HARNESSING THE INVALUABLE TRIBAL KNOWLEDGE HIDDEN IN YOUR ORGANIZATION

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Today's Presentation

- Outline
  - Part 1: Stage Setting – 5 things to know about KM
  - Part 2: Illustrative case studies in harnessing tribal knowledge
  - Part 3: Key Takeaways / Bonus material

- I have a dual role of **KM Leader for Manufacturing** and **Pharma Regulatory Science Researcher** – today's content is a mix
  - Watch for PRST logo to differentiate research-derived insights → Pharmaceutical REGULATORY SCIENCE Team

- All opinions expressed are my own and not necessarily those of Merck & Co.

* All references to Merck are to Merck & Co., Inc., Rahway, NJ USA

Five Things to know about KM in Pharma:
#1: We are a Knowledge Industry

- Our workforce is comprised of **knowledge workers** who perform **knowledge work**
  - We expect them to **think for a living to develop and run complex processes:** to solve problems, to learn & improve how work is done, to make good decisions, to innovate, to learn from failures
- Our **knowledge is thus an asset** and should **flow effortlessly** to benefit our patients and create value
- HBR / IDC survey data suggest $31.5 B/year in losses for Fortune 500 companies in intellectual rework, substandard performance and wasted time searching for knowledge
  - Clearly this challenge is not pharma specific - yet **other industries have proactively embraced KM** to improve their businesses – leaders include aerospace, energy, technology, consulting, engineering
  - While commodity technology can be a KM enabler, it has also made KM more complicated and diffuse
  - We tend to lack (a) guidance to tell people what to do and (b) explicit mindsets which foster healthy knowledge seeking and sharing

Five Things to know about KM in Pharma:
#2: There is no single definition of KM

"systematic approach to acquiring, analysing, storing, and disseminating information related to products, manufacturing processes and components."

– ICH Q10

"a key goal of KM is to deliver the 'right' or best available information, to the right person, at the right time, to make the right decision and/or give the right advice"

– I. Martin, et al

"Management with regard to knowledge," noting (a) It uses a systemic and holistic approach to improve results and learning, and (b) It includes optimizing the identification, creation, analysis, representation, distribution and application of knowledge to create organizational value.

– ISO 30401:2018 (KM Standard)

"A collection of systematic approaches to help knowledge flow to and between the right people at the right time (in the right format at the right cost) so they can act more efficiently and effectively to create value for the organization."

– APQC

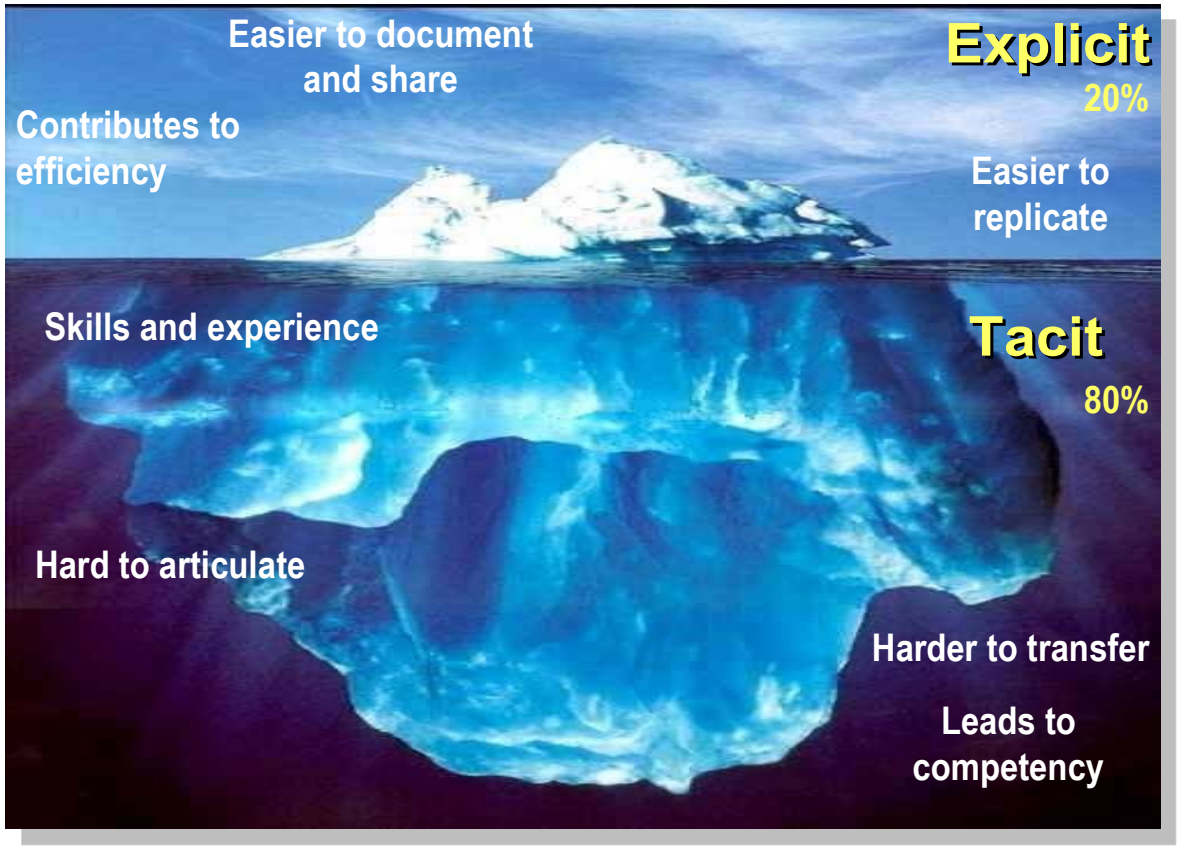
Five Things to know about KM in Pharma:
#3: There are multiple types of knowledge

