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Knowledge Management – A Japanese Perspective

by Dr. Yukio Hiyama

This article presents a historical reflection on knowledge management issues related to ICH discussions and a change to the 2005 Pharmaceutical Affairs Law in Japan.

I am delighted to see details emerging with expanded presentations on knowledge management, particularly the case studies from industry, in this e-supplement from ISPE. The ICH Quality Implementation Working Group (QIWG) team, of which I was a member, could not provide such practical advice on the topic at the time of our work.

Early ICH Discussion and Japanese Regulation Change

First, let me present my personal reflection on *knowledge management* related issues at ICH and in regard to the regulatory framework development for 2005 Pharmaceutical Affairs Law (PAL) change of Japan.

In July 2003, the ICH GMP workshop adopted the following vision: *"Develop a harmonised pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to risk management and science."* The US FDA, who proposed the workshop, suggested knowledge sharing and transfer models, as a basis of efficient post approval change management and defined optimal knowledge content and knowledge sharing as agenda items for discussion in their proposal.[1] The MHLW presented the new Pharmaceutical Affairs Law framework to become effective in 2005[2] and the outcome of the 2002 MHLW study.[3] At that time, MHLW expected ICH to take on *technology transfer,* as the MHLW study in 2002 had identified poor communication between Research & Development (R&D) and manufacturing as one of the significant problems. The study group sorted key information that should be transferred from R&D to manufacture and issued a Technology Transfer Guideline.

The PAL change in 2005[4] was intended to allow the (Japanese domestic) pharmaceutical industry to contract out manufacturing activities. Very often contract givers are R&D based organizations, while contract recipients are of course manufacturing organizations. This was one of the reasons why the Japanese authorities had significant concerns over the effective communication between R&D and manufacturing.[5]

Having those concerns in mind, I participated in the ICH discussions in the following years. The first ICH Q10 meeting in November 2005 produced a proposed structure of the Quality System Guideline. The initial structure contained four chapters:

1. Introduction
2. Pharmaceutical Quality Management System
3. Management Responsibilities
4. Life Cycle Models

The Life Cycle Models Chapter had a subchapter called ***Technical Transfer/Knowledge Management*** with a note; *"resolve terminology Knowledge Management: intent manage knowledge through lifecycle."* The subchapter had an additional heading of **Organizational Learning** (i.e., learn from one product to next). This represents the early thinking about KM by the Q10 team.

In October 2006, the team produced draft version 8.0 which went outside the team for the first time. The draft expanded the *Life Cycle Models* Chapter into two separate chapters for Product Lifecycle and for Quality System Lifecycle. Knowledge Management (KM) and Quality Risk Management (QRM) were then described as principles and

tools in the Product Lifecycle Models Chapter. At that time, there was NOT consensus on the difference between the Quality system's elements (or functions) and tools that should be used in the quality system. After extensive discussion, the team reached a conclusion that QRM and KM are the most important tools that should used in the quality system and declared that they are not PQS functions. In the step 2 document for public consultation issued in May 2007, the two tools are finally identified as *Enablers*. The four PQS elements (Monitoring System, CAPA, Change Management System and Management Responsibilities) are required directly as tasks in the PQS while QRM, KM and others are tools to ensure the performance of the PQS. This was confirmed by extensive discussion at Q10 meetings between draft 8.0 and final step 4 document.[6] Later, in order to reconfirm this, QIWG wrote the Q&A document[7] stating that KM is not a system and that there is no regulatory expectation to see a formal knowledge management approach.

More Recent ICH Discussion

In 2008 at the QIWG first meeting in Portland (OR), there were three breakout sessions for Quality by Design (QbD), pharmaceutical quality system, and KM. The team decided to write Q&As on the three topic areas and to invite case studies from outside. The KM sub team, which I was a part of, struggled in obtaining practical cases studies and Q&A proposals. As a result, the sub team was not as productive as the others in terms of writing Q&As. However, during the course of QIWG training material development, QIWG was able to write recommendations on KM in various parts of the training documents.[8] (See breakout box.)

It should be noted that during the ICH discussions, only explicit knowledge (see the definition in this supplement) was discussed. At one time in a QIWG meeting, there was a proposal to take up tacit knowledge (see the definition in supplement) for discussion. However, others did not support that proposal. This may be because there was a view that explicit knowledge is the only knowledge that can be actually formally used; tacit knowledge may be useful to connect knowledge to create new explicit knowledge, but cannot be used directly (formally) for actions.

Some Thoughts on Knowledge Management to Conclude

Yakushi-ji Pagoda Rebuild Story

It may be appropriate to bring up the 10-year long (2009-2019) disassembling and rebuilding project of East Pagoda of Yakushiji Temple[10] (Yakushi is Medicine

Knowledge Management Plays a Vital Role in the Pharmaceutical Quality System

In 2009 and 2010, QIWG wrote extensive training materials (http://www.ich.org/products/guidelines/quality/training-programme-for-q8q9q10/presentations.html) which included six presentations (Introduction, How ICH Q8, Q9, Q10 Work Together, Case Study, Regulatory Assessment, Manufacturing/PQS, and Inspection) and four breakout session slides (Design Space, Control Strategy, PQS, and QRM). Below are extracts from these training documents on knowledge management.

- Prior knowledge to support the understanding, risk assessment and scope of DoE in development *(Work Together slide 14)*
- Maintain and update knowledge management in commercial manufacturing stage *(Work Together slide 17)*
- List of prior knowledge for the case study *(Case study slide 14)*
- Manufacturing have a key role to play; using knowledge gained during development; Using current site knowledge (e.g., similar products); building on knowledge through transfer, validation, and commercial manufacturing activities; feedback of knowledge to development *(Manufacture slide 4)*
- General on PAI Drug Product; Is there a process for acquiring and managing knowledge? *(Inspection slide 21)*
- Information from technology transfer activities, scale up, demonstration, and process qualification batched is particularly valuable *(Inspection slide 38)*
- DS development-prior knowledge (*Design Space session slides 8, 9)*
- Assess prior knowledge to understand materials, process and product with their impact in the process for defining the control strategy *(Control Strategy session slide 11)*
- Expand body of knowledge for continual improvement of product and PQS *(PQS session slides 16, 17)*
- Linkage between QRM and KM; risk assessment in relation to knowledge management can be linked to identifying data to be collected (risk identification), analyzing raw data (risk analysis), evaluating the results from measurement will lead to information (risk evaluation); new information should be assessed and risk control decision captured; knowledge management facilitates risk communication among stakeholders *(QRM session slide 14)*

Feedback from the training sessions, which were held in the three regions, showed that there were not significant questions about knowledge management at that time. As a result, knowledge management is not among the six topics included in the *Points to Consider* document[9] issued by QIWG.

Budda) in Nara, Japan. The Pagoda was built in 730 and it retains the original structure with original materials that have survived earthquakes, typhoons and war fires. The last rebuilding project was finished in 1900 and the one before was in 1644. Major building components include wood pole, wood beams and Japanese nails (Wakugi), which are expected to last for a thousand years. So selecting components is very challenging. Knowledge transfer for rebuilding is even more challenging. Training of Shrine/Temple carpenters is difficult because they have rare opportunities to use their expertise. Techniques or the craftsmanship they use would be extremely difficult to document. In a recent (only two decades ago) rebuilding project at Horyuji Temple, the head of carpenters conducted an assessment of the existing structure during the disassembling process in order to identify the previous building process and the tools. Compared to the challenges Shrine/Temple carpenters face, the challenges pharmaceutical manufacturing professionals have in terms of knowledge management seem to be straightforward. However, there are common challenges between the two different tasks. That is to obtain and develop explicit knowledge that can be used.

Lessons from Yamamoto Science History

If you look carefully at the history of science and technology (e.g., Yoshitaka Yamamoto[11]), they have been developed through the dynamics between strong belief (even religious) and observations. Among them is the modern scientific breakthrough of the 17th century, based on Johannes Kepler's laws of planetary motions, the theory of which heavily relied on the precise and comprehensive Mars orbit observations by Tyco Brahe.

Recent technology development have a tendency to use a <*Develop theory (hypothesis) first and conduct experiment(observe)*> approach rather than <*Observe first and interpret the result*> approach that was historically employed. Although the <develop theory first> approach may provide the quickest solution, one cannot discovery something that has not yet been thought of. So, do not abandon the <observe and interpret> approach totally.

I also learned from Yamamoto's masterpiece that scientific knowledge gained by humans is very limited compared to the natural rules that govern Universe. So the value of "20" discussed in 80/20 rule of knowledge management (see article in this supplement by Nuala Calnan, DIT) might indeed be overestimated.

Publications to Share Knowledge and Build Common Knowledge Base

Based on my personal experience as an NDA reviewer at NIHS, techniques and approaches found in dossiers are commonly used between companies. So those techniques are unlikely unique know-how to one company. In order to use prior knowledge more effectively, by every party including the regulatory authorities, I would like to encourage industry to publish more on the learnings gained from actual development.

Thank you very much for reading this long introduction. Please enjoy reading the rest of this KM supplement.

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About the Author

Yukio Hiyama, visiting (retired) Scientist at National Institute of Health Sciences (NIHS), Ministry of Health, Labour and Welfare. Dr. Hiyama received his PhD in chemistry from the University of Tokyo in 1979. He leads MHLW's study groups to draft GMP related guidance and to propose the regulatory framework. He led an industry-government human science project on evaluation methods for pharmaceutical development and manufacturing control. He has been involved in the ICH discussion for Q8, Q9 and Q10. He is still active in reviewing new drug applications and in participating in JP committees as PMDA's external expert. His work experience includes positions at Upjohn Co., scientist at National Institutes of Health, USA and post-doctoral fellow at University of Illinois.

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A Practical Approach to Managing Knowledge – A Case Study of the Evolution of Knowledge Management (KM) at Merck

by Marty Lipa, Samantha Bruno, Michael Thien, ScD, and Robert Guenard, PhD

This case study presents the development of a knowledge management program, including the creation of a strategy, a suite of capabilities and model for sustaining the flow of knowledge, and establishing and maintaining the connection to improved business outcomes.

One of the most important "products" in today's businesses is *knowledge*. It is experience and expertise. It is what we know about products and processes. It is rationale behind decisions. It informs risk-based decisions. It is know-how and know-*why*. According to Drucker,[1] "The basic economic resource – the means of production – is no longer capital, nor natural resources, nor labor. It is and will be knowledge." One of the premier knowledge management organizations, the American Productivity and Quality Center (APQC) suggests that "Everyone competes on how much they know."[2] As Fred Miller from Kaleel Jamison Consulting Group states, "The main competitive advantage organizations now have is the ability to transfer and apply knowledge."[3] Yet, knowledge is seldom treated like a crucial asset. With the right approach, companies can leverage knowledge management (KM) to drive critical business outcomes, such as improved customer service and quality, financial and operating benefits, and higher employee engagement.

So what is knowledge management? From a practical perspective, *knowledge* is information in action. *Until people take information and use it, it isn't knowledge.*[2] Further, *knowledge management* is a systematic effort to enable information and knowledge to grow, flow and create value.[2]

Knowledge is a critical product – a crucial asset – in all industries, and the pharmaceutical, biotech and related sectors are no exception. For example, consider the development cycle of pharmaceutical products. The physical value of the clinical supplies is insignificant compared to the knowledge that has been compiled about the mechanism, molecule, and means to manufacture. Every day knowledge workers seek, share and leverage knowledge to develop, support and manufacture products.

Current trends further highlight the importance of an emerging expectation for managing knowledge in the pharmaceutical sector. The recently published International Conference on Harmonisation (ICH) guidelines which establish the paradigm for Quality by Design and development and manufacture of drug substances, specifically ICH Q8 (R2) *Pharmaceutical Development*,[4] ICH Q9 *Quality Risk Management*,[5] ICH Q10 *Pharmaceutical Quality System*,[6] and ICH Q11 *Development and Manufacture of Drug Substances*[7] establish knowledge management as an enabler

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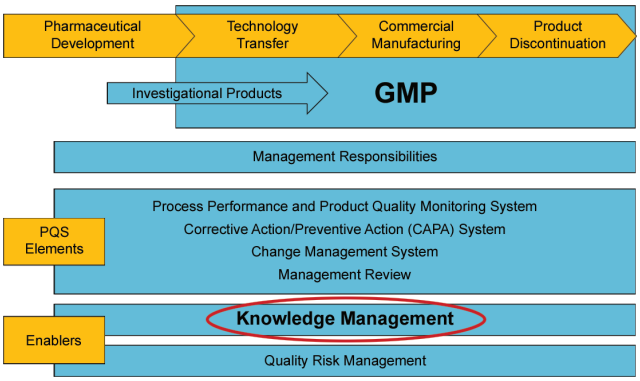

Figure 1. ICH Q10 Pharmaceutical Quality System Model.

of the entire lifecycle of a pharmaceutical product - *Figure 1*. Q10 defines knowledge management similar to APQC as a "Systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes and components."

So the need to manage knowledge is clear, but what does this mean in practice? Where to focus? Where to start, and how? This article will present a practical approach to knowledge management by way of a case study at Merck, showcasing the development of a KM Program including the creation of a strategy for managing knowledge, a suite of business capabilities and support model for sustaining the flow of knowledge, and establishing and maintaining the connection to improved business outcomes.

Origin of the KM Journey for Merck Global Science, Technology and Commercialization

The Global Science, Technology and Commercialization (GSTC) function at Merck performs late stage product development, launch and ongoing technical support of the manufacture of all pharmaceutical products. GSTC also provides manufacturing operations for clinical studies and commercial supply. The function is comprised of approximately 3000 highly skilled scientists, engineers, technicians, and support persons who are dispersed in more than 50 locations and 20 countries around the globe.

In addition to the typical challenges of operating a large, global, knowledge-rich business that is highly dynamic and undergoing unprecedented change due to a multitude of internal and external trends, the following key factors were converging in 2008 and 2009:

- Anecdotal evidence pointed to the opportunity to better leverage knowledge across the product life-cycle. Experiences included difficult technology transfers of products between manufacturing sites; difficulties in finding information for routine business operations such as problem solving and investigations; inefficiencies and missed business opportunities for how products were developed and filed; and missed opportunities to capture critical insights and expertise gained from years of experience from highly knowledgeable experts leaving or retiring from the Company.
- The paradigm for Quality by Design (QbD)[4,5,6] was emerging and Merck recently had first-hand experience as a participant in the Food and Drug Administration Center for Drug Evaluation and Research Chemistry, Manufacturing, and Controls Pilot Program where firms worked closely with the Agency reviewers to build in a QbD approach on an actual New Drug Application. QbD presented a new perspective for the opportunity to leverage "prior knowledge" and the expectation to effectively manage knowledge across the product lifecycle.
- The merger between Merck and Schering-Plough, which was a large and complex integration doubling the size and scope of the company. At this point, even tenured experts knew only a fraction of the expertise available in the new, expanded global organization.
- The growing emergence of the field of knowledge management and awareness of successful practitioners in other industries, as well as change forces such as social computing, expanding demographics (generational differences, pending retirement of baby boomers), and mobility.

