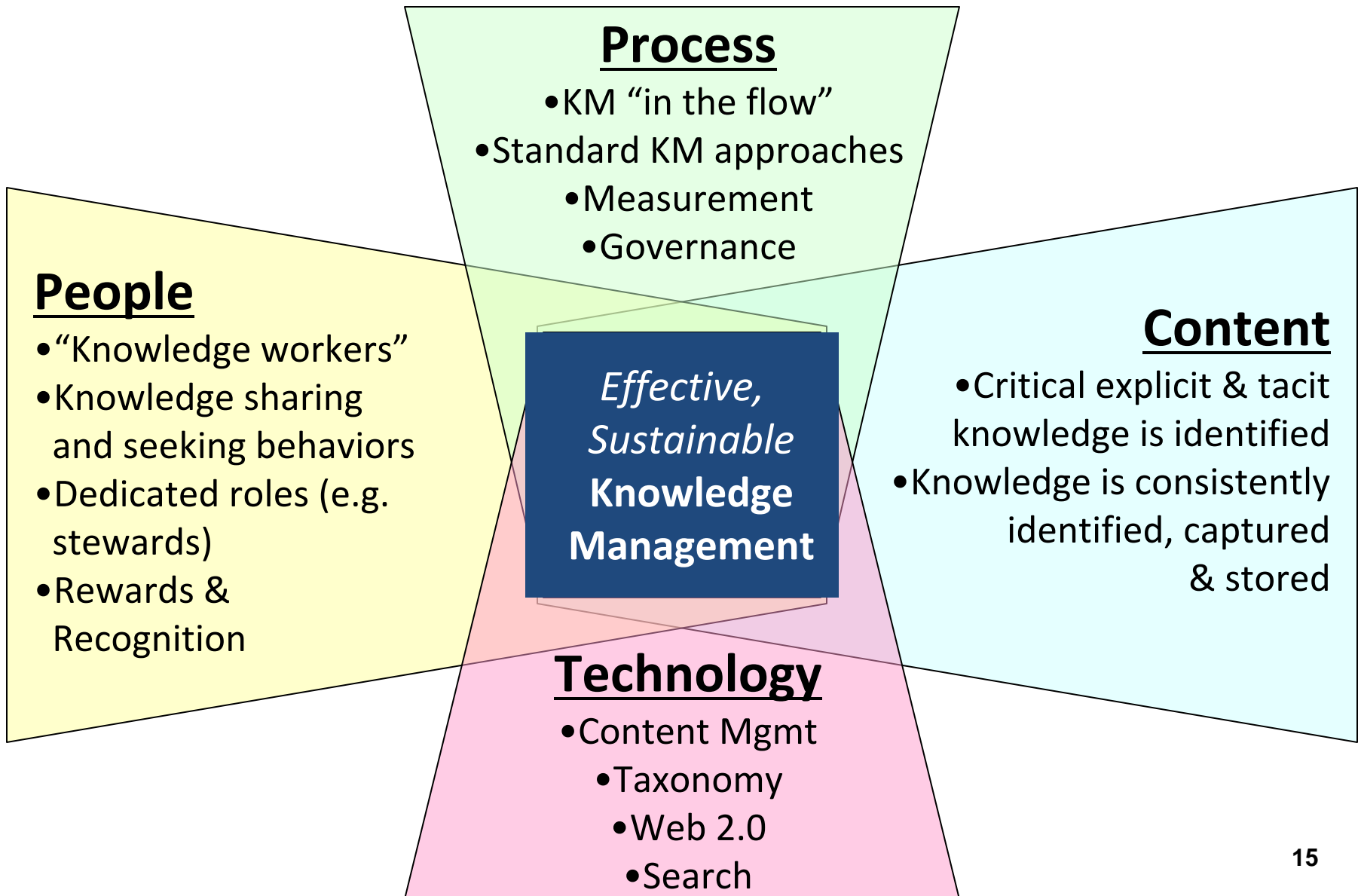
COP: Community of Practice

- Many well established approaches exist to help enable knowledge to flow:
 - Communities & Networks
 - Content management
 - Collaboration capabilities
 - Expertise location
 - Rationale capture
 - Federated Search
 - Transfer of best practices
 - Knowledge harvesting, e.g.
 - Critical knowledge retention
 - Lessons Learned
 - After Action Reviews
 - Peer Assist...Ideation...and more
- These approaches can be replicated to similar knowledge flow gaps and opportunities
 - Result: standard set of enabling capabilities

Case Study

Effective KM requires a holistic solution

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- Embed KM ‘in the flow’ of work
- Recognize tacit knowledge and the value it has in your organization
- Align KM approach to size and complexity of the task
 - Consider how you will use the knowledge
 - Certain aspects may be company-wide or site-specific
- Clearly define roles & responsibilities for KM

- Q: Does Q10 suggest an ideal way to manage knowledge?

A: No

- Q: Is a specific computerized information management system required for implementation of KM?

A: No, but such systems can be invaluable in capturing, managing & assessing complex data and information

- Q: Will regulatory agencies expect to see a formal* KM approach during inspections?

A: No. However it is expected that knowledge from processes and systems is appropriately utilized

*Formal refers to a structured approach using recognized methodology or tools, executing and documenting something in a transparent and detailed manner.

- Q: Software Solutions – Is it necessary to purchase “ICH compliant” software solutions in order to successfully implement these ICH guidelines?

A: No. ICH has not, nor does it intend to, endorse any commercial products.

- Knowledge Management is a key enabler of ICH Q10 and can help your organization realize the objectives of an effective PQS
- Effective knowledge management supports the iteration and advancement of product and process understanding as knowledge flows, grows and evolves across the lifecycle
- Your knowledge is an asset to your organization, and approaches exist to help manage as such

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Thank You!

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