Explicit Knowledge

- A declarative type of knowledge that can be readily articulated (in words or images), coded, stored and accessed

Tacit Knowledge

- Knowledge that resides in the minds of individuals and is surfaced in response to a situation or action
  - Tacit knowledge is often referred to as *know-how* or *tribal knowledge*
  - 70-80% of what we know as organizations lies in tacit knowledge (McKinsey, APQC)



credit: APQC

Five Things to know about KM in Pharma:
#3 (cont'd): Examples of [typically] Tacit Knowledge

- Historical knowledge
- Past problems and how resolved
- Details of order of operations and why important
- Unusual operation of items of equipment
- Interventions, workarounds
- 'What good looks like' (e.g., clues of appearance, sound, etc. which indicate something is working normally)
- Tips, tricks, techniques
- Failure modes / what could go wrong
- What has been tried in the past
- Lessons
- Best practices
- Mental models
- Rules of thumb (e.g., what to do when)
- Insights, ideas, continuous improvement opportunities
- Ability to see patterns / recognize trends / anticipate response
- Decision rationale / history
- Understanding "why"
- Resources and processes used to solve problems or get help (e.g., the network of SMEs)

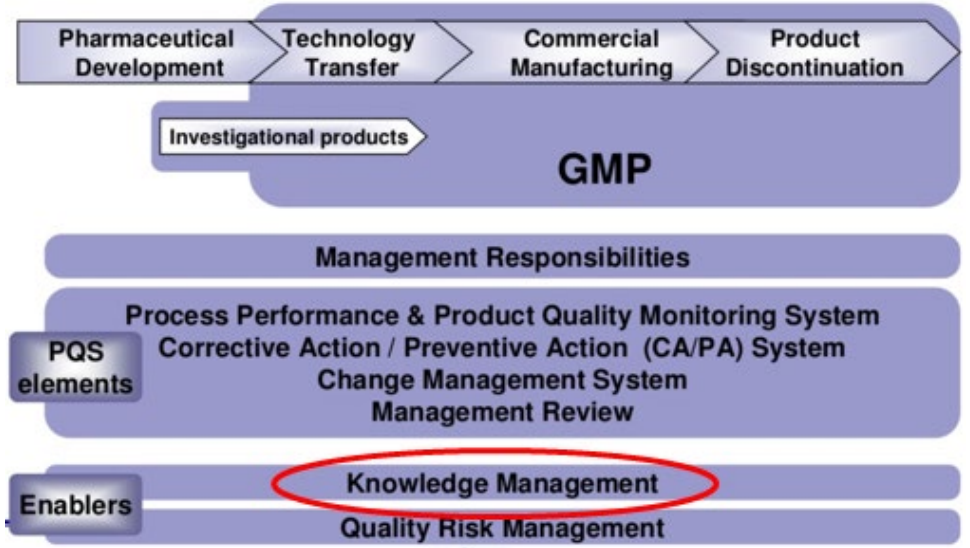
Five Things to know about KM in Pharma:
#4: KM Expectations for Biopharma

- ICH and FDA guidelines outline Knowledge Management requirements
  - ICH Q9 – Risk Management: **Reduce patient risk** through applying best knowledge
  - ICH Q10 – Pharmaceutical Quality System: KM a critical enabler to an **effective PQS**
  - ICH Q8/Q9/Q10 Q&A – (5) questions and answers dedicated to KM
  - ICH Q12 – Post-approval Lifecycle Mgmt: apply knowledge to **enable regulatory relief**
  - Others, e.g., ICH Q14 on Analytical Methods
- ISO 30401:2018
- Synonyms for 'knowledge' found in ICH documents:
  - prior knowledge, scientific knowledge, science, product and [or] process knowledge, experience, product development history, expertise, know-how, product and [or] process understanding, 'lessons learned', etc.

Coming soon:

ICH Q9(R1) emphasizes KM and links to all 6 revision topics

[subjectivity, product availability, formability, RBDM, risk review, hazard identification]



Five Things to know about KM in Pharma:
#5: KM has lagged behind…but change cometh

- KM is described as an *orphan enabler* for the PQS, yet our industry is unique in defining quality as a KM driver
- Pharma KM programs are generally lower in maturity than other industries
- Recent developments
  - BioPhorum: "KM considered to be one of the top six strategic challenges facing biopharmaceutical companies"
  - ISO 30401:2018
  - ISPE Good Practice Guide for Knowledge Management in Pharma
  - Guidance recognizing role of KM in technology transfer (ISPE 2018 / PDA 2022)
- Coming attractions
  - ICH Q9(R1)
  - PDA Task Force to develop a KM Roadmap (in flight)
  - Expanding academic research on KM in pharma (e.g., KM role in QRM, RBDM, Q12)