These issues pointed to sub-optimal performance, missed opportunities and general "waste" in how knowledge was managed, putting various business objectives at risk. Merck senior management saw an opportunity to secure the value of knowledge as an asset and address these issues. The stage was set – and the first step was to create a strategic plan.

Creation of the Strategic Plan

Strategy development commenced with the following primary objectives:

- **Create Alignment** – Align on the problem and opportunity, increase competency and create a shared mindset for how to think about knowledge management. Ensure direct alignment with broader business direction and outcomes.
- **Set direction** – "Strategy renders choices about what not to do as important as choices about what to do,"[8] and the strategy must define specific objectives and outcomes, the priorities on where to start (including where *not* to focus), a clear vision for the future state and a roadmap of actions to get there.
- **Concentrate resources** – Define and apply what is needed to achieve the strategy, including people, specific skills, financial investment and other resources and capabilities such as change management, training, communications, and information technology.

A Design for Six Sigma (DFSS)[9] approach, specifically the Define-Measure-Analyze-Design-Verify) (DMADV) methodology,[9] was employed to develop the strategy. While not discussed in detail here, the DFSS approach ensured an outcome (i.e., the strategy) that was aligned with stakeholder needs and a line of sight to business strategy; had a baseline measurement established; and had a control plan to measure future effectiveness. APQC was selected as a partner to help teach, coach and advise during strategy development, bringing rich experience in knowledge management and an extensive practitioner network.

Table A depicts a high level description and selected deliverables for each step of the DMADV methodology. Additional discussion on selected activities and deliverables (**bold** in table) follows.

DMADV Steps	Key Activities and Deliverables
Define – What are the goals of improved knowledge management?	• Charter project, establish team • Gather anecdotal evidence, including baseline performance • Assess risk to realization of business strategy
Measure – What knowledge is most important to core work and associated impact?	• Stakeholder input ("voice of business") • Benchmarking (internal and external) • Define specific impact to business strategy
Analyze – How does knowledge currently flow through business processes?	• **Knowledge maps** for target business processes • Gap analysis for high impact opportunities • Business cases
Design – What is future state and what steps to get there?	• Strategic plan, including definition of: - **Strategy principles** - **KM principles** - **KM program** - **Pilot projects** for core capability development • **Roadmap** for KM implementation, including performance targets
Verify – Did the strategy deliver intended outcomes?	• Stakeholder feedback and repeat performance assessment • Establish control and monitoring plan • Measure and sustain

Table A. DMADV for KM strategy overview and selected deliverables.

Knowledge Maps

Knowledge mapping[10] was used as a powerful diagnostic to identify the knowledge requirements for prioritized business processes. During strategy development, knowledge maps as depicted in Figure 2 were used to capture specifically what explicit and tacit knowledge was *required* for a given business process. A subsequent gap analysis, including an impact assessment, clearly identified high-priority, high-impact opportunities to improve knowledge flow.

Principles to Guide Strategy Execution

Principles for the execution of strategy were adapted from APQC models[2] and other perspectives:

- *Align with business process and associated business case:* focus on areas of highest business impact and align KM activities with core business processes.
- *Learn by doing:* partner with appropriate subject matter experts, build for immediate use and optimize in place.
- *Leverage common approaches, processes and platforms:* create standard capabilities to adapt and expand to similar knowledge needs.
- *Measure KM approaches and associated business outcomes:* capture, quantify and communicate direct and indirect benefits of improved knowledge management related to critical business objectives.
- As learned from Charlie Honke and colleagues while at IBM's Fishkill semi-conductor facility (2008), "*think big, start small, but start.*"[11]

Knowledge Management Principles

In addition to strategic principles, a methodology on how to

Process Step	Knowledge Needed	Created By	Used By	Explicit or Tacit	Where is it	Flow	Impact	Gap / Opportunity
A	Early Risk Assessment	API Engineering	Pharma Engineering	Explicit	Document Repository			None
				Tacit	Partially captured on RA			Rationale not consistently captured
B	Safe operating conditions	Safety Eng	API Engineering	Explicit	Document Repository			Not sure which is latest version
C	Summary of lab development	Analytical	Registration Team	Explicit	Local team work space			No standard repository
D	Performance of similar product							Limited access to
E	Knowledge on powder processing							

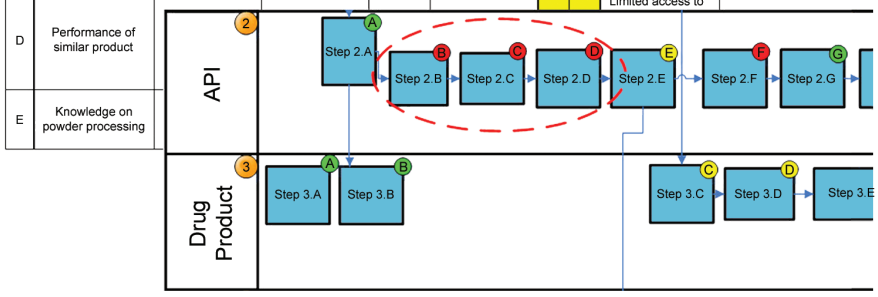

Figure 2. Knowledge map.

approach knowledge management was established. This was adapted largely from APQC[2] framework and learnings during strategy development.

- A majority (~80%) of knowledge is *tacit* (experiences, expertise, insights, etc.) and is not easily captured. Only ~20% is *explicit* (easily documented and transferred). Both are necessary although may be addressed by different tactics.
- Knowledge management is about enabling *knowledge flow*. That is, knowledge flows through a process where knowledge is created, identified, collected, reviewed, shared, accessed and used – and ultimately, reused. Given this mindset, one can begin to discern breakdowns in the *flow* of knowledge.
- Capabilities for managing knowledge need to be embedded "*in the flow*" of business processes. This will change these KM activities from being extra or discretionary to becoming part of how work gets done. Managing knowledge should be a routine, expected and implicit part of daily work.
- Knowledge management capabilities require a holistic approach including *people, process, content,* and *technology* considerations. *Content* refers to knowledge, but also taxonomies, templates and other supporting elements.

Knowledge Management Program

Models were established for the various elements of governance, as well as teams with the skills required to establish successful knowledge management. This included establishing a dedicated KM Program Office. The KM Program Office was formed to:

Figure 3. Knowledge flow (credit: APQC[2]).

- Educate on best practices based on benchmarking, research and experience
- Facilitate design and implementation of KM capabilities to solve critical business problems
- Lead change management efforts
- Steward, sustain and improve established capabilities
- Create additional capabilities as new opportunities are identified

The roles for the new KM Program Office require a different skillset than the typical scientist or engineer. A typical GSTC employee will have expertise in technical areas such as chemical synthesis or materials characterization, but may not have mastery of the skills required to lead or facilitate such a change to how people work. As such individuals were sought to have skills including strategic/systems thinking, lean six-sigma, change management, facilitation, and project management.

Pilot Projects for Core Capability Development

Prioritization criteria were established based on business impact and aforementioned principles and applied to the completed knowledge maps. A total of four pilot projects were initiated on which to build core capabilities for managing knowledge (described in further detail in the section of this article titled *Core Capabilities: Getting Knowledge to Flow*):

1. *Product knowledge* – knowledge about products and how to manufacture them
2. *Process and Technology Knowledge* – knowledge about core technologies and manufacturing platforms
3. *Connectivity* – Connections to tacit and experiential knowledge involving critical technical topics
4. *Expertise* – Unique technical knowledge held by an individual

Business cases were created to clearly draw the link between improved knowledge flow and the desired business outcomes.

Roadmap for Knowledge Management

A multi-year plan was established, which mapped out the evolution of each KM capability and of the overall KM Program as seen in Figure 4 including target business outcomes. Each capability has a supporting plan that outlines goals for deployment, replication and evolution.

Putting KM Strategy Into Action: Delivering On Strategic Intent

A strongly sponsored, robust strategy anchored around core KM capabilities and supporting KM Program infrastructure positioned the KM Program to begin conducting the initial

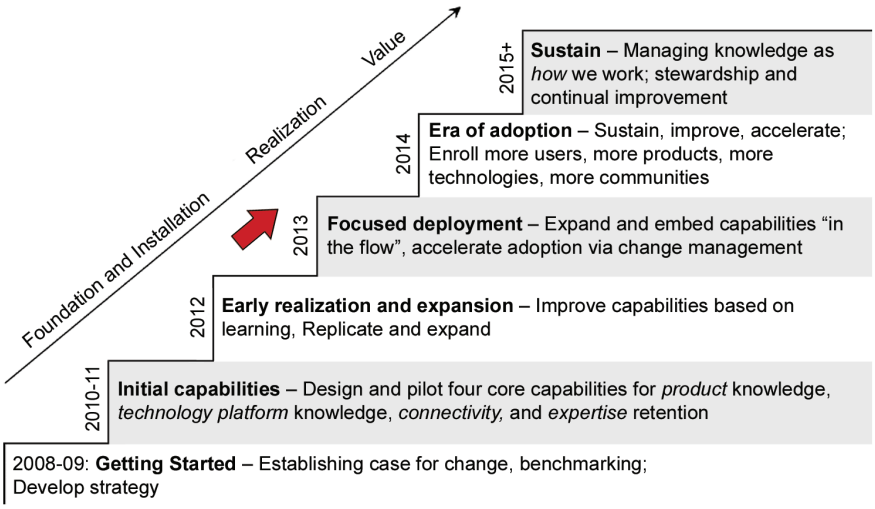

Figure 4. KM roadmap.

capability pilots. The four core capabilities were selected to solve specific knowledge flow gaps in the organization. They also were designed and implemented with long term sustainment, expansion and replication as the ultimate goals. KM could not and would not be another "initiative" which would come and go quickly. In parallel with execution, the guiding principles were applied and through "learning by doing," critical design factors emerged that were common to all capabilities. These factors translated to specific design requirements and a KM solution framework for each capability based upon **P**eople, **P**rocess, **C**ontent, **T**echnology (**PPCT**) – all critical to sustained success. Figure 5 provides an illustrative subset of these requirements.

People and Commitment to Change

Although KM was being led by the KM Program Office in GSTC, all people in GSTC are knowledge workers and managing knowledge is everyone's responsibility. However this was not yet part of the company's culture or designed into business processes or practices. Said differently, there were no expectations for knowledge seeking and sharing behaviors built into how individuals complete their work. The four core capabilities had to include two key things: 1. What individuals would use to help knowledge flow and 2. How they needed to use these core capabilities as part of their "day jobs."

To move beyond installation and achieve full realization of intended outcomes, sustainable shifts need to be achieved in the mindsets and behaviors of a wide range of people. These mindsets and behaviors need to fundamentally change each person's commitment to a new way of thinking and operating. Commitment to change is reflected in the consistency by which the mindsets and behaviors are displayed, even in the face of challenges.[12] These can be addressed though *change management* which is a risk-based change approach to address human aspects of change and increase commitment through targeted actions.

Commitment to change can be visualized as moving targets (people) up a change curve as seen in Figure 6, until internalization of the change[12] is realized.

It is important to determine how to reach the realization tipping point or "the moment of critical mass, the threshold, the boiling point."[13] At this tipping point, KM capabilities are institutionalized, becoming how work is done, and there is no slipping back into the former state. One model for analyzing potential barriers, getting the desired behaviors, and reaching the tipping point is **DCOM**® model.[14] This is a tool to assess what antecedents and consequences are triggering a behavior. From this, one can diagnose what in the environment may need to change in order to realize a change in that behavior. There are four factors that can influence the behavorial change:

- **Direction** – are people directed so the change has the right level of priority/intent?
- **Competence** – do people have the necessary skills?
- **Opportunity** – do people have the time and level of empowerment?
- **Motivation** – what consequences – both positive and negative – are people experiencing? Do they "want to" comply or are they being "forced to" comply?

It was quickly realized that leaders in the organization provide the proper direction, opportunity, and motivation as sponsors for managing knowledge. Without active sponsorship and applied consequences, sustainable change would be difficult if not impossible.

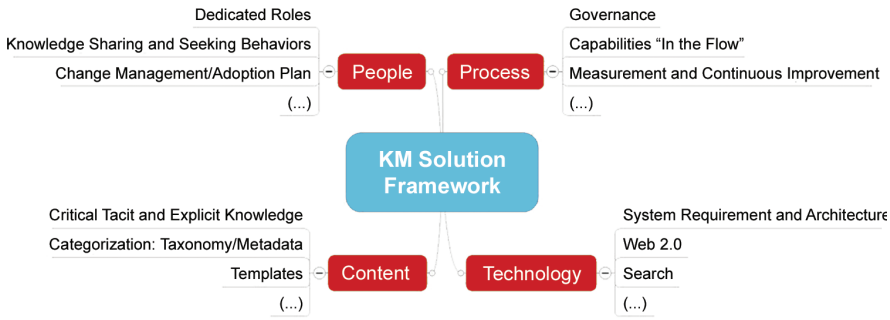

Figure 5. KM solution framework.

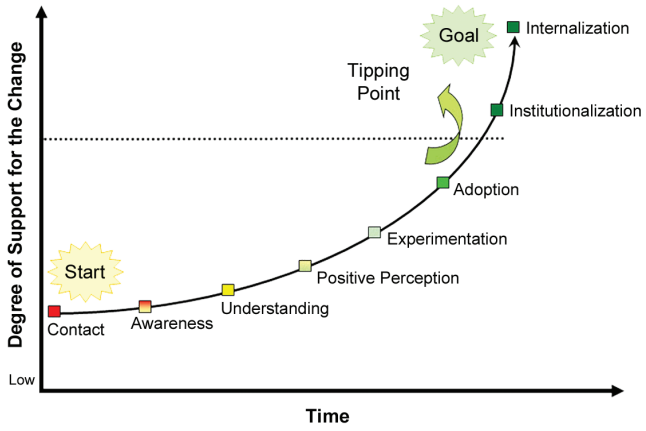

Figure 6. Change Commitment Curve adapted from Connor Partners.

Core Capabilities: Getting Knowledge to Flow

The KM Program Office partnered with GSTC technical functions on the design and development of the four initial capabilities. Figure 7 provides a snapshot of the knowledge landscape they cover. The technical functions sponsored specific pilot projects, and provided co-leadership along with the KM Program Office. This created a sense of ownership and accountability for the technical functions. This also created advocates for KM from the bottom up in the organization – which was very powerful when combined with top down sponsorship. The teams utilized the *people, process, content,* and *technology* framework described previously and designed each capability around standard processes. Playbooks were created which allowed each capability to be modular and adaptable for future iterations.

Products: Technical Knowledge (TK)

Intent: Technical knowledge related to a specific Active Pharmaceutical Ingredient (API, or drug substance) or pharmaceutical product (drug product) is readily found and generally accessible by all those who need it at any stage of the product lifecycle. Knowledge associated with changes

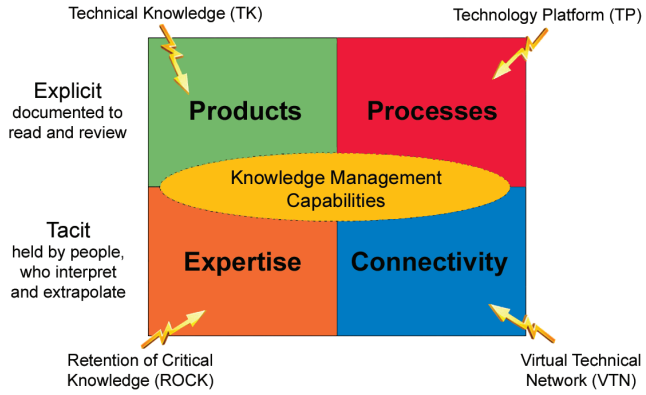

Figure 7. The four core KM capabilities for GSTC.

and experience from testing and manufacturing of a given product is continually captured with context so that it can be used by others. Each project can refer to relevant historical knowledge during development and manufacturing, rather than relying primarily on the personal experience of individuals working on the program.

Description: a unified framework for storage, retrieving, and using product knowledge. The type of technical knowledge in scope is specific to a given product; is generated across the entire lifecycle from development through supply; and encompasses analytical, product and process development, and manufacturing experience. The main elements of this framework are standard content templates to capture knowledge; dedicated stewardship roles; a taxonomy (i.e., classification schema) to tag knowledge; an electronic repository to store knowledge; flexible searching and filtering from multiple business perspectives to find knowledge; and a governance structure to sustain and improve the capability. TK serves as a single access point for the relevant content.

Critical Success Factors:

- **Faceted Taxonomy** providing common language for a diverse set of users
- **Content Stewards** responsible for ensuring product knowledge is kept up to date and knowledge is properly tagged for future retrieval
- **Rationalization of Historical Content** out of hundreds of SharePoint sites, file shares, and other repositories into TK, consolidating to provide a single point of entry for users to find existing information
- **Broad Access** to individuals across the product lifecycle avoiding, "access denied"
- **Search** akin to shopping for products on a website - flexible, easy to refine, and familiar to users

Processes: Technology Platform (TP)

Intent: knowledge related to a specific technology or platform that can be applied across multiple programs is standardized, captured and broadly accessible. The knowledge gained from program experience using a given technology is appropriately captured with context so that it can be reused. Each program incorporates all relevant historical knowledge during development and execution, rather than relying primarily on the personal experience of the individual working on the program.

Description: a Technology Platform is a framework for the capture, storage, maintenance and use/reuse of general knowledge, both tacit and explicit, which applies to a given technology. The type of platform knowledge in scope is generally applicable across multiple programs, including best practices and lessons learned. It encompasses analytical,

process development, equipment, manufacturing science, and operations. The main elements of this framework are a knowledge stewarding Community of Practice (COP) and an electronic repository. The knowledge stewarding business process identifies and captures new general knowledge relevant to the platform and translates lessons learned into best practices.

Critical Success Factors:
- **Relevance of Content** to individuals with a wide range of experience levels (novice to expert)
- **Continuous Growth** of the body of knowledge as new experience is gained on a platform
- **Standardized Look and Feel** across all technology platforms
- **Stewardship** via a COP accountable for sustained knowledge stewardship

Connectivity: Virtual Technical Network (VTN)

Intent: people seeking technical advice and/or access to existing knowledge can efficiently and effectively connect with relevant expertise across the organization. The collective institutional knowledge is harnessed to create business value, enable a more inclusive environment, share best practices, and make problems visible and solve them once.

Description: a professional networking capability for connecting with expertise, enabling discussion and sharing of technical knowledge, anchored in core values held about how people should engage and interact with one another. This capability is comprised of expertise profiles and technical topic communities of practice. The communities are centered on mission-critical technical topics with a direct tie to desired business outcomes. Their main purpose is to serve as a "helping community" for solving problems, but also serve as a place for best practice sharing and innovation.[15] There is no limitation on membership and there are designated stewards to serve as knowledge brokers and sponsors as topic champions.

Using **Inclusion as the *HOW***,®[16] a focus for the manufacturing division, provided a platform for the behavioral elements of the framework. Inclusive behaviors enable people to have a sense of belonging; to feel respected, valued, and seen for who they are as individuals; and a level of supportive energy and commitment from leaders, colleagues, and others so that people – individually and collectively – can do their best work.[16] Energy is a primary determinant of whom we seek out and learn from,[17] and having an inclusive work culture creates that energy in the social space to unleash the knowledge and creativity of people. Further details on this work are reviewed in a related case study.[18]

Critical Success Factors:
- **Dedicated Roles** reflected in annual objectives of community stewards and community sponsors
- **Community Stewards** with the proper skills to be effective knowledge brokers, encouraging and nurturing interaction on their communities
- **Business Focused Topics** determined by business impact/urgency, potential audience/demand, and how well knowledge flows around the topic
- **Success Stories** communicating value and creating relevance for users to reinforce adoption

Expertise: Retention of Critical Knowledge (ROCK)

Intent: knowledge is captured from people who have developed unique technical expertise through challenging and technically complex work and/or through years of experience.

Description: a structured interview process designed to transfer critical knowledge from experts or specialists to others in the organization such that the knowledge can be retained and reused. Criteria are applied to determine the knowledge most critical to the ongoing work in the organization. It may be useful in cases where experts with valuable, unique, and difficult to replicate knowledge transfer, retire or other depart from the company. This practice was developed based on insightful benchmarking discussions with Royal Dutch Shell in 2009 (Donna Hendrix).

Critical Success Factors:
- **Focused Scope** around priority topics and knowledge unique to that individual
- **Standard Work and Facilitation** of the interviews to ask right questions and cover proper scope
- **Sponsorship and Ownership** of the process and the resulting outputs for action

Progress to Date

The initial pilot projects have completed for each KM capability and successfully demonstrated improved knowledge flow through enhanced global collaboration, faster problem solving, improved project execution, and other outcomes. These capabilities are now in "production" use, and are being deployed to more users and teams, more products and technologies, and more functions within the company. The journey is still in its early stages, but results are positive and the future is very promising. Realization of managing knowledge better has already started, with many success stories reported, capturing the value. Success stories include proactive resolution of manufacturing issues, leveraging the global Merck network to more quickly tackle difficult problems, more effective and faster employee onboarding, and more. As anticipated, this value has come in the form of financial, quality, employee engagement and other – often unexpected – benefits.

Key Lessons in Execution

The KM Strategy proved invaluable in establishing purpose, principles and direction for managing knowledge. During strategy execution, several key lessons emerged which are critical to future success.

a. **Alignment with business priorities** and measuring in terms of current metrics is critical to get the attention of leaders and demonstrate value in what matters. It is about helping people do what they already need to do, but better. The sooner value can be established, the sooner the transition will occur from "knowledge management as an initiative" to "managing knowledge as how work gets done."
b. **Sponsorship, Sponsorship, Sponsorship** – sponsors are the individuals that can legitimize a change and provide meaningful consequences (positive and negative). They have ownership and accountability for success. Proactive sponsorship through consistent expectation setting, regular communication, advocacy, and prompting for results pushed the program forward. KM had – and still has – a passionate executive sponsor. In addition, there were individual sponsors for each capability and sustaining sponsorship at varying levels in the organization.
c. All four elements of the construct of **People, Process, Content, and Technology (PPCT)** had to be addressed in a balanced manner. Often technology is the first element a team focuses on when thinking about knowledge management. As an example, this results in force fitting a process around a tool and potentially losing the ability for that process to meet the needs of the audience.
d. **Stewardship, Stewardship, Stewardship** – stewardship roles are critical to provide energy and help people connect. They need to be carefully specified in partnership with internal customers so they are understood and staffed with the right individuals. Each of the above capabilities features a stewardship role central to its success and sustainability. Stewardship roles are great development opportunities for future leaders in the organization, as they become knowledge brokers who understand how to connect people to people and people to knowledge.
e. **Embedding managing knowledge "in the flow"** of business processes is a key accelerator to making knowledge a recognized and valued element of how work gets done.
f. **Tell the story** – the value KM provides is difficult to measure and often confounded with other activities and initiatives. Measurements need to be a blend of qualitative and quantitative ones that can be tied directly back to overall organizational strategic goals and tangible business value. One of the most impactful tactics used was through telling success stories. Success stories helped people understand success though examples from their peers and created personal relevance for them.

The Road Ahead

As the overarching intent of the KM Program in GSTC is in support of the core business objectives of GSTC and Merck, the near term priorities will focus on full realization of the core capabilities discussed. This includes: a) continued expansion to additional users, b) replication of standard KM capabilities to similar knowledge flow problems, c) capability evolution and optimization via enhanced features, and d) ongoing change management and communications. Metrics and corresponding business value will be assessed on an ongoing basis.

In addition, the following further defines the GSTC KM Program for the next two to three years:

- Continue efforts to fully operationalize – that is, to put in the flow – core capabilities
- "Knowledge knows no boundaries," and as such, focus will include expanding to partner groups across Merck
- Opportunistically develop new capabilities to support problem solving and innovation
- Further expand the linkage with creating a high performing organization, including integration with learning and development processes such as new employee on-boarding
- Evolve the linkages between the capabilities to create an integrated "knowledge ecosystem" for knowledge workers to more easily navigate and leverage these capabilities
- Evolve the KM Program Office from strategic initiative leadership to a Center of Excellence on managing knowledge, ensuring long term sustainability of KM capabilities, and providing internal consulting

Conclusion

The term "knowledge management" is a broad and ambiguous term that means many different things to many different people. Hopefully, this article has helped give further meaning to the concept by profiling a practical approach to establishing a plan and supporting capabilities to more effectively manage knowledge. This case study for Merck GSTC highlights some key insights that are broadly applicable, regardless of the scope of knowledge in question. The results of the efforts for Merck GSTC have been quite favorable, delivering benefits in many categories, including improved quality, internal efficiencies, cost reductions and cost avoidance, improved employee engagement, and the ability to leverage a diverse, global, interconnected network. Anticipated future benefits include top line business impact as the capabilities scale.

It is important to understand this strategy has been effective for GSTC; however, KM is not one size fits all. Consider what knowledge matters most to your organization's success, regardless of what your organization does, and tailor your tactics to the business priorities, culture, and practices within your organization.

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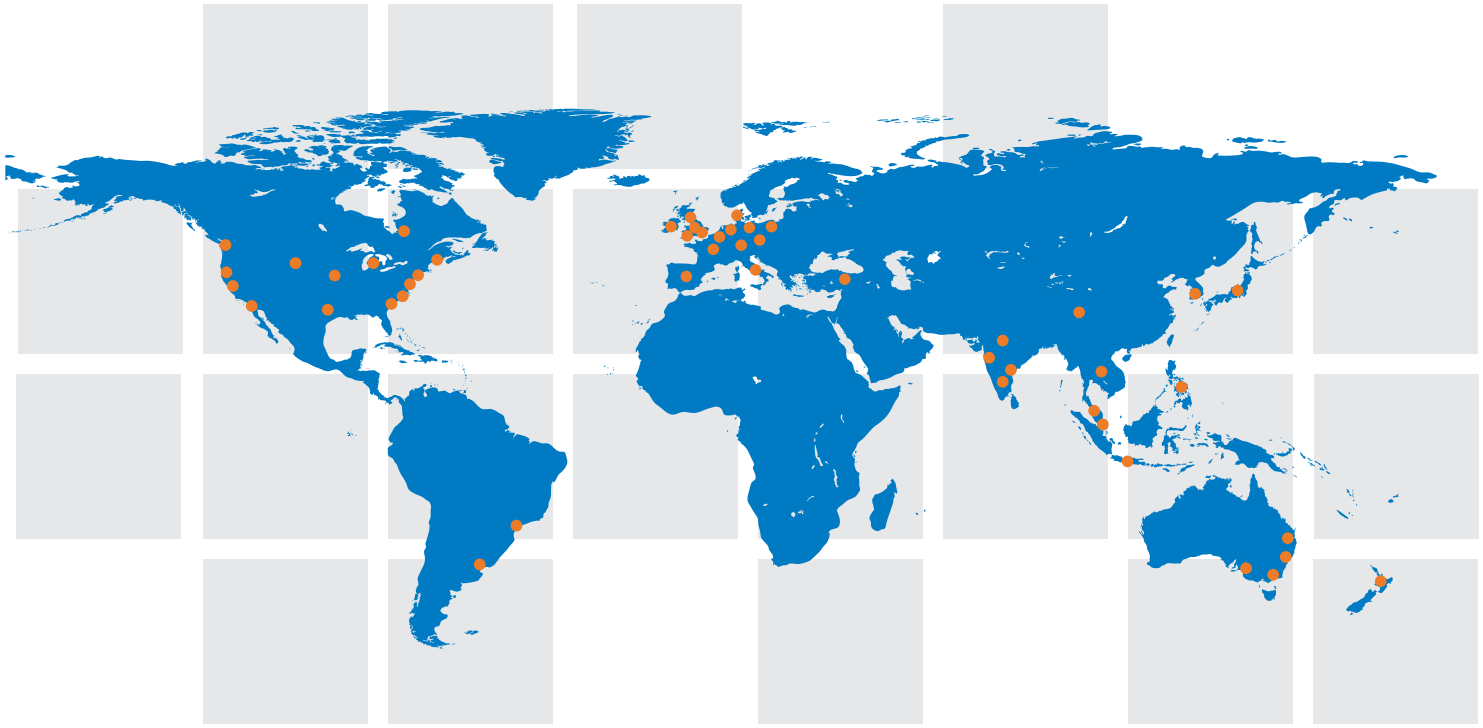

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The Know-How and Know-Why: An Interview with Merck

Following their well-received article in the November/December 2013 edition of *Pharmaceutical Engineering*, Vol. 33, No. 6 entitled, "A Practical Approach to Managing Knowledge – A Case Study of the Evolution of Knowledge Management (KM) at Merck," we caught up with two of the authors, Marty Lipa **[ML]** and Dr. Michael Thien **[MT]**, to delve deeper into their experiences of managing knowledge in a global pharmaceutical organization. This interview was conducted in conversation with **Nuala Calnan, DIT.**

You point out at the beginning of your article that many influential business thinkers consider the ability to transfer and apply knowledge, a key source of competitive advantage, yet organizations seldom treat knowledge as a crucial asset. Could you bring us through the main internal and external drivers, which led to Merck recognizing just how crucial your knowledge assets were to the business?