Key Success Factors for Tacit Knowledge Transfer

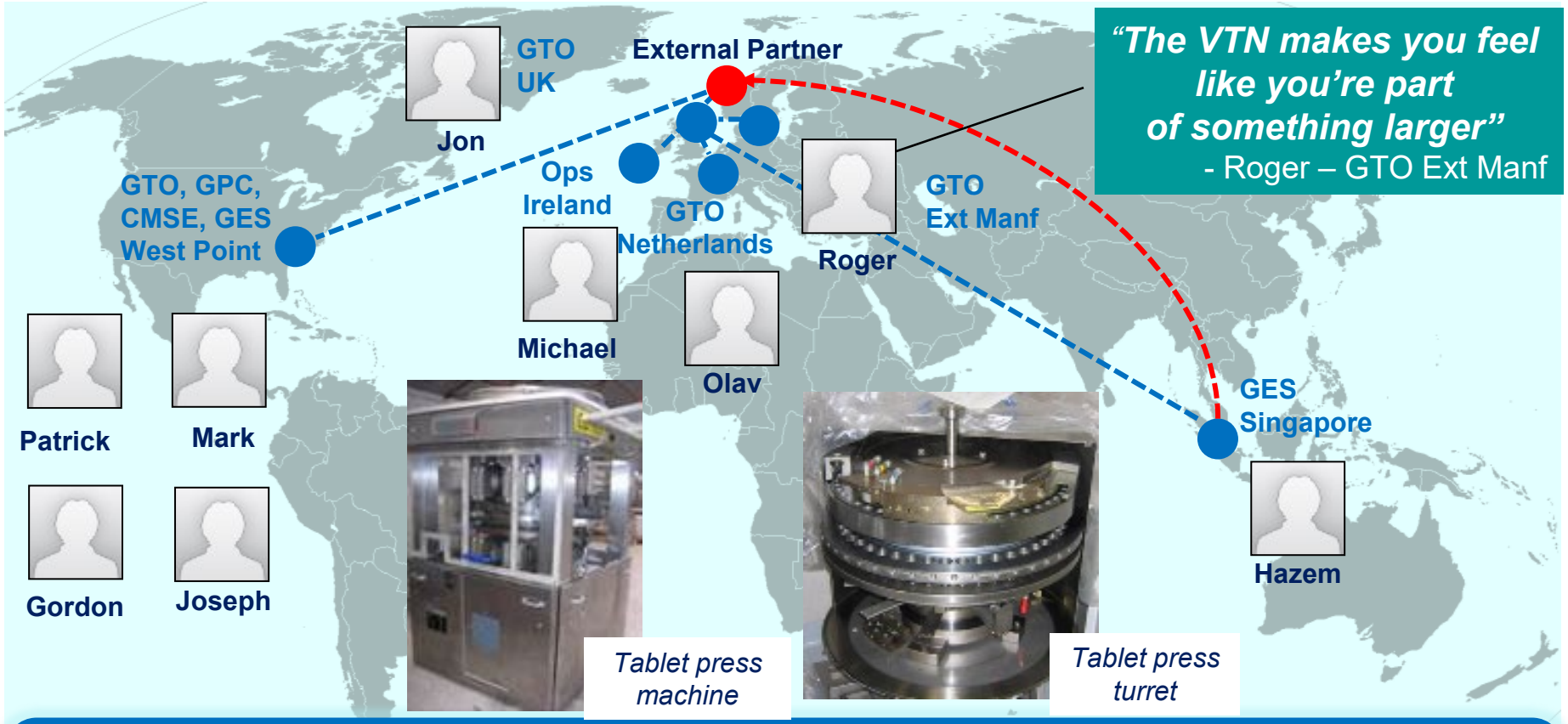
- **Context**
  - For example, a process being tech transferred – or better yet – associated CPPs
  - Perhaps without saying – the underlying expertise
- **Open ended questions**
  - For example, asking questions that probe decisions, asking 'why?' asking 'what if?'
- **Mindsets**
  - SME: reflective, teaching, explaining (the thought and *the thinking*)
  - Transferee: curious, asking follow up questions, seeking to understand what and *why*
- **Process & Governance**
  - An underlying process to guide the knowledge transfer (i.e., KM standard work) and establish how the knowledge will be used afterwards, and governance to prioritize actions

Case studies included:

1. **CoP:** Community of practice for connecting the manufacturing network
2. **AAR:** Standardized reflections to embed continual improvement
3. **Tech Transfer:** Pre-job briefs and other knowledge transfer embedded during technology transfer
4. **QRM:** Knowledge as an input to – and output from - QRM

Case Study 1: Community of Practice (CoP)

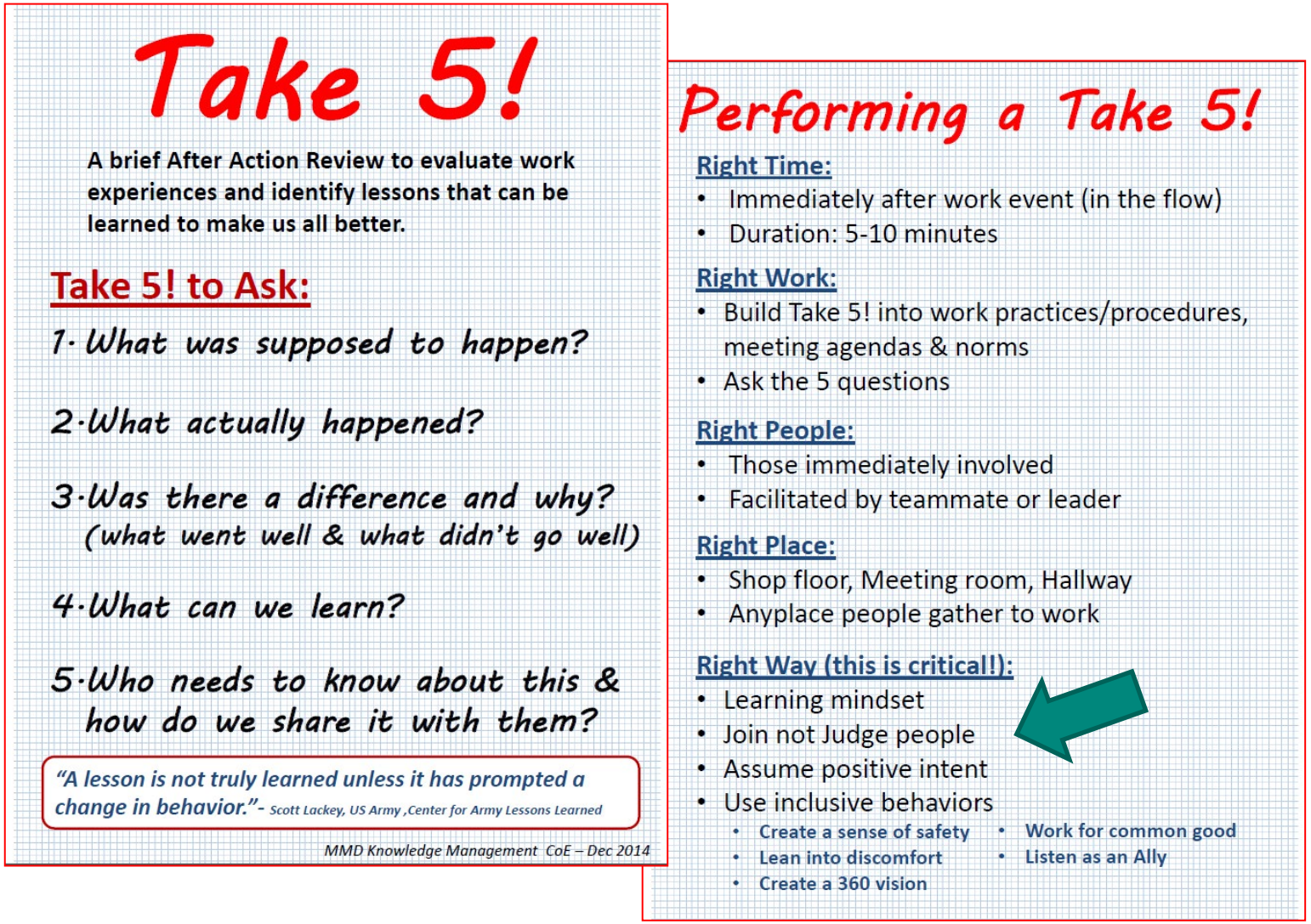
$3MM and 20 weeks saved when our global network leveraged *Tier Process*, *Virtual Technical Network (CoP)* and *Compression Technology Platform* to ensure reliable, cost-effective Supply of a Key Product



"The VTN makes you feel like you're part of something larger"
- Roger – GTO Ext Manf

- Our global network engaged rapidly to locate a spare turret in Singapore within <u>1 business day</u> to replace a damaged turret used for a Key Product in the UK
  - Operational in 4 weeks versus 24 weeks for new turret from vendor
  - Direct benefits plus great credibility building with partner, enhanced relationship for the future

Case Study 2: After Action Review (AAR)
(a.k.a. Lessons Learned)



Take 5!

A brief After Action Review to evaluate work experiences and identify lessons that can be learned to make us all better.

Take 5! to Ask:

1. What was supposed to happen?
2. What actually happened?
3. Was there a difference and why? (what went well & what didn't go well)
4. What can we learn?
5. Who needs to know about this & how do we share it with them?

"A lesson is not truly learned unless it has prompted a change in behavior."- Scott Lackey, US Army ,Center for Army Lessons Learned

MMD Knowledge Management CoE – Dec 2014

Performing a Take 5!

Right Time:
- Immediately after work event (in the flow)
- Duration: 5-10 minutes

Right Work:
- Build Take 5! into work practices/procedures, meeting agendas & norms
- Ask the 5 questions

Right People:
- Those immediately involved
- Facilitated by teammate or leader

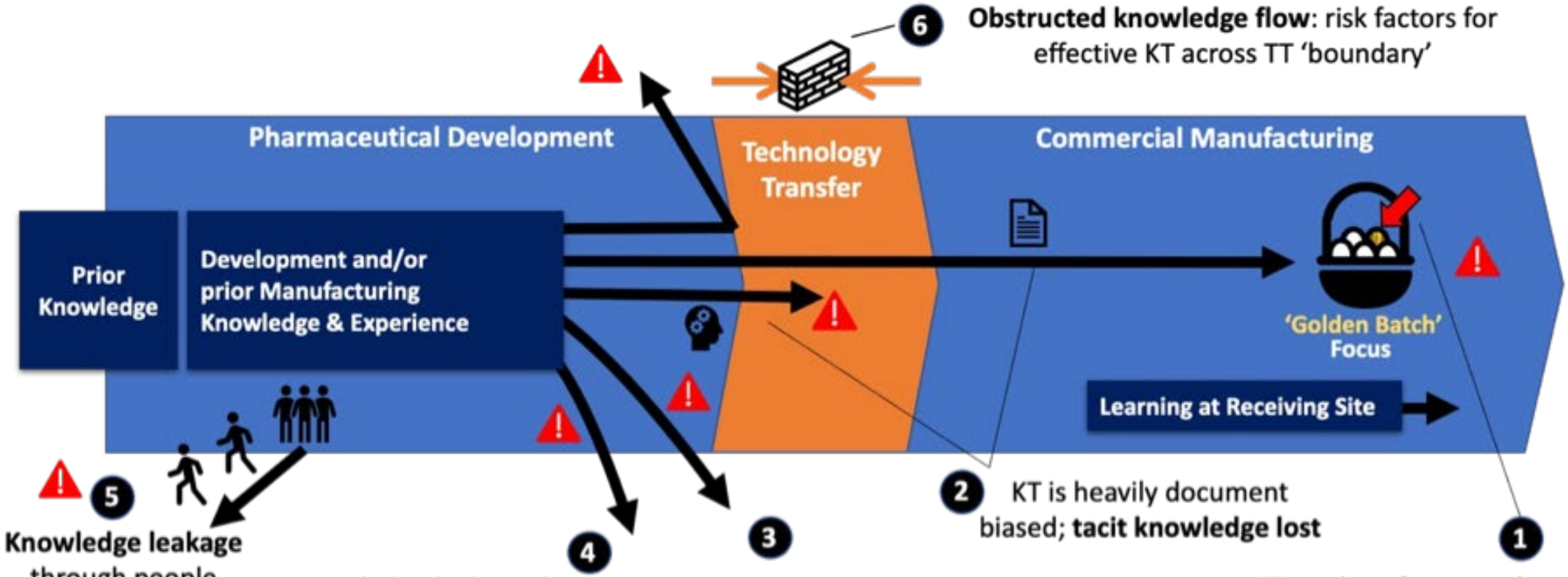
Right Place:
- Shop floor, Meeting room, Hallway
- Anyplace people gather to work