[MT]: Our organization, the Global Science, Technology and Commercialization (GSTC) function at Merck, covers two aspects of the *product lifecycle*. The first is the late-stage development of new products and the second includes providing technical support for our in-line products. As we looked at the mission of our organization, one of the things that became clear was that when new products were transferred to in-line production, not all of the knowledge was there for us to do what was necessary to support and maintain those new in-line products.

A second element included a recognition of what our group does – GSTC enables the production of the product, but we also produce knowledge. While we go to great lengths to preserve the quality of the product, we realized that we were not attending, with anywhere near the same discipline, to the quality of the knowledge we were creating or its future usability. When we did an assessment, we realized we were "bleeding knowledge" and we really didn't have a way of capturing this knowledge for future application. We had all sorts of *electronic team rooms* available, yet it was difficult to locate particular knowledge in those rooms and even more difficult to locate experts on particular products or platforms. We realized that we had an acute need for knowledge management. Then Merck merged with Schering-Plough and we tripled the manufacturing network and doubled the size of our technical organization. That more than doubled the need for knowledge, and we found ourselves acutely in need of some type of *Knowledge Management (KM)* system.

We recognized there were many dimensions of knowledge, that there was *tacit* knowledge and *explicit* knowledge, there was *product specific* and *platform* knowledge and we really didn't have a system for any of that. Those were the key drivers to go ahead and create a KM strategy, to understand deeply what KM is and then to implement a comprehensive KM program.

Another quote, often attributed to Peter Drucker, asserts "Culture eats strategy for breakfast!" How did the Merck KM Strategy address the cultural challenges, which often beset knowledge sharing and seeking?

[MT]: The breakthrough for us was in taking the time to understand what KM *really* is. We had rolled out data repositories in the past; these efforts ended in great failure, with hardly anyone using them or with no one using them well. When we took that time, we realized the KM had three critical components. There is the **IT platform**, but that is just a small piece, and then you must have the necessary **business processes**, but most importantly you have to have to create the **culture** in which

KM is not an extra thing to do, but an expectation of what everyone does. It must become a natural thing that occurs in the flow of work and not something that occurs outside the flow of work. When we realized this, we understood that our KM program was going to be a three to five year program, because you don't change culture overnight.

Furthermore, how did these cultural factors impact on the roll out of the Merck Virtual Technical Network (VTN)?

[ML]: It starts with **people**. *People*, as well as *process, technology* and *content* are the four facets of how we think about getting knowledge to flow. But it has to start with changing behaviors and how people to think differently. So from day one, we approached VTN recognizing that we wanted to highlight desired behaviors and give positive reinforcement to people exhibiting those behaviors, and over time to apply negative consequences for people not doing so. We started by making VTN both business relevant *and* relevant to people. We did that by creating a design team that had people from every function of the *target user base* for VTN; so that we could translate the value of VTN into how it would help their respective functions and help them see the value of collaborating across geographical and functional boundaries. We spent a lot of time up-skilling the design team so they had a hand in shaping it [the VTN].

We also had a comprehensive change plan, and still do today. We spend a lot of time looking at how we can move VTN and its associated business impact forward. Number one is that we have invested a lot into nurturing energetic *knowledge stewards*. These stewards act as knowledge brokers who really help to keep the conversation going and also give energy back to people in the community. We continue to spend a fair bit of time increasing people's awareness of VTN, as well as their competencies for using VTN, and in removing barriers related to their fears of engaging in the conversation. We have enrolled *sponsors* to model the changes that we wanted to see and to assist in applying positive and negative consequences.

Finally, we have spent a lot of time capturing and communicating *success stories* relating to VTN delivering business benefits. I feel strongly that success stories create relevance for people, because they can then see themselves how VTN creates value. For example, they can see how someone who collaborated through VTN made a problem visible that in turn drove a business benefit and then see a senior leader has said thank you. Those are some of the key highlights of how we tried to address the cultural issues in the VTN implementation.

Many still associate knowledge management with a software package or IT based system in a similar vein to a document management package. What do you say to them?

[ML]: The first thing I typically hear when I start talking about KM is that people think that it is a *search* tool or that it is a *Document Management (DM)* or *Content Management System (CMS)* of some sort. As mentioned previously, we did a lot of upfront work to really understand what KM means. That included a lot of internal and external benchmarking, and we have found no two companies with the same KM program. Some companies focus more on the *explicit* knowledge, things that you would capture in a document management system; some focus more, or exclusively, on *tacit* knowledge through Communities of Practice (CoPs) and so on. We have a balanced approach to what we are doing. We feel like document management [explicit knowledge] is kind of like learning to walk, before you can learn to run with *tacit* knowledge. But DM/CMS systems only capture a portion of knowledge within the organization, the 20% explicit knowledge if you will,[1] and it can only capture that if it is done properly. In my opinion, many examples of DM/CMS are not effectively implemented because of the lack of effective taxonomies, and they are typically not intuitive to the user base nor in the flow of the business as Mike has said earlier.

[MT]: Anyone who is getting into the KM business owes it to themselves to really learn about what KM is. To learn about the *people, process, platform* concepts, to understand about the differences between tacit and explicit knowledge. To understand how one taps into both of these different knowledge types and to understand the uses for each of these different types of knowledge. Once you really learn about the width and breadth of KM and see how that applies to your own organization, I think your eyes are opened and you say *"Wow, we have a long way to go!"*

Your knowledge management solution outlines a comprehensive approach encompassing people, process, content and technology. Which of these

- Presented the starting point
- Presented the greatest challenge
- Presented the greatest opportunities

[MT]: *Content* was the starting point – we were generating it, but we really couldn't find it. Particularly for our older products, the content we sought

may not even have existed in a written form. After we merged, we found that we had products that had little or no background – or at least none that we could find. We soon realized we needed to create both repositories for knowledge needed and also to be able to find content that is tacit. So it all started with the content piece – it is where we launched.

[ML]: Our journey did start with *content*, because that was where we felt the most pain. We had tens of thousands of places that we could store content across the company, and this was where we could feel the pain on a daily basis, as in: *"I can't find my stuff."* But, if we started this again today, I think we would take the same approach balanced between explicit and tacit knowledge flow. Which is, while we feel very strongly about the need to address that content [explicit] element, the tacit knowledge element potentially has a higher Return On Investment (ROI) although it is more elusive. I would advise anyone going forward to think holistically about their pain points – and the business opportunities – and not rule out the importance of the tacit.

[MT]: I think the area that really presented the greatest opportunity was our recognition that there were two major axes that we needed the KM strategy to address. One was this axis of *tacit* and *explicit* knowledge and the other was a *product* and *platform* axis. We need our strategy to provide approaches in all four of these knowledge areas.

How did that insight about the two axes come about?

[MT]: The *product vs. platform* concept emerged relatively quickly, because it became clear that, on the one hand we had a lot of *product-specific knowledge*, while on the other hand, every piece of knowledge about the product contributed directly to the knowledge base we had about the *platforms* that those products used. Also, from a Quality by Design (QbD)[2] perspective, as we were thinking about *prior knowledge* and questioning where does that prior knowledge come from and where does it reside, we realized that it's in the platforms.

Regarding the *tacit* and the *explicit* elements, the need for access to the explicit content was really clear. In regard to the tacit component, once we had merged with Schering-Plough, we suddenly had more than 90 sites within our internal manufacturing network (recall our network size tripled) and no one knew anyone. Our technical leaders found themselves acting like telephone switchboard operators – they had to find out what the technical problems were at a given site, then talk to other technical leaders to see where there might be expertise available at another site in order to "plug" that in. This was really slow and inefficient. We needed a solution that would allow people to directly interact – and that was the start of our realizing we needed a tacit knowledge platform as well.

The article outlines a practical perspective on knowledge as "information in action" and defines knowledge management as "enabling knowledge flow." How did these perspectives underpin the development of your Virtual Technical Network (VTN)?

[ML]: One way we think about VTN is as a **persistent source of potential energy**. We have this network of people, more than 20,000 colleagues just in the manufacturing division alone, and of course we collaborate with other divisions, such as research. If you think about this in terms of a network diagram ("pin cushion" diagram), VTN offers the potential to make that network diagram much more dense – perhaps even ten times as dense as before VTN. We can now make connections on demand when we need to solve problems, find an expert, search for a best practice – whatever the business need is.

When this happens, we have *information in action*, and knowledge is flowing across the network between two people, from where there is a source to where there is a demand. VTN also can remove barriers to knowledge flow as we now have a place where anybody can go on business-focused topics, which are important to people as part of their core job. So, it is these things coming together that enables the knowledge flow, that *information in action*, to drive a business outcome. One interesting statistic we have found is when people search for expertise on the VTN, the response comes from a much broader audience than their own personal network; responses come from people they would never have normally contacted. In fact, more than 50% of VTN connections are between people who don't know each other. That has been a phenomenal statistic on being able to connect on demand.

[MT]: VTN is like the old story of the lost coin. The people who lose the coin only look in the lit spaces of the room and never find it because the coin is in the dark. In our case, the VTN allows our people to look in the dark! For someone to post a question and then people they don't know – on the other side of the world – come in to assist. People they never had contact with previously can come in with their expertise and help them with their issue and provide knowledge. I mentioned earlier that our

technical leaders were like telephone operators. Well, now we don't need that. We can go *directly* to someone we don't know; it has been incredible from that perspective.

A very interesting fact noted in your article identifies that typically 80% of knowledge within an organization is *tacit knowledge* (experiences, insights, expertise) and only 20% tends to be *explicit knowledge* (documented and easily transferred). The pharmaceutical industry, as a whole, has traditionally over-emphasized the value it places on explicit knowledge (in its SOPs, specifications etc.) and has often systematically under-valued the importance of the tacit knowledge available within its people resources. What features of the Merck KM solution were specifically designed to address this?

[ML]: Yes, we learned that first principle of KM from our colleagues in American Productivity and Quality Center (APQC), http://www.apqc.org], and candidly I did not believe it on day one! However, you saw in our article that we undertook some knowledge-mapping activities, and from those, we in fact validated this principle for ourselves. We could see where the barriers to knowledge flow were when we did not have access to tacit knowledge. For example, where there was only a single point of contact for a given question, or where we couldn't find an expert. Now, we think about tacit knowledge as an integral part of our KM strategy. We don't, however, try to make everything explicit; you can't do that – it is not practical or tenable. We do try to highlight where we need access to tacit knowledge and build that into our business processes, so that it is routinely, reliably available – repeatedly across all processes. To do that, we have our VTN which allows connections across time and space on a variety of technical topics.

We also have a capability around *knowledge retention* – which we learned from our colleagues at Royal Dutch Shell, among others. We have learned to have a healthy, business-focused conversation with an expert around critical knowledge and experiences they have, whether that person is either leaving the company or just simply leaving their role and moving on to another job. Sometimes, I describe my job as "connecting people to people and people to information," where the "people to people" bit is the tacit knowledge piece where we get people to experts and people to communities to help them solve their problems.

[MT]: I would just add that the VTN itself is often just a gateway. People will often start on a conversation on the VTN by asking a question or posting an issue, and then once the connection is made, those people can get on the phone and have a conversation themselves, getting even deeper into the tacit knowledge rather than just rely on something that is typed into the VTN. Managing knowledge is not just about releasing the value in the 80% (tacit knowledge), it is about building the expectation that people will seek the value in the 80%. So, using the VTN to reach out to get that knowledge is not an option, it is part of the normal way in which we do our work.

You reference another recent article published in *OD Practitioner*, entitled "A New Way of Working through Inclusion and Social Media – A Case study," which provides further insight into the organizational, cultural and technical challenges associated with the roll out of the VTN. What role does inclusion play in the success of this network?

[MT]: *Inclusion*[3] can be seen as a *catalyst* for the VTN. The Merck Manufacturing Division had already been doing work with inclusion, and while we may have been able to connect people without inclusion, putting VTN and inclusion together has been opportunistic and very powerful. Inclusion provides us with a set of behaviors that we can use as the rules of engagement for the VTN. Some of these key rules include it being ok to *lean in* to discomfort, to say things you might be a little hesitant to say. This has been very important as one of the first challenges the VTN faced involved people not wanting to put a question out there in case others thought they were "stupid" because they didn't already know the answer. But the *inclusion behavior* says "No, that's really good." Another inclusive behavior involves giving "energy" back when someone does help you and that puts more energy into the system, which makes people want to do it again.

Our community stewards also went through a lot of inclusion training, and they infuse the VTN system with good examples of inclusive behaviors. So now people know how to use *social media* in the most productive way. The fact that we married up the VTN with this *inclusive behavior* piece really supercharged the social media approach to tacit knowledge.

[ML]: With regard to *leaning in* – the VTN is really changing behavior. In the past, people worked to solve the problem themselves, because that was the best way they knew how; they believed there were no other resources available to them. Inclusion has shown the benefit of linking people to the greater good. Where solving this problem or seeking that best practice

is for the greater good, it can help to get a better outcome for the company or for the customer. So our ability to help people to "ask for help" – that ability to lean in and ask the question – is part of the new paradigm that we are driving for. Getting people to ask those questions has been fundamental to getting knowledge to flow on the VTN.

What exactly is the VTN platform and how does it work?

[ML]: VTN sits on a technology platform that is available across the Merck enterprise – every employee has access to the VTN on our enterprise portal (intranet), and the specific technology is a combination of a product called NewsGator and a Microsoft SharePoint platform.

We have put this technology together, and it is available to every employee. It does require a sign-up step to opt in, largely due to privacy requirements of our global organization, and we address that barrier with enrollment campaigns and sponsorship messages. Once an individual asks for help, we have a variety of ways to get that question into the hands of those who can answer it. Many people have alerts set up so they instantly get a message on a topic of interest to them, for example, processing of powders. However, as not everyone is monitoring VTN daily yet, we use our stewards, who also play a key role. The steward will send out an email message to alert the community (typically several hundred people) that someone is seeking help. Others subscribe to daily message alerts to enable them to get a daily digest of what's happened in their communities that day on topics of interest to them.

For example, we had an issue at our plant in China, and a person posted the problem to their community on the VTN. The stewards put it out and within 24 hours there were almost a dozen responses from four continents, and the problem was actually solved within 48 hours. The person who put the problem up there in the first place knew none of the respondents, so it was a hugely powerful.

What stage of the global implementation has the Merck KM Strategy reached?

[ML]: We are well on our way. We have a full suite of capabilities implemented, and we still have more up our sleeve. VTN has membership from 40 different countries, and we have delivered significant business benefits against a number of different key performance indicators that the manufacturing division has. We are continuing to address issues of scale and scope including any cultural or organizational gaps in order to get VTN, and the other knowledge capabilities, everywhere that they can be. In terms of awareness and global reach, we are well on our way.