Right Way (this is critical!):
- Learning mindset
- Join not Judge people
- Assume positive intent
- Use inclusive behaviors
  - Create a sense of safety
  - Lean into discomfort
  - Create a 360 vision
  - Work for common good
  - Listen as an Ally

Illustrative outcomes:

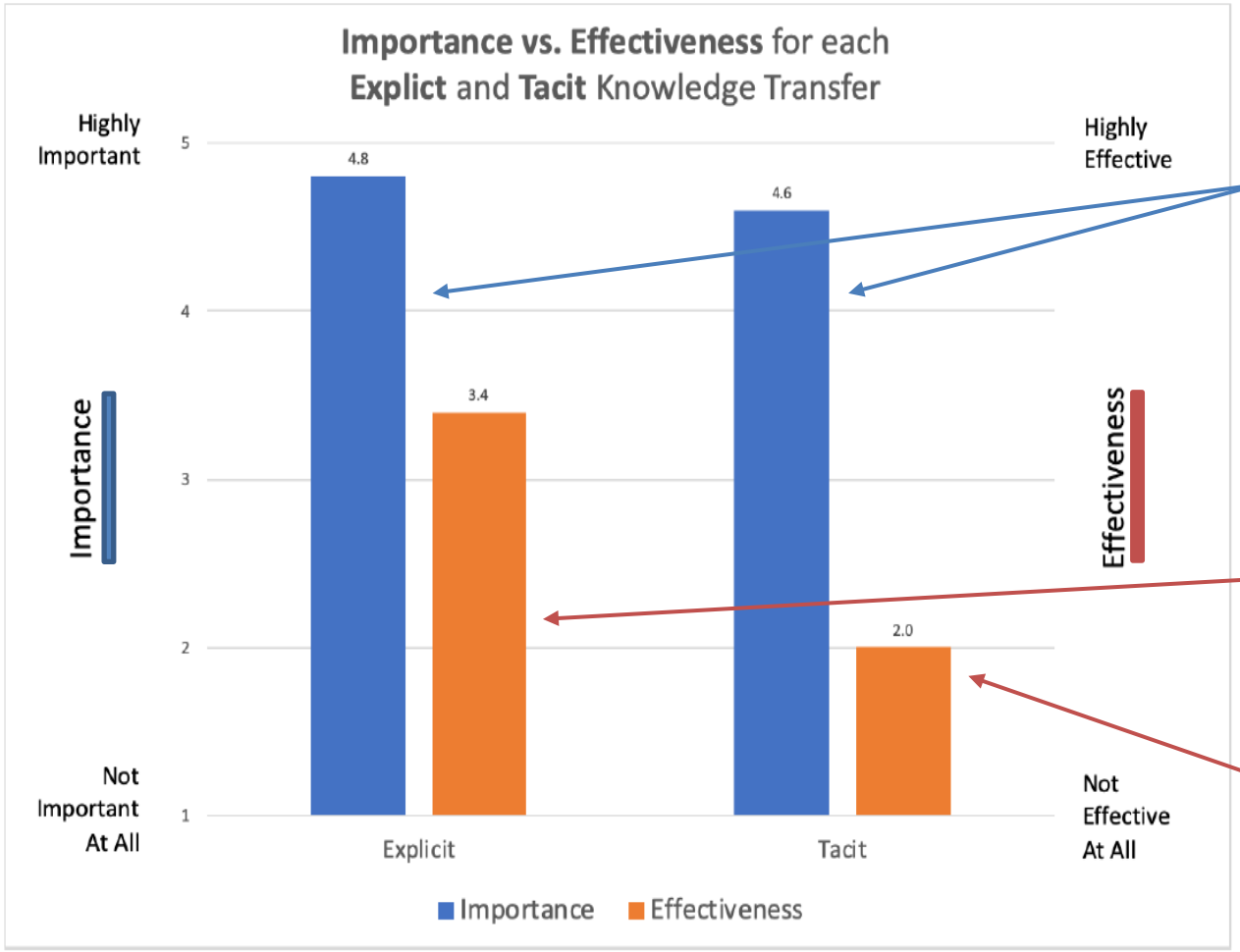
- Improvements to key processes, including Product Development and Registration through improved Right First Time
- Cost reduction and cost avoidance (capital & expense)
- Improved relationships with external partners
- Avoidance of disruption to product supply
- >$50MM in business value, over ~5 years…

Case Study 3: Tech Transfer



https://journal.pda.org/content/75/1/64

Case Study 3: Tech Transfer



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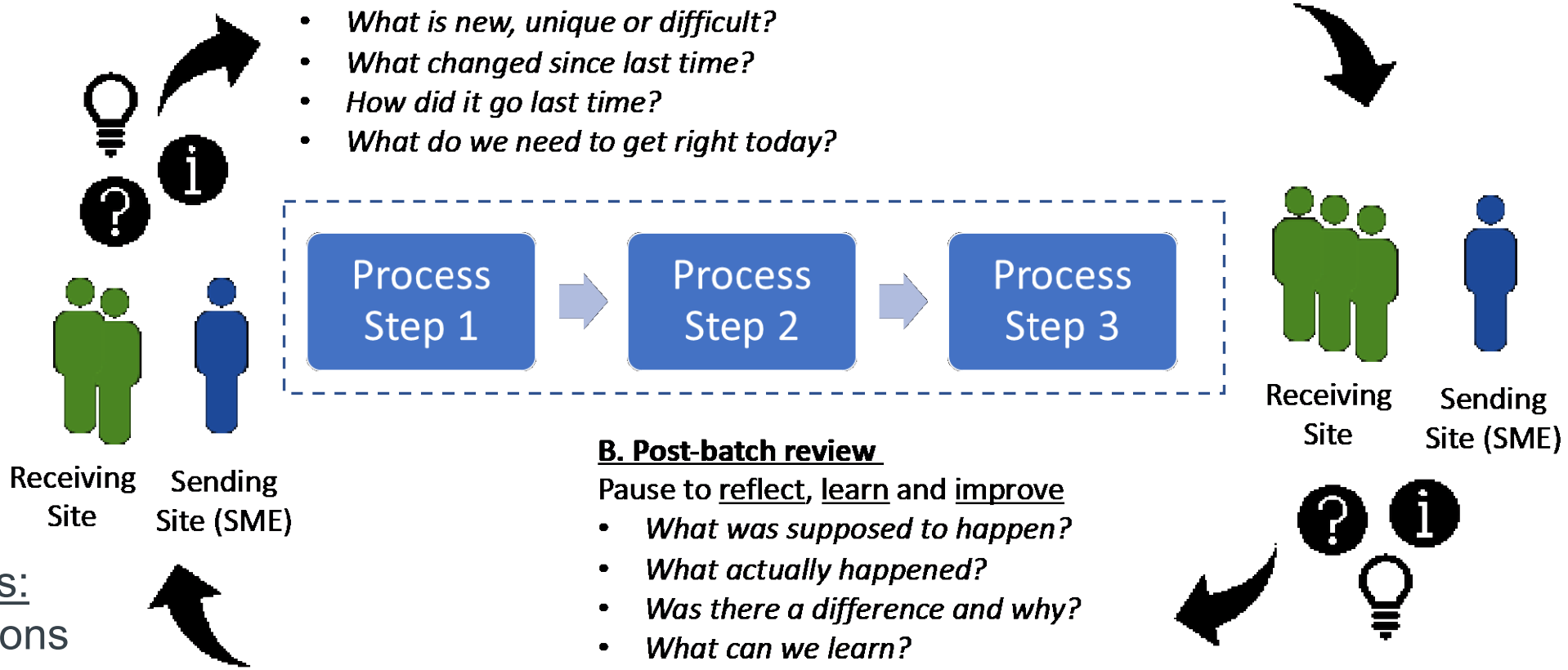
Explicit and **tacit** knowledge are considered critically important to *efficient* and *effective* technology transfer.

However, on average, the industry is…

- only **marginally effective in the transfer of explicit** knowledge (documents), and
- somewhat **ineffective in the transfer of tacit** knowledge (know-how, experience, decision rationale, etc.)

Case Study 3: Tech Transfer



Case Study Results:

- 82 potential actions
- 52 implemented
- **43 potential deviations avoided!**

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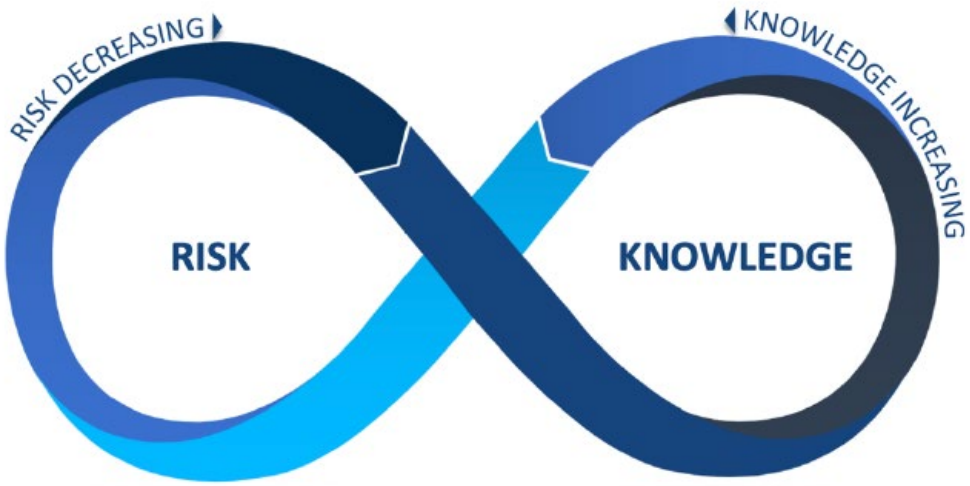
https://arrow.tudublin.ie/level3/vol15/iss2/20/

Case Study 4: QRM

- Knowledge is **both an input to and an output from** risk management
- Knowledge has an **inverse** relationship with risk
- The **concept of *flow***; knowledge flows effortlessly and on demand to inform risk, and risk informs new knowledge



- The cycle is **continuous and perpetual**; knowledge is always evolving and should be continually applied to inform risk

https://arrow.tudublin.ie/level3/vol15/iss2/4/

Key Takeaways

- The need for managing knowledge effectively is as clear as ever –
  - …and is as important as ever considering ATMPs, geopolitical pressures, expectations for new therapies and speed to market, cost pressures, product availability challenges, …
- KM requirements in regulatory and industry guidance exist – and are increasing
- Guidance on ‘how’ exists, and more is coming
- KM feels elusive, but it does not need to be that difficult!
  - Focus on a problem area and develop pragmatic approaches to address & improve
- Take some time to learn – plenty of literature available in pharma and beyond
- KM is more elusive for QRM for many reasons – but don’t not start for this reason
- For those considering KM:
  Think big, start small, but start!