[MT]: As we continue to expand both the tacit and the explicit features of the KM strategy, the one thing we are being very careful to do is to preserve the quality of knowledge management. We don't generate communities unless there is genuine interest and we can find stewards who will live up to the spirit of what we need for those communities. Similarly, for the explicit knowledge platforms and product base, we are careful not to expand too quickly. We also will work to ensure the right mechanisms are in place including the right business processes and infrastructure, and that we are "readying" the culture in these areas so that we know we can be successful. We are being really thoughtful about planning how we expand for success.

What are your key recommendations for those starting their knowledge management journey?

[MT]: The first thing people need to do is to "spend some time" to learn what KM really is. They can read the right books or go to consultants, but it is really important to get a true understanding of what KM is. The second thing is to be willing to make the commitment in resources, in dollars and most importantly in sponsorship, so that they can be successful. That level of commitment for a three to five year period will not happen without visible sponsorship from the senior most leaders in the organization. The last piece is ensuring you have dedicated resources to help create and drive the KM solution. You need resources that are focused both on developing the solution and in helping the organization to implement the solutions.

This interview was conducted in February 2014 and the author would like to thank both contributors for their generosity in sharing their time and their insights.

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Implementing a Successful Knowledge Management Program

by Joseph A. Horvath, PhD

This article provides some guidance on implementing a successful knowledge management program.

The preceding articles have outlined the opportunities that knowledge management presents for improved development, manufacturing and quality assurance. But these opportunities cannot be realized unless the knowledge management program is implemented skillfully and systematically. To do so, the current state of the organization must be evaluated and impediments to change addressed. The implementation of new processes, knowledge structures, and technologies must be well managed. And the impact of the knowledge management program must be monitored to ensure that the expected benefits were obtained. Without these elements of skillful implementation, a knowledge management program is likely to disappoint.

In this article, we briefly describe some principles – derived from available literature and personal experience – for successfully implementing a knowledge management program. The article is organized around the three, basic elements described above: preparing the organization, executing effectively, and monitoring results.

Prepare the Organization

Articulate Business Benefits

Every knowledge management program must be grounded in a clear understanding of how it will benefit the business. Improved process understanding is, of course, an overarching objective, but what exactly will this look like and how will we know that we have obtained it? Where will the return on improved knowledge management be greatest? The preceding articles provide an overview of opportunities across the product lifecycle and form a good starting point for discussion. Being specific about the intended benefits of knowledge management – and the linkage between those benefits and proposed investments – is critical to success.

Senior leaders play a key role in defining business benefits. They do this, at the outset, by insisting that investments in knowledge management be supported by a solid business case. Once that business case is in place, leaders draw upon it to explain, in the clearest possible terms, why changes are taking place and how the business stands to benefit. This helps to engage employees, puts an official "stamp" on the effort, and sets the knowledge management program on a strong foundation.

Identify and Remove Organizational Impediments

Knowledge management programs almost always require employees to modify their accustomed ways of working. Employees may need to change the ways in which they document or store information. They may need to be more forthcoming with colleagues about what they know. They may need to be more proactive in searching for prior knowledge and more receptive to the expertise of others. These sorts of behaviors are critical to the success of a knowledge management program, but they are notoriously difficult to compel. For this reason, organizational impediments need to be carefully considered.

Incentives

Misaligned incentives can be a serious impediment. For example, when innovation is recognized and rewarded as an individual accomplishment, employees or teams may be incented to keep valuable knowledge to themselves. Pitting teams, functions, or sites against each other in competi-

tion for resources can have a similar, dampening effect on collaboration. Finally, when time and resource targets are very aggressive, time spent on documenting and sharing knowledge can be inadvertently penalized. Indeed, the most common disincentive to adopting new knowledge sharing practices may simply be existing workload.

Although the benefits of improved knowledge management to a company may be clear, they often constitute a "common good" from which individual employees may draw benefit without contributing. Contributing, in this context, means changing the way one works and this requires time and effort, particularly at the outset. Employees who are already stretching to meet their existing commitments need a reason to change that goes beyond the common good of improved knowledge management. They need an array of incentives that encourage the right behaviors. These may range from soft incentives such as recognition and encouragement to so-called "forcing functions" that embed knowledge capture or re-use into electronic workflows. The particular mix will vary by program; the important point is that incentives must be addressed when preparing to implement knowledge management.

Ownership

Another common impediment is the failure to engage employees and teams effectively – particularly with respect to their preference for self-determination. We all respond to extrinsic rewards such as money and recognition, but we also find rewarding a sense of ownership and autonomy in our work. When a new knowledge management program presents employees with new directives, but little personal discretion on how to go about fulfilling them, engagement is likely to suffer, and with it, the voluntary knowledge sharing behaviors on which the success of the program often rests. By giving employees and teams the freedom to organize content, tailor document formats, or configure screens and workflows in ways that make sense to them, their ownership over these new practices will be increased. Certainly, the desire to grant flexibility to employees must be balanced against the value of standardization (particularly with respect to terminology and classification frameworks), but time spent thinking through these trade-offs is likely to be rewarded.

Culture

The subject of culture often comes up when discussing organizational impediments to knowledge management. For our purposes, culture may be defined as the set of values, norms and expectations that are widely shared within the organization. In cultures where trust, transparency, and cooperation are highly valued, unspoken norms and expectations tend to develop that subtly, but firmly shape employee behavior in ways that are conducive to effective knowledge management. In the absence of these values and norms, the full value of knowledge management becomes harder to achieve.

Organizational culture cannot be changed in the way that business processes or IT systems can be changed. Culture evolves over time and in response to a myriad of factors, including organizational history, structure, incentives and leadership. Culture change is a complex, uncertain undertaking and one of the chief concerns of executive leaders. Unfortunately, an adequate discussion of the topic is beyond the scope of this article. Readers interested in learning more about organizational culture in relation to knowledge management may wish to consult several sources, listed in the references of this article.[1-3]

Just because it is possible to automate an activity does not mean that it is advisable.

Execute Effectively

Technology

Don't Over-Automate

When implementing a knowledge management program, it is a good idea to use technology sparingly, particularly at the beginning. Just because it is possible to automate an activity does not mean that it is advisable. Software vendors tend to compete based on the completeness of their platforms and so offer products that are loaded with more features than an organization can realistically use. Don't overwhelm your users. Frequently, initial assumptions about how people will use a new technology turn out to be wrong. For this reason, it can be a good idea to gain experience with a new process before trying to automate it or, at least, to make the initial configuration of a new tool as simple as possible. Taking a relatively low-tech approach at the outset can save you from making a costly mistake. You can always layer on more automation later.

Leverage In-House Technology

Although selecting the right technology is fundamentally a matter of fit to requirements, it makes sense to try to leverage in-house technology where possible. All else being equal, adapting in-house tools will be cheaper than implementing new ones and will pose less technical and vendor-related risk. In-house tools should already be well-supported by the IS organization and your employees should already have been trained and provisioned as users. Finally, using existing technology will encourage you to embed new, knowledge-sharing activities into existing workflows rather than creating new ones. This reinforces the idea of knowledge

management as simply the way we should work rather than something "off to the side" and somehow extra.

Partner with the IS Function

Another key to executing well is to partner effectively with your IS function. Knowledge does not respect organizational boundaries and so knowledge management systems need to span those boundaries. But there is a danger that sites or functions, acting independently, will pursue their own knowledge management goals and end up creating "silos." As an enterprise function, IS is well positioned to link related efforts to one another and to establish governance around the build-out and on-going operation of knowledge-management systems. They are also the keepers of the company's IS strategy and application architecture which are keys to future system integration. Treat them as partners, not order-takers.

> *"Standard, agreed knowledge structures allow knowledge from disparate sources to be effectively aggregated.*

Knowledge Structures

One of the most important, but time-consuming activities in developing and implementing new knowledge management capabilities is the development of shared semantic frameworks – what we have referred to in this report as "knowledge structures." Knowledge structures may include:

- Data models: Schemata and data dictionaries that organize structured data in relational stores or data warehouses.
- Document types and templates: Standard ways of reporting the results of data analysis and interpretation, description of methods, etc.
- Taxonomies and ontologies: Classification frameworks used to organize information in ways that support retrieval and inference.
- Controlled vocabularies: Agreed ways of naming things that are established for any of a number of purposes (including those listed above).

Standard, agreed knowledge structures allow knowledge from disparate sources to be effectively aggregated. They allow two instances of the same concept, named differently, to "find each other" within a repository. They can be the difference between a mere collection of information and a true knowledge base. Although software tools can facilitate the development and application of knowledge structures they cannot decide how to classify and name things. That is work that only the people in the organization can do.

The development of shared knowledge structures in complex domains is intellectually and organizationally challenging. Different disciplines may have their own accustomed ways of seeing the world and so discussions intended to establish standard ways of naming and organizing can become contentious. It also can be difficult for teams to identify a point of diminishing returns in such an effort. Even after agreement is reached, the process of re-coding and re-organizing existing data and information to accord with the new structures can be time-consuming and expensive. Despite these considerable challenges, well-formed knowledge structures are a key element of knowledge management capability and implementation plans need to allocate sufficient time and resource for their development.

Support Model

Training and Job Aids

As previously stated, a knowledge management program will invariably require some employees to work differently and these changes will need to be rationalized and explained. Employees will need to be trained on how to participate in new knowledge-sharing processes and on how to use new technologies. Those in pharmaceutical development and production functions tend to carry heavy training burdens already so "one size fits all" training should be avoided. Rather, target training to particular roles and, within those roles, focus the content on critical competencies. If a group of employees (e.g., senior managers) require only broad awareness of the knowledge management program, create brief, summary-level training for that purpose. Don't get off on the wrong foot with your users by assigning a lot of "just in case" training.

Even when training is well designed, the concepts and skills acquired will decay rapidly in memory, particularly if they are not used. When trainees are expected to use a new system only intermittently (as is often the case with knowledge management systems), training should be augmented with job aids. Job aids can take many forms (e.g., checklists, annotated screen shots, look-up tables), but they have a common purpose – to deliver information that supports the performance of specific tasks at the moment of need. Ideally, job aids are developed in tandem with training materials and used during training activities as a way of reinforcing their use in the future. Making job aids easily accessible

(e.g., through an enterprise portal or Sharepoint team site) also will promote their future use. Of course, job aids that describe regulated activities must be adequately controlled.

Dedicated Support Roles

The importance of dedicated support roles in sustaining a knowledge management program was captured succinctly by a pharmaceutical executive of our acquaintance. He said that "unless someone owns it, it turns to [garbage]." Put another way, if knowledge management is everyone's responsibility, it is no one's responsibility. Knowledge management programs that don't make anyone accountable for the day-to-day success of the program are setting the bar very high for themselves. Instead, they should consider creating two types of support roles: power-users and content curators.

Just as employees may need job aids to remind them how to perform new tasks, they occasionally need assistance from power users who can answer their questions and who will make the time to help them. Power users can answer questions and solve problems that job aids can't. They also can check-in with users periodically to encourage, cajole and even shame them into new ways of working. With a relatively modest time commitment (three to four hours per week), a single power user can often support a surprisingly large number of end users.

Knowledge management programs, by their nature, tend to generate and transform content; raw data, analyses, reports, etc. In order to maintain the currency, quality and accessibility of that content, some form of active management or curation is typically required. Unless employees find the knowledge available to them to be up-to-date, accessible and of high quality, their willingness to draw upon (or contribute to) the knowledge base will rapidly erode.

Although well-designed software can take some of the strain, there is no substitute for a human being when it comes to pruning the contents of a document repository or ensuring that controlled vocabularies and other metadata standards are being consistently applied. Employees with background in library sciences and records management can be a particularly good fit to these roles, as can biostats or IT professionals trained in data modeling. It is difficult to over estimate the importance of adequate curation to the success of a knowledge management program.

Creating dedicated roles does not necessarily mean hiring additional employees, but it does mean, at a minimum, carving out some resource from within the existing organization and adding knowledge management tasks to the responsibilities of at least a few people. The nature of these support roles makes them highly developmental and so can be a good fit for high-potential, junior employees interested in deepening their knowledge and broadening their exposure within the organization.

On-Going Communication and Outreach

As described previously, the launch of new knowledge management systems and processes need to be communicated effectively so that people understand what changes are taking place, why they are taking place, and what is expected of them. A well designed communication plan is essential to ensuring that these activities are not subordinated to system testing, procedure revision, and other activities that tend to occupy the attention of the project team as the system launch date approaches. A well designed plan will avoid focusing all planned communications on the period immediately preceding system "go-live" as this is a time when, ironically, people are least likely to be paying attention. In busy organizations, employees will tend to pay attention to communication about a new system at the moment they need to use it—and not before. For this reason, communication and user outreach should peak in the weeks and months following the roll-out of the new system, when people are actually forced to come to grips with it and will be more receptive to help.

Monitor Results

Part of implementing successfully is monitoring results. We monitor results in order to learn from experience and make course corrections as needed. We also may monitor results in order to confirm that expected business benefits are being realized (e.g., to justify continued investment in knowledge management). Regardless of the reason, post-implementation monitoring needs to be part of the project plan.

Regardless of the reason, post-implementation monitoring needs to be part of the project plan.

Informal feedback from users (particularly power users) is perhaps the most valuable form of feedback and an excellent basis for course corrections. Other, more objectives indicators may include:

- Growth or improvement in the contents of knowledge repositories
- Frequency with which those contents are accessed by employees
- Percentage of provisioned users who access or contribute to the repository

- Awareness of knowledge management resources, as measured by survey
- Ratings of value and usefulness of the knowledge management system, as measured by survey

Another indicator of progress may be changes in patterns of collaboration between individuals and groups. Knowledge management systems and processes help to connect people with common interests and so may lead to new or more intensive interactions. Social network analysis is a method (unrelated to Facebook) that can be used to capture and analyze patterns of interaction within an organization. This approach can be quite persuasive in demonstrating the effects of knowledge management on the organization. It typically requires assistance from a consultant with expertise in these methods.

> *"...the progress and impact of the knowledge management program must be monitored using a combination of objective and narrative methods that is appropriate to the situation and acceptable to key stakeholders.*

With respect to the business impact of the knowledge management program, it is conventional to say that this cannot readily be measured because knowledge is itself intangible. Certainly, effective knowledge management does not impact the business in the same, very direct way that a new process innovation or a new supplier agreement may do. But by promoting greater process understanding, it can set the stage for benefits of these types, and others, ranging from faster process characterization to higher quality submissions to more effective troubleshooting of production problems. The key is to be able to trace these outcomes to the use of shared knowledge bases and to trace the robustness and accessibility of those knowledge bases, in turn, to the use of knowledge management systems and processes. Developing a narrative of this kind can be a time consuming and expensive, but it is possible. Whether it is worth it will likely depend on the expectations of senior stakeholders.