Bonus material in the annex:
- Additional case study details
- References for additional learning
- ICH Q10 KM-related Q&A
- Overview of ISPE KM Good Practice Guide

THANK YOU

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Learn more about the PRST @ www.prst.ie

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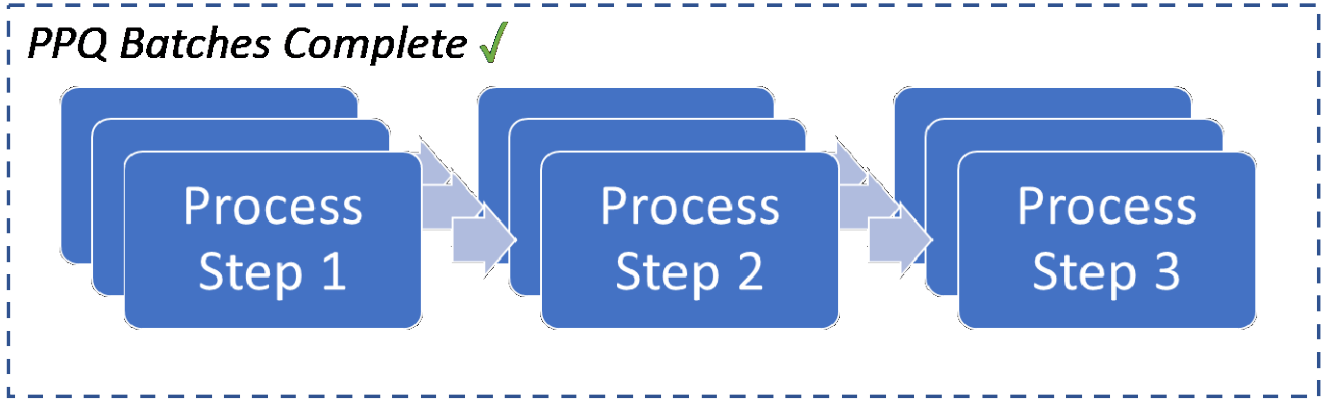
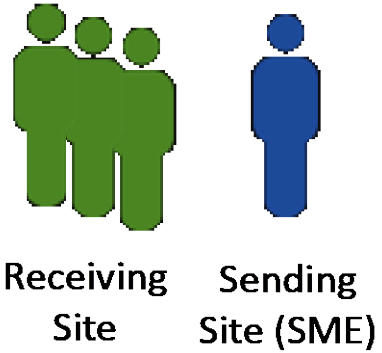
Bonus Material

Case Study 3c: Tech Transfer





Case Study Results:

- 70 'answers'
- **39 proactive actions** to transfer history, ideas, improvements, explore rationale and risks

End of tech transfer knowledge transfer review

Pause to reflect and consider 'the big picture'

- *What happened that you did not expect?*
- *What didn't happen that you expected would?*
- *What is least repeatable?*
- *What keeps you up at night?*
- *What may not be solved at root cause?*
- *What are top improvement opportunities (yield, cycle time, safety, robustness)*

Question Info Idea

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Case Study 4: QRM

Node 3: Use KM practices to capture the knowledge outputs of QRM

Have you captured the 'why' behind decisions? What was known at the time? Alternatives considered?

Node 2: Manage risk via the QRM process

What are you doing to reduce subjectivity (e.g. hazard lists)?

Node 1: Ensure the best available knowledge flows into QRM activities

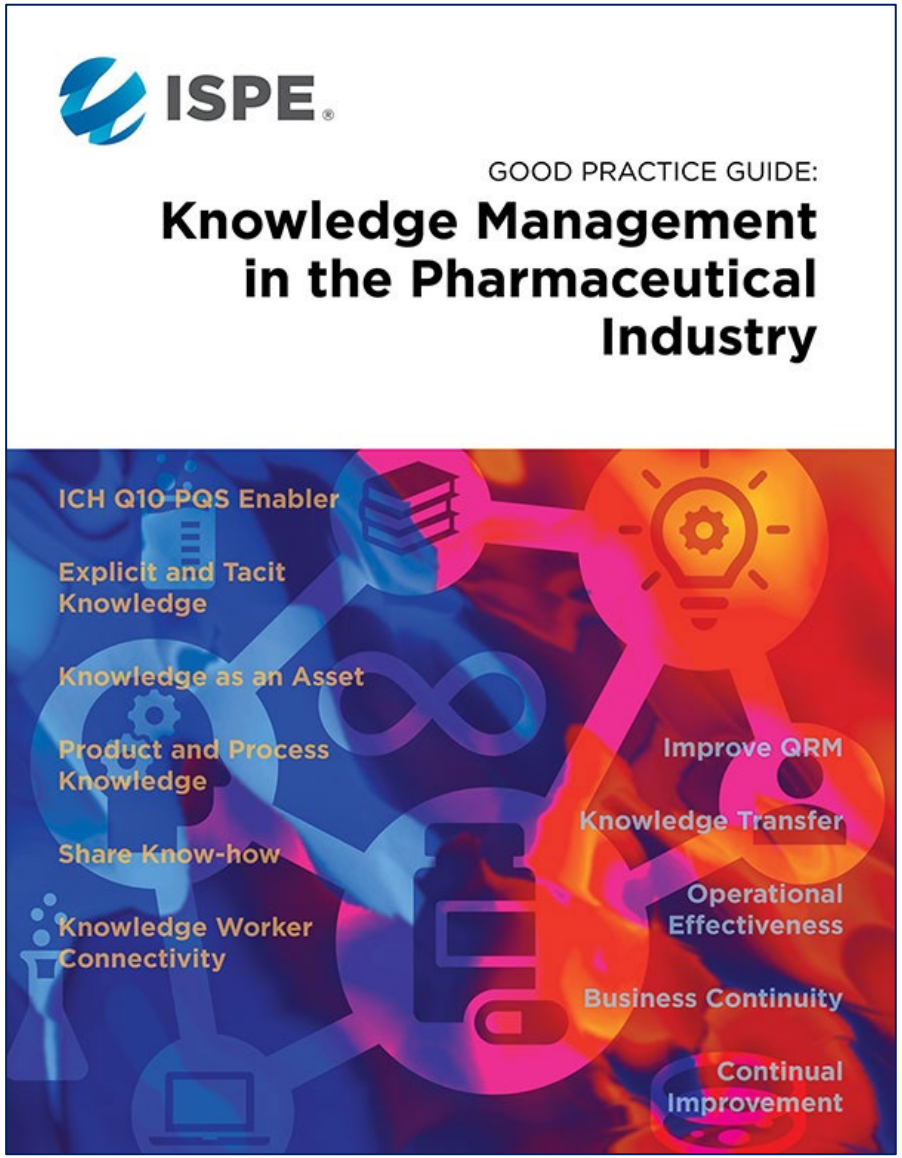
Do you have the right SMEs in the room? Do you have the context of past decisions?

Node 6: Ensure all knowledge is available to QRM, PQS processes and all business processes

Node 5: Manage knowledge via the KM process

Node 4: Ensure means to acquire, grow, capture & retain new knowledge

Now Available!



The Guide discusses KM as an enabler to a firm's PQS and to deliver benefits in operational effectiveness and engagement of a knowledge workforce

Highlights include:

- **Multiple methods and tools** to help start or mature a sustainable KM program
- The **relationship between KM and QRM**
- KM in relation to **each facet of the PQS**
- Numerous references to **other industries** with successful KM programs and **pharmaceutical industry-specific case studies**
- Emphasis on **Technology Transfer**, including references to the ISPE Good Practice Guide: Technology Transfer
- Linkages to the **ISPE PQLI Guides**
- How the Guide relates to the **ISO standard for KM**, ISO 30401
- Discussion on **digitally enabling KM**
- The importance of **Organizational Change Management**

ICH Q10 Q&A (1/3)

Question	Answer
How has the implementation of ICH Q8, Q9, and Q10 changed the significance and use of knowledge management?	Q10 **defines** knowledge management as: 'Systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components.' **Knowledge management is not a system**; it enables the implementation of the concepts described in ICH Q8, Q9 and Q10.
Does Q10 suggest an ideal way to manage knowledge?	No. **Q10 provides a framework and does not prescribe how to implement knowledge management**. **Each company decides how to manage knowledge**, including the depth and extent of information assessment based on their specific needs.

ICH Q10 Q&A (2/3)

Question	Answer
What are potential sources of information for Knowledge Management?	Some examples of **knowledge sources** are: • **Prior knowledge** based on experience obtained from similar processes (internal knowledge, industry scientific and technical publications) and published information (external knowledge: literature and peer-reviewed publications); • Pharmaceutical development studies | Mechanism of action | Structure/function relationships | Technology transfer activities | Process validation studies | Manufacturing experience (e.g.: Internal and Vendor audits; Raw material testing data) | Innovation | Continual improvement | Change management activities | Stability reports | Product Quality Reviews/Annual Product Reviews | Complaint Reports | Adverse event reports (Patient safety) | Deviation Reports, Recall Information | Technical investigations and/or CAPA report | Suppliers and Contractors | Product history and /or manufacturing history | Ongoing manufacturing processes information (e.g., trends) Information from the above can be sourced and shared across a site or company, between companies and suppliers/contractors, products and across different disciplines (e.g., development, manufacturing, engineering, quality units).

ICH Q10 Q&A (3/3)

Question	Answer
Is a specific dedicated computerised information management system required for the implementation of knowledge management with respect to ICH Q8, Q9 and Q10?	**No**, but such computerised information management systems can be invaluable in capturing, managing, assessing and sharing complex data and information.
Will regulatory agencies expect to see a formal knowledge management approach during inspections?	No. **There is no added regulatory requirement for a formal knowledge management system**. However it is expected that knowledge from different processes and systems will be appropriately utilised. Note: 'formal' means: it is a structured approach using a recognised methodology or (IT-) tool, executing and documenting something in a transparent and detailed manner.

Key References & Learning Assets

- Knowledge as the Currency of Managing Risk: A Novel Framework to Unite Quality Risk Management and Knowledge Management https://arrow.tudublin.ie/level3/vol15/iss2/4/
- Simple Practices to Facilitate the Flow of Valuable Tacit Knowledge During Biopharmaceutical Technology Transfer: A Case Study https://arrow.tudublin.ie/level3/vol15/iss2/20/
- Integrating Knowledge Management and Quality Risk Management https://ispe.org/pharmaceutical-engineering/july-august-2022
- ISPE Good Practice Guide: Knowledge Management in the Pharmaceutical Industry https://ispe.org/publications/guidance-documents/good-practice-guide-knowledge-management-pharmaceutical-industry

Additional references and reading available on request

Pharmaceutical
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Team

The Technological University Dublin
Pharmaceutical Regulatory Science Team (PRST)
was founded in 2005 in response to the drive for a paradigm shift towards more science and risk-based approaches to ensure pharmaceutical product quality.

PRST actively engages with global industry and regulators to **address the challenges and opportunities of implementing Science and Risk based decision making and manufacturing approaches**.

PRST research emphasis is on the development of **patient-focused strategies, frameworks, models and tools** to enable those involved in the manufacture of drug products to meet the evolving international regulatory expectations **ensuring the availability of high-quality medicinal products**.

Learn more at http://prst.ie