Conclusion

Like any business improvement effort, the effective implementation of knowledge management requires strong sponsorship, careful planning, and crisp execution. Because participation in knowledge sharing is easily resisted; however, the behavioral and cultural aspects of these projects require particular attention. Although knowledge management is a relatively new topic in pharmaceutical development and production, upstream functions such as discovery research and medical affairs have accumulated considerable experience. This experience suggests pitfalls to avoid, including an overly technology-centric approach, the neglect of knowledge structures, and failure to adequately resource content maintenance and user support. Finally, the progress and impact of the knowledge management program must be monitored using a combination of objective and narrative methods that is appropriate to the situation and acceptable to key stakeholders.

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How Smart Leaders Leverage Their Experts: Strategies to Capitalize on Internal Knowledge and Develop Science, Engineering, and Technology Expertise

by Carla O'Dell and Lauren Trees

This article presents strategies and tactics for leveraging scientific and technical experts more efficiently while accelerating the rate of learning for new hires and mid-career professionals. The findings are based on in-depth research conducted by APQC, a member-based nonprofit benchmarking organization.

Many industries are contending with shortages of experts in Scientific, Technical, Engineering, And Math (STEM) specialties. Rather than revisit the well-known efforts of companies to recruit STEM talent, the American Productivity and Quality Center (APQC) turned the problem on its ear and asked: How can organizations leverage the experts they have, while at the same time, accelerating the rate of learning for new hires and mid-career employees? Although training for new hires is critical, our findings suggest that organizations are focusing more attention on newcomers while investing less to develop mid-career professionals than the urgency led us to expect.

To identify needs and approaches, we interviewed APQC members from a variety of industries in organizations with large contingents of scientific, engineering, and technical employees. We would like to thank executives from the organizations shown in Table A for being part of our initial round of interviews. Your perspective helped shape our subsequent research.

Initially, we focused our research through the lens of Knowledge Management (KM), thinking about the role of communities and networks, content platforms, expertise locators, and collaboration tools in leveraging current experts. However, our interviews quickly revealed that these KM approaches were being combined with a host of others – everything from structural approaches (e.g., consolidating senior experts in a regional or global center of excellence) to

• Alcoa	• MWH Global
• Baker Hughes	• Nalco
• Chief Oil and Gas	• NASA
• Deere & Company	• Pfizer
• Devon Energy	• Rockwell Collins
• Ecopetrol	• Schlumberger
• Merck	• U.S. Army ARDEC
• MITRE	

Table A. Organizations which were part of the initial round of interviews.

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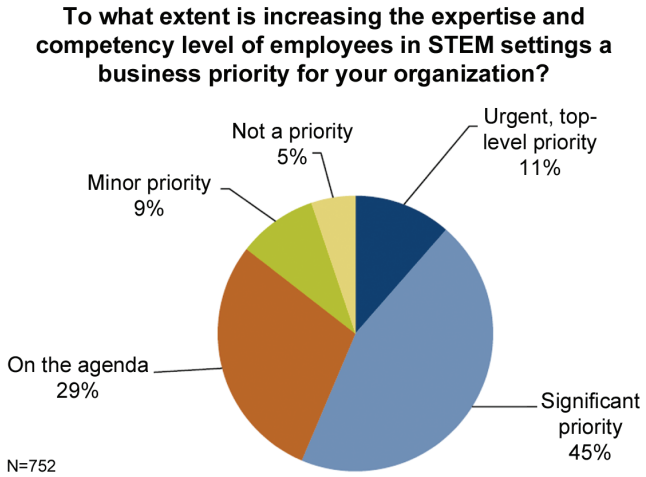

Figure 1. Survey of APQC's audience in technical and engineering disciplines, business excellence, KM, and HR.

HR-driven technical talent management[1] and training and development programs.

We then conducted a short survey of APQC's audience in technical and engineering disciplines, business excellence, KM, and HR to get their perspective on the issues raised in the interviews. Clearly, we touched a chord. We immediately received more than 750 valid responses with more than half rating STEM competency and expertise development as an urgent or significant priority for their organizations - *Figure 1*.

In this first of a series of white papers and research bulletins, we present highlights of our findings and invite commentary and suggestions for future research. Among the big questions we addressed:

1. Where are the expertise gaps faced by scientific, technical, and engineering organizations?
2. What is driving the urgency to close these gaps?
3. How are organizations leveraging the experts they have to close the knowledge gap between experts and mid-career employees?
4. How does this differ from the approaches used to build the competency of novices and newcomers?

Three Crucial Knowledge Gaps

Technical leaders told us they are contending with three knowledge gaps needed to meet today's technical needs and tomorrow's growth: one focused on turning mid-career employees into true experts, another on developing novices and newcomers so they can work independently and begin contributing to the organization, and a third related to the speed with which new knowledge is created and applied to emerging challenges and opportunities.

Developing Experts

At the top end of the expertise ladder, few organizations have sufficient candidates qualified to step into senior roles, whether as technical leaders or subject matter experts. We refer to this disparity between mid-career employees and long-tenured experts as the "expert/nex'pert" gap, borrowing a term coined by Lockheed Martin's KM team.

Heretofore, this gap had not reached crisis proportions because employees nearing retirement have been induced to stay on longer due to incentives by the firm, declines in their retirement portfolios during the last recession, or both. With the economic recovery, cracks in this stop-gap are starting to emerge. The current pool of experts is spread thin, and there simply aren't enough mid-career employees ready to step into their shoes.

Bringing Newcomers Up To Speed

The second gap is the need to help novices and newcomers increase their competency, perhaps faster than previously required. Based on our data, this second knowledge gap is being addressed more comprehensively and strategically than the first. Fifty percent of our audience reports that their organizations have significant or fully integrated efforts to support learning and development for novices, whereas only 37 percent have similar initiatives in place for mid-career professionals - *Figure 2*. Many – 42 percent – say they see a

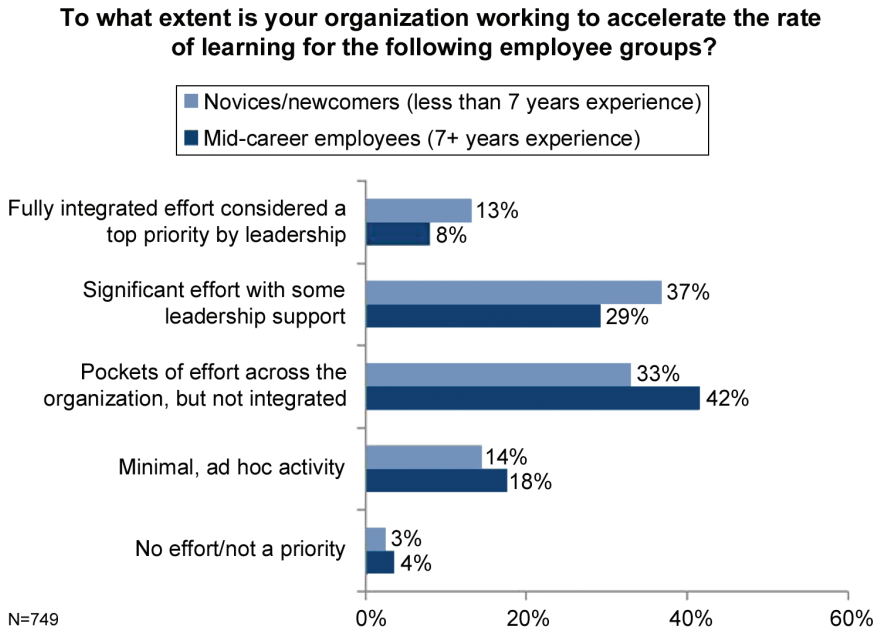

Figure 2. Support for learning and development of novices and mid-career professionals.

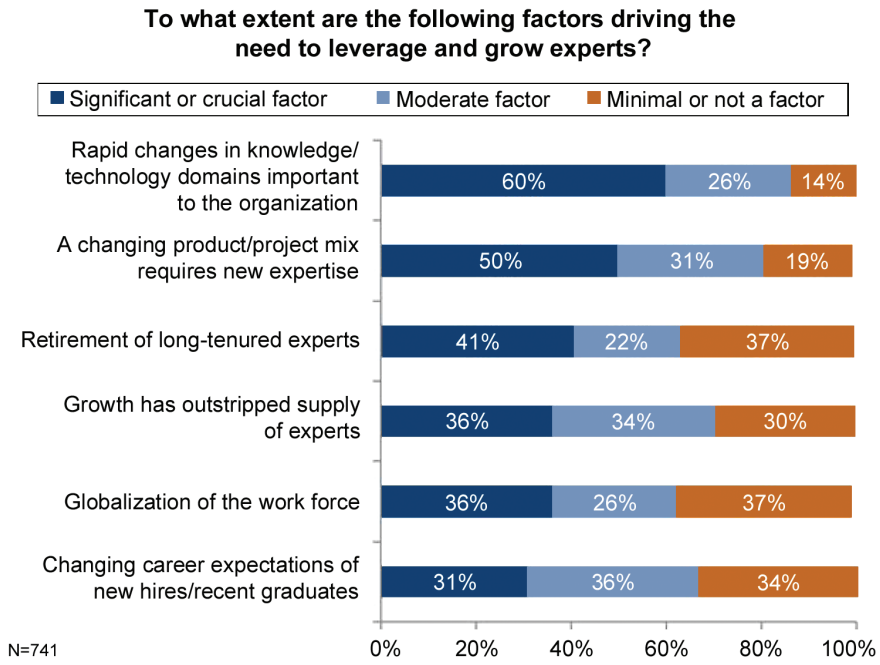

Figure 3. Reasons behind the need to leverage and grow experts.

smattering of activity to develop nex'perts into experts, but no overarching strategy guides and sustains these efforts.

It is possible that the type of specialized knowledge mid-career employees need does not lend itself to an integrated approach. However, we suspect a different reason: whereas the need to bring new-hires up to competency is a broad, obvious challenge recognized by both HR and business leaders, the gravity of the nex'pert shortage is clear only to those who fully understand the knowledge domains and work processes in each corner of the organization.

From the outside looking in, a nex'pert may look prepared to step into a technical leadership role, with the true knowledge and experience gaps becoming apparent only after the long-tenured expert has walked out the door.

Addressing New and Emerging Knowledge

The third gap may be the most urgent piece of this problem, and it is not a function of retiring employees or green newcomers. In many cases, technologies and markets are changing so rapidly that it is new knowledge and expertise that is in short supply.

When we asked our audience about the reasons behind their need to leverage and grow experts, the most common responses focused on emerging technologies and shifting product mixes – not the aging work force or the requirements of globalization or expansion - *Figure 3*.

The type of expertise in demand at these organizations cannot be transferred from departing veterans and yet must be developed quickly, sometimes by conscripting talent and content from other disciplines.

What Shapes an Organization's Approach?

We found that three elements fundamentally shape the approaches used to close these gaps:

1. The nature of the knowledge
2. The nature of the work
3. The nature or style of technical teams

The Nature of the Knowledge

In technical areas, it has become a truism to say that the amount of content is exploding. Deere, MITRE, Nalco, Baker Hughes, and many others cited the challenge of dealing with an overwhelming amount of data and information, housed in multiple locations, and not tagged the same way. Not surprisingly, enterprise content management is a very high priority.

Probing further, we discovered that technical organizations need and benefit from three distinct kinds of expert knowledge, depicted in Figure 4:

- *Explicit* knowledge, which includes theories, frameworks, facts, basic courses, techniques, processes, and algorithms core to specific STEM disciplines as well as the results of external research.

Figure 4. Skills and knowledge needed in STEM Disciplines.

- *Tacit* knowledge, which is derived from years of hands-on experience.
- *Deep* knowledge, which is organization-specific and cannot be hired from outside.

In addition, firms need to foster more fundamental business skills, such as the ability to manage projects and balance the needs of diverse stakeholders.

Explicit Knowledge

STEM fields lend themselves to clearly defined knowledge domains, officially designated experts, and career ladders leading to expert status. While these divisions provide many advantages, the compartmentalization can lead relevant knowledge and solutions to be buried in discipline-specific taxonomies and silos – which becomes a serious problem when organizations are faced with emerging cross-disciplinary technical challenges.

Another defining characteristic of STEM knowledge is that it changes with every new invention, discovery, or best practice from both inside and outside the organization. STEM workers need consistent access to experts as well as the latest research and innovations to stay current. MITRE, Merck, and other scientifically focused firms maintain productive and very symbiotic relationships with a larger ecosystem of academic and government researchers for this purpose, and many organizations rely on special libraries to help them manage the flow of internal and external content.

The extended value chain – including partners, suppliers, and customers – represents an additional source of potential knowledge. For example, Merck has 150 – 200 external partners just in one small area of its business, all of whom have knowledge and experts that Merck wants to tap into. This type of collaboration requires the development of sophisticated business rules and secure technologies.

Tacit Knowledge

STEM workers need easy access to content to do their jobs, but it is perhaps even more important to give them opportunities to develop deep, experience-based knowledge.[2] However, our interviewees emphasized that many of the tacit knowledge and experience gaps organizations are seeing are not simply technical.

At NASA, for example, employees need a range of competencies, including project management skills (legacy of excellence at NASA), lessons learned, product knowledge, and an understanding of how to work in complex environments.

NASA CKO Ed Hoffman has a very insightful definition of complexity: the number of knowledge exchanges and the diversity of the participants needing to be coordinated determine the complexity of a NASA project. The greater the multidisciplinary complexity encountered with new technologies and big projects, the more social and organizational skills project managers must acquire and use.

This point was emphasized by many of our interviewees, along with the importance of more classic project management skillsets.

Transferring Tacit Knowledge at Lockheed Martin

Lockheed Martin employees must learn a lot that is not taught in schools, partly because it is classified and partly because the fields are too specialized to merit college tracks. The organization uses mentoring and on-the-job training to fill in some gaps, but it also supports formal knowledge transfer and technical talent management programs to pass on critical skills and expertise.

A formal knowledge continuity process assembles dedicated teams of experts, nex'perts, and more junior employees to identify critical knowledge in a particular discipline, transfer that knowledge in the context of real work, document what was transferred, and then have the nex'perts and novices apply the knowledge with the expert present in order to cement the learnings. Lockheed Martin's business areas have embraced this team-based knowledge transfer process, and the corporate function views it as a competitive differentiator.

Deep Knowledge

To further complicate the knowledge needs of STEM disciplines, a significant subset of the required tacit and explicit knowledge is unique to a particular firm and can take many years to acquire. Organizations cannot hire this type of knowledge from outside, even by luring seasoned professionals away from their competitors. For this reason, STEM fields have a stronger history of apprenticeship and on-the-job learning, as well as an established focus on learn-do-teach embedded in the career life cycle.

In sum, much of the most valuable knowledge is unstructured, tacit, and based on experience in the context of the organization.

Leveraging the Experts You Have

The nature of technical knowledge, work, and teams underpins a strong business case to improve access to knowledge and expertise while providing targeted development opportunities for the next generation of experts. And there is no question that stakeholders across technical organizations see a need to close current expertise gaps.

Our research suggests that a majority of technical, HR, talent, knowledge, and content managers see this as a priority and are using the tools in their arsenals as shown

Going Back to School at General Mills

Over the past 20 years, General Mills has developed internal schools to train technical employees in the making of particular products and more generally applicable technical expertise. Product-focused programs include cereal school, soup school, yogurt school, and bars school, whereas technical training programs include food chemistry, microwave heating, and food polymer science.

These schools also help ensure global consistency of products regardless of the location of the plant. The use of pilot plants allows for a hands-on learning experience.

"We say that you have to learn cereal-making through the soles of your feet, so you have to get out of the plant and actually experience it, smell it, and learn how to make it," explains Shari Keivit, training and development manager for General Mills' Innovation, Technology, and Quality group.

Collectively, the schools are staffed by one manager, who has a technical background and practical R&D experience and who guides the work of the schools. In addition to the manager, approximately 80 subject matter experts provide content development and instruction.

The natural competition that has arisen between experts has generated a spirit of continuous improvement in the schools and helped them become a key tool to transfer deep technical knowledge.

in Figure 5 to address the challenge. Classic solutions like training, technical conferences and forums, content repositories, and mentoring are in place at almost all the firms we surveyed, whereas programs targeting high-potential employees, expertise locators, and formal programs to capture and transfer knowledge from those nearing retirement are slightly less prevalent.

Given that all the approaches we tested were in place at more than 50 percent of the participating organizations, the survey revealed few truly new or emerging solutions.

However, even though most organizations gravitate toward the same approaches, their perceived effectiveness varies widely across the survey population - *Figure 6*.

Training and mentoring receive the highest overall ratings – a testament to the value of in-depth learning. Organizations interested in developing nex'perts must engage their current crop of experts in direct person-to-person knowledge sharing, whether one-to-many through lectures and team-based learning or one-on-one through mentoring and apprenticeship.

Unfortunately, mentoring requires a significant time investment from the technical leaders who serve as mentors, and advanced training can be equally high-touch when experts help design and deliver lessons.

Most organizations do not have enough expert trainers and mentors to bring nex'perts up to speed, nor do they have the years to wait for training and mentoring programs to achieve their full effect.

APQC recommends several categories of complementary approaches to help address the scarcity of experts and enable nex'perts and newcomers to take on additional responsibility in the short term. These include:

1. *Structural approaches* – gathering experts into a center of excellence or allocating them to specific regions or project areas
2. *Knowledge management approaches* – leveraging technical networks and forums, communities of practice, profile-based expertise locators, technical conferences, and formal processes to codify and transfer expertise
3. *Content management approaches* – improving access to content and learning through contextual search, special libraries, and clear ownership of content

Technical Management	HR and Talent Management	Knowledge Management	Content Management
• Standardized processes and designs	• STEM recruiting partnerships	• Communities of practice	• Enterprise content management systems
• Technical networks	• In-person and virtual training	• Profiles and expertise locators	• Central repositories
• Technical conferences and forums	• Dual career tracks	• Formal knowledge transfer approach targeting experts	• Taxonomies
• Mentoring and assignments	• Competency management programs	• "Books" or databases of critical knowledge	• Federated search
• Internal technical "schools"	• Programs targeting high-potential employees		• Customized views and alerts

Figure 5. Approaches by discipline.

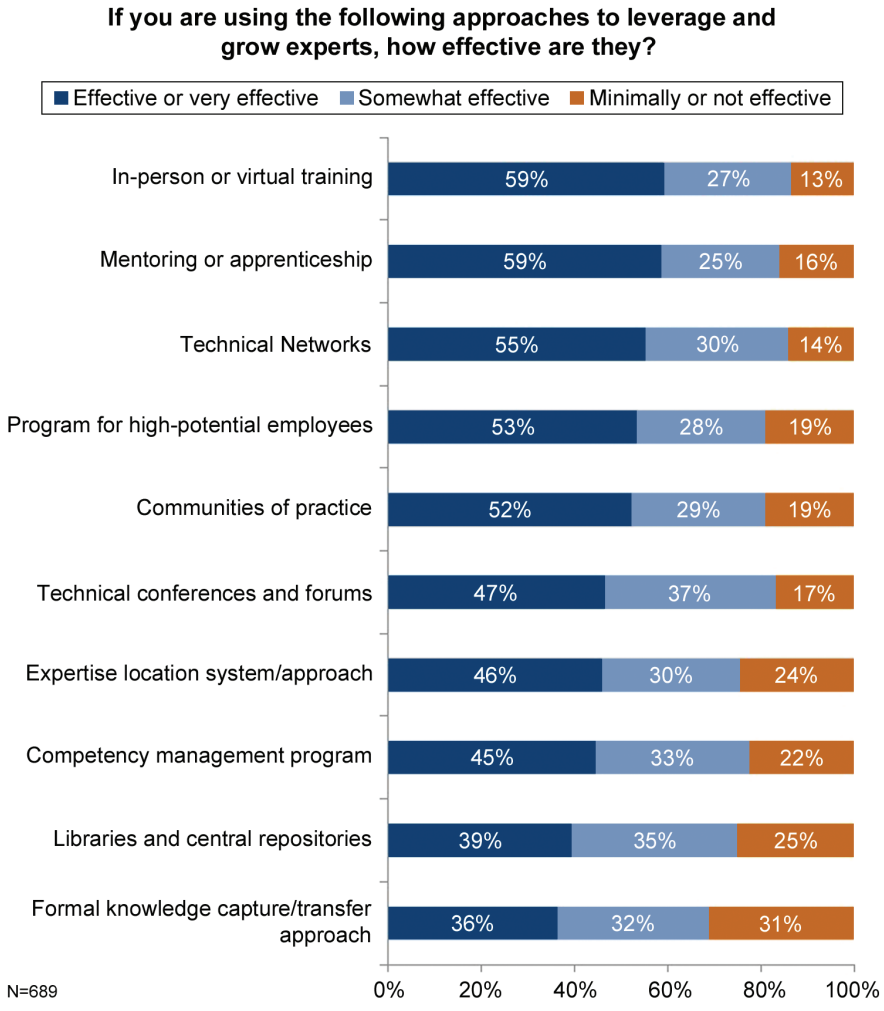

Figure 6. Approaches and perceived effectiveness.

The data suggests that some approaches – such as communities of practice and technical networks – are already providing significant value to organizations looking to leverage experts more effectively and build skills and competencies. Others – most notably expertise location, libraries and repositories, and knowledge transfer approaches – may represent opportunities for improvement.

Structural Approaches

As demand for expertise grows, many organizations are rethinking how they allocate senior-level staff across projects and locations - *Figure 7*. Experts who used to focus more narrowly are being asked to provide high-level support to a broad array of programs and projects, guiding nex'perts and mid-career professionals on strategic planning and design, reviewing their work at key milestones, and helping any tricky technical problems that arise.

When done right, this approach allows organizations to get the most out of their existing experts while providing valuable development opportunities to those a few rungs down the career ladder.

Central and Regional Technical Hubs

The most comprehensive structural approach to capitalize on a small group of experts involves creating a center of excellence or central team to deliver expertise and technical support.

In addition, some organizations are exploring the idea of allocating mid- or senior-level engineers to guide their younger counterparts in specific regions or time zones. Engineers would still have access to global subject matter experts through communities of practice, but regional representatives can build more intimate relationships with newcomers while taking some of the burden off global resources to answer lower-level questions.

Fellows Programs

Another strategy with a long history at technical firms involves designating an elite core of experts as official Fellows of the organization. At Lockheed Martin, the LM Fellows program recognizes the top one percent of technical experts and makes them available to support programs and supply expertise where it is needed. The program allows Lockheed Martin to maximize the contributions of its top experts, rather than siloing them

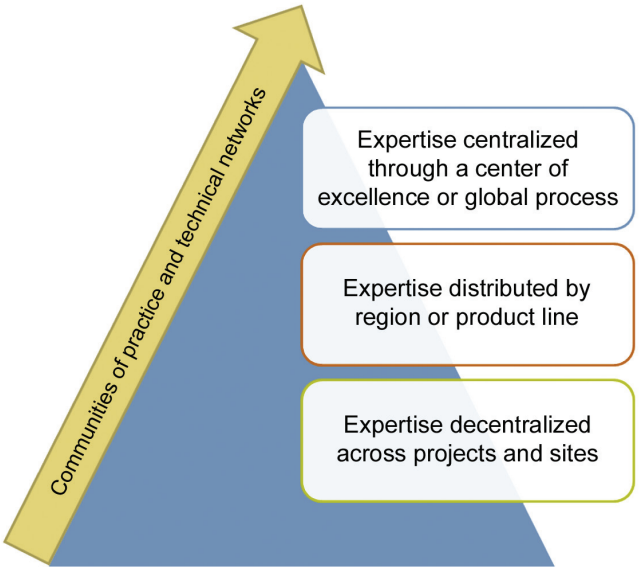

Figure 7. Structural approaches to distribute experts.

in one program. It also brings together the organization's greatest minds and allows them to engage in targeted collaboration around technical and strategic challenges.

> *"In addition to structural solutions, organizations are applying a range of knowledge sharing tools and approaches to address expert shortages and promote competency development for newcomers and mid-career professionals.*

Global Standardization

A third structural approach involves creating standardized design and operational best practices, embedding them in the flow of people's work, and using these tools to help nex'perts and newcomers work on projects that might once have been the sole purview of experts. This approach is more applicable to some industries than others and is especially suited to repeatable processes performed at multiple sites.

At MWH Global, for example, an official design framework lays out a standard approach to design work and specifies templates that can be used to jumpstart new design projects. The organization also has built standardized tools, called mTOOLS™, to support information management and project delivery. By using the mTOOLS repeatedly and constantly improving on them by driving insights gained into real-time changes, MWH Global has created a mechanism for capturing and deploying continuously improving knowledge into the flow of work in collapsed timeframes.

Knowledge Management Approaches

In addition to structural solutions, organizations are applying a range of knowledge sharing tools and approaches to address expert shortages and promote competency development for newcomers and mid-career professionals.

The most prominent– and, we would argue, most vital– include communities of practice, technical networks, collaboration workspaces for project teams, formal knowledge capture and transfer processes, and tools to help surface experts and knowledgeable people across the organization.

Communities and Technical Networks

In general, communities of practice,[3] technical networks, and team workspaces serve different purposes. Communities tend to steward content and knowledge related to scientific or technical disciplines, such as reservoir engineering or polymer science, in order to enable professional development and cross-boundary collaboration.

Communities are often built to enable long-standing technical networks, which in earlier times met periodically for brown-bag lunches. Both communities and technical networks are designed to connect people around a body of knowledge, which is what sets them apart from project-focused team spaces like those housed in SharePoint.

Communities and networks are ubiquitous within technical organizations these days: 86 percent of organizations responding to our survey report using both. They are also among the most valuable tools for managing access to expertise and accelerating competency development. Although technical networks have a slight advantage, more than half of organizations with communities and networks consider both to be effective at bridging expertise gaps.

The resources that communities and networks provide to members vary widely, with some focusing on self-service content and learning and others emphasizing collaborative problem solving through technical conferences, discussion forums, and social media.

In many organizations, communities and networks are where people go to search out and talk to technical experts– an approach that tends to work well as long as the experts are engaged and participating. But communities also can help regulate the stream of questions and requests with which experts are bombarded, enabling organizations to make the most of a scarce resource.

At Devon Energy, for example, community moderators act as gatekeepers and buffers between experts and the rest of the community membership. The moderator brings the appropriate SME into conversations when needed, but if a request can be answered easily through existing documentation or solutions, the moderator may redirect the member to other resources instead.

This helps minimize the burden on experts while still ensuring that critical questions get answered quickly and accurately. It also familiarizes newer employees with content and learning resources that may help them with future problem solving.

Expertise Location

A prerequisite to leverage the experts you have in the organization is to know who and where they are– in other words, you need an expertise location tool. People search is a major objective at many of the organizations we interviewed and applies to the search for both experts and hidden knowledge and expertise.

For novices and newcomers, knowing who to ask for help and advice is often a big problem. Many of the interviewed organizations have identified this as a priority and have

adopted technology and other approaches to address the issue. While some have built custom tools, others –including Deere –are using SharePoint MySite as a simple, integrated solution for profiles.

APQC's research on expertise location suggests that the best approaches combine profile-based expertise locator tools with communities of practice, discussion forums, and collaboration sites. Blogs and social networking platforms are also useful in connecting people to experts, but they tend to supplement– rather than replace – other tools.

When it comes to expertise profiles, organizations should import as much data as possible from HR and other systems, limiting the number of fields employees must fill out themselves. Firms should also answer the "What's in it for me?" question by making it clear that participation is part of people's jobs and tying it to leadership visibility and career advancement.

Knowledge Capture and Transfer

Along with efforts to connect nex'perts and newcomers to content and expertise, many firms have approaches designed to capture and communicate at-risk knowledge that is essential to strategic objectives and ongoing operations.

In APQC's 2013 *Transferring and Applying Critical Knowledge* study, we observed two distinct strategies at play at the best-practice organizations. Some– including Lockheed Martin, Kraft Foods, and Lloyd's Register– have formal, top-down processes to identify experts with critical at-risk knowledge, pull that knowledge out of their heads, and share it with the next generation of experts coming down the pipeline.

Most of these organizations treat knowledge capture as a project with a defined project plan, clear roles and responsibilities, milestone reviews, and a deadline. They also tend to engage their nex'perts in the knowledge capture process as a development opportunity, asking them to help codify and steward the body of knowledge over time.

Other best-practice organizations have more organic approaches to capture and transfer critical knowledge. They provide infrastructure to support transfer, but they do not dictate how and when transfer occurs to the same degree.

Based on the high number of organizations citing rapidly changing knowledge domains, technologies, and product/project mixes as key drivers of their need to grow and leverage experts, we expect the less structured knowledge transfer techniques to become bigger players over the coming years. This does not mean that organizations will stop formally codifying expertise, but it may impact the tools and processes used for that purpose, especially in rapidly progressing industries.

Content Management Approaches

Knowledge and content management are often intertwined, but we have opted to separate the two in order to highlight content management as an urgent need.

Many of the organizations we interviewed, including Deere and MITRE, cited access to internal and external content as a key success factor for operating with a limited pool of experts and supporting learning and development.

A rich collection of well-structured, easily accessible content helps less experienced people get up to speed and reduces the burden on experts to answer common questions. It also helps nex'perts and experts stay on top of developments in their fields, whether that means keeping up with external research and trends or learning about best practices and lessons learned from inside the organization.

Open Sharing

For many firms, the first content management hurdle is creating an environment where scientists and engineers feel comfortable sharing content in a central repository or another location where it can be indexed for search. STEM work often touches upon intellectual property, trade secrets, and proprietary processes, so the inclination is to lock everything down and throw away the key. However, the most successful organizations make open sharing the default, restricting access only when there is a specific need to do so.

Search and Findability

The next challenge is to make content as easy as possible to access. Sometimes, the tactics are as basic as choosing the

Enterprise Taxonomy at Baker Hughes

Baker Hughes' enterprise taxonomy is designed to standardize technical terms and definitions across the organization. Prior to its development, different divisions had their own acronyms and terminology, which made it difficult for them to work together. The current system provides a common language that helps employees from different parts of the organization collaborate to deliver cross-product solutions to customers.

Baker Hughes has integrated the taxonomy into its other content and KM tools so that policies, processes, and procedures as well as documents, wiki pages, and discussion questions are tagged with the appropriate terms. This means that, if an employee is interested in a particular topic, he or she can use the taxonomy to filter or drill down to the relevant content in search results across multiple formal and informal repositories. The ability to make content more visible and improve enterprise search were key to the taxonomy's value proposition and to obtaining buy-in from both leadership and the work force as a whole.

right format; however, the biggest concern is making content visible to employees when they have questions or encounter challenges.

Search is the most obvious solution, especially as algorithms improve and are able to return results from diverse repositories. However, top firms combine search with a range of other tools and enablers, including taxonomy, opt-in alerts, customized views based on an employee's role or past history, and data on how popular or well-rated a particular content item is.

Special Libraries

Several organizations we interviewed also emphasized the importance of special libraries and librarians to facilitate use of external research and information. Given the pace of change, it is impossible for STEM workers – even full-blown subject matter experts – to keep up with trends and developments on their own. Librarians not only manage subscriptions and ensure access to the latest information, but they also perform targeted searches on employees' behalf and help them filter through published research to identify breakthroughs and trends with implications for the business.

Approaches to Create New Knowledge

The structural, KM, and content management approaches discussed above are vital to operating with a limited pool of experts and preparing the next generation for technical leadership roles. However, our survey suggests that some of the biggest challenges organizations are facing are less about a shortage of experts than about how experts can help leaders respond to rapid changes in technical disciplines, technologies, and markets. In addition to making experts available for sharing and learning, firms need experts and nex'perts from different domains to put their heads together to develop new ideas and ways to apply emerging knowledge to strategic goals.

Figure 8. Approaches to create and apply new knowledge.

Technical disciplines already have a range of tools to address these issues, from dedicated innovation labs to crowdsourcing and open innovation[4] programs - *Figure 8*.

Special libraries also play a role by streamlining access to external breakthroughs and developments. However, KM teams can support these efforts by supplying tried-and-true collaboration solutions, especially when the goal is teamwork across different parts of the business. In fact, some of the same KM approaches used to support access to content and experts can be adapted slightly to facilitate cross-disciplinary innovation and the creation of new knowledge.

Lockheed Martin uses its LM Fellows Program to give experts and nex'perts opportunities to explore emerging fields and tackle cross-program challenges. All the LM Fellows are invited to attend an in-person conference every 12 to 18 months, and they are encouraged to invite rising technical talent in their areas to attend as their guests. The conferences feature collaborative meetings and workshops where attendees brainstorm on topics important to the organization, including both technical issues and strategic ones such as affordability and program sustainment.

Fellows and nex'perts are also encouraged to participate in LM Fellows action teams, ongoing groups that meet virtually to explore subjects ranging from systems architecture to fluid dynamics. Usually, when a conference workshop or virtual meeting leads to the development of a new idea or solution, the LM Fellows involved are invited to present those findings to organizational leadership.

While some industry leaders are already taking advantage of communities and collaboration tools to support cross-disciplinary innovation, we believe this represents an untapped opportunity for many technical firms.

Activities where experts push the boundaries on collective knowledge and nex'perts participate as learners and secondary contributors have the potential to address both innovation and learning and development objectives.

And as an added bonus, they tend to be more appealing than traditional knowledge-sharing and mentoring structures, garnering improved engagement and participation from all levels of the work force.

A More Cohesive, Integrated Approach

Our research has revealed many organizations that are successfully harnessing the tools at their disposal to address expertise shortages, accelerate learning and development, and encourage the co-creation of new knowledge.

However, the effectiveness statistics on key approaches

– everything from communities of practice to expertise locators and knowledge transfer programs – suggests that a large percentage of firms need to rethink, redesign, or reemphasize the techniques they are using to bridge the expertise gap. In addition, technical leaders are still grappling with ways to address rapid change and build the knowledge and expertise needed for the future.

…a large percentage of firms need to rethink, redesign, or reemphasize the techniques they are using to bridge the expertise gap.

Although most of the approaches we have cited can be implemented on their own, we recommend looking at the issue more holistically and purposefully combining techniques from executive management, HR, KM, content management, and the technical disciplines themselves.

Important problems often require cross-functional solutions, and our data suggests that the degree of integration among multi-disciplinary approaches is positively correlated with their effectiveness, both individually and in totum.

Even organizations with mature knowledge and talent management programs may benefit from more inclusive strategies to address expertise gaps and accelerate time to competency – especially for the mid-career professionals in which some firms appear to be underinvesting.

Read the full report: *How Smart Leaders Leverage Their Experts: Strategies to Capitalize on Internal Knowledge and Develop Science, Engineering, and Technology Expertise*, http://www.apqc.org/knowledge-base/documents/how-smart-leaders-leverage-their-experts-strategies-capitalize-internal-kno.

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About the Authors

Carla O'Dell, Chief Executive Officer of APQC, is considered one of the world's leading experts in Knowledge Management (KM). Under O'Dell's direction, APQC launched its first KM Best Practices Study, "Emerging Best Practices in Knowledge Management," in 1995. Since then, APQC has conducted more than 30 consortium studies on topics related to KM, involving more than 500 participating organizations and producing the world's largest body of actionable best practices in designing, implementing, and measuring KM programs. O'Dell is the author of *The Executive's Role in Knowledge Management* (APQC, 2004) and co-author of *If Only We Knew What We Know: The Transfer of Internal Knowledge and Best Practice* (Free Press, 1998). She most recently co-authored the definitive book on implementing a KM program, T*he New Edge in Knowledge: How Knowledge Management Is Changing the Way We Do Business* (Wiley, 2011).

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From Science to Knowledge: An Overview of the Evolution of Knowledge Management in Regulatory Guidance

by Dr. Anne Greene and Dr. Kevin O'Donnell

This article explores the emergence of the importance of knowledge management in key regulatory guidance over the last decade.

"The views expressed in this paper are those of the author and should not be taken to represent the views of the Irish Medicines Board."

A quick dive into the questions *"what is knowledge?"* and *"how is it formed?"* will open up a world of theories and beliefs on the subject that even Aristotle and Plato could not agree on! It is no wonder, that the pharmaceutical regulators have only relatively recently addressed the complex subject of ***knowledge management*** in their guidance documents.

The recent draft of Annex 15 to the EU Guide to Good Manufacturing Practice "Qualification and Validation" (issued for comments on 6 February 2014) refers to knowledge nine times, and includes a definition for knowledge management in its glossary.

The new draft explicitly links knowledge with risk assessment, (process) understanding and validation. Stating that a quality risk management approach should be used for validation activities, with risk assessments repeated as required, in light of increased knowledge and understanding from any changes during the project phase or during commercial production. It makes reference to the use of existing product knowledge when determining the number of process validation batches that may be required, and it states that process knowledge from development studies should be the basis for validation activities.

Conversely, the current Annex 15 (issued in 2001) has no mention of the topic, let alone a definition in the glossary, leading one to deduce that in the years between 2001 and 2014, *knowledge management* became an important issue for regulators in the manufacture of safe effective medicines.

This article explores the emergence of the importance of knowledge management in key regulatory guidance over the last decade.

The Evolution of Knowledge Management Within the New Paradigm

In August 2002, the FDA announced the Pharmaceutical cGMPs for the 21st Century Initiative promoting, *"A science- and risk-based approach to product quality regulation incorporating an integrated quality systems approach."* The emphasis in this new approach was on risk and science. On rereading this document 12 years later, one can't help but notice the absence of the term "knowledge" in it. However, what is interesting is the number of times science is mentioned (more than 15 times), while *knowledge* is only mentioned once in a section under the heading *"science-based policies and standards"* the document suggests:

"Significant advances in the pharmaceutical sciences

*and in manufacturing technologies have occurred in the last two decades. While this **knowledge** has been incorporated in an ongoing manner into FDA's approach to product quality regulation, the fundamental nature of the changes dictates a thorough evaluation of the science base to ensure that product quality regulation not only incorporates up-to-date science, but also encourages further advances in technology. Recent science can also contribute significantly to assessment of risk."*

The inherent relationship between science and knowledge cannot be disputed, as evidenced by the various definitions shown in Table A.

The inherent relationship between science and knowledge cannot be disputed…"

However, if we limit the knowledge we value to that which is aligned with science, which one could argue is truly *"explicit knowledge,"* one is ignoring a whole range of *"tacit knowledge"* spanning across the life cycle of the product. In fact, to quote one of the most famous scientists of recent times, Albert Einstein; *"knowledge is experience, everything else is just information."*

Indeed one could ask:

As the value of knowledge became more apparent throughout the decade, has regulatory thinking emerged over the journey to recognize knowledge as the key, and science to be a subset of knowledge, rather than knowledge itself?

A review of key regulatory guidance documents, in the order they were released, for mention of *knowledge* and *knowledge management* throws some light on this question.

1. Guidance for Industry PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance – *September 2004*

In September 2004, the FDA issued their PAT guidance. A review of this document shows that there are more than 20 references to knowledge included, half of which occur in a section on PAT tools under the heading *"Multivariate Tools for Design, Data Acquisition and Analysis."* The development of a knowledge base consisting of scientific understanding is encouraged, through the use of multivariate mathematical approaches, in conjunction with knowledge management systems. There is a further section entitled *"Continuous Improvement and Knowledge Management,"* that mentions knowledge approximately five times, and here 'information technology systems that support knowledge acquisition' through data collection are encouraged. The article suggests:

"Today's information technology infrastructure makes the development and maintenance of this knowledge base practical."

The emphasis in this PAT guidance is on *understanding*, (product, process and equipment understanding) and *continuous improvement*. The word *understanding* appears more than 25 times, and the section titled "Process Understanding" concludes by stating:

"Therefore, continuous learning over the lifecycle of a product is important."

So while the PAT guidance recognized the importance of process understanding and continuous learning, the emphasis is on explicit scientific or mathematical knowledge with the use of IT knowledge management solutions to analysis and store the knowledge, there is no real evidence of the importance of capturing tacit knowledge in the document.

A branch of knowledge or study dealing with a body of facts or truths systematically arranged and showing the operation of general laws	Dictionary .com
Systematic knowledge of physical or material world gained through observation and experimentation	Dictionary.com
Knowledge, as of facts or principles; knowledge gained by systematic study	Dictionary.com
A systematically organized body of knowledge on a particular subject	Oxford English Dictionary
Archaic Knowledge of any kind	Oxford English Dictionary
Knowledge about or study of the natural world based on facts learned through experiments and observation	Merriam Webster Dictionary

Table A. Science definitions.

2. ICH Q9 – *November 2005*

As the tripartite suite of ICH guidelines Q8-Q10 were prepared in parallel rather than sequential, the thought process in the development of them most likely straddles the three documents. However, we will review them here in the order of release to keep with the spirit of the article.

> *"knowledge is experience, everything else is just information.*
>
> – Albert Einstin

ICH Q9 boldly states that one of the two key principles of quality risk management is:

> *"The evaluation of risk to the quality should be based on* ***scientific knowledge****."*

The document then goes on to mention "new knowledge," "current knowledge" and "available knowledge," with the clear emphasis on *scientific knowledge*. The section on Preliminary Hazard Analysis (PHA) identifies "prior experience or knowledge" as a method of determining risks.

However, most noteworthy from ICH Q9 is a discussion around uncertainty, where the occurrence of "knowledge gaps" is mentioned. It is suggests that uncertainty can be:

> *"…due to combination of incomplete knowledge about a process and its expected or unexpected variability. Typical sources of uncertainty include gaps in knowledge gaps in pharmaceutical science and process understanding…"*

By linking science and understanding gaps, to knowledge gaps, we are beginning to see the emergence of knowledge as an overarching concept, of which both science and understanding are a subset, albeit still with a leaning toward explicit knowledge.

3. ICH Q8 – *November 2005*

The first revision of ICH Q8 was issued in November 2005, and while this was subsequently revised to Revision 2 in 2009, it is worth a quick review to capture the evolving thought process, in light of the question we are exploring here. As ICH Q8 focuses on pharmaceutical development (a mainly scientific process), it is not surprising that *knowledge* appears in the document (10 times). However, on reading Q8, the actual management of knowledge is not that strongly emphasised. That came later, with ICH Q10. But what is beginning to emerge is a tendency to use the term knowledge rather than understanding, and the emphasis on "knowledge gained" implies knowledge through experience (rather the just the information Einstein refers to in the quote above).

Indeed ICH Q8 suggests that:

> *"It should be recognized that the level of knowledge gained, and not the volume of data, provides the basis for science-based submissions and their regulatory evaluation."*

4. FDA Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations – *September 2006*

In September 2006, the FDA issued guidance for industry on a Quality Systems Approach to Pharmaceutical cGMP regulations, to demonstrate where and how elements of modern quality systems can fit within the requirements of cGMP regulations. This document provides a comprehensive overview of how pharmaceutical companies can integrate robust quality systems which comply with cGMP regulations, based on a "science based approach…..and an understanding of the intended use of the product." While knowledge is mentioned seven times, the emphasis is on using technical experts (engineers and development scientists) who have an *understanding* of pharmaceutical science, risk factors and manufacturing process.

In addition in the guidance, the need for establishing and evaluating training is identified, as also is capturing of data. For example:

> *"A quality systems approach call for the manufacturer to develop procedures that monitor, measure and analyze the operations (including analytical methods and/or statistical techniques). Monitoring of the process is important due to the limiting of testing. Knowledge continues to accumulate from development through the entire commercial life of a product."*

Again, we are seeing a strong emphasis on explicit knowledge, gained from science, data, or training.

5. ICH Q10 – *June 2008*

It is with the publishing of ICH Q10 that we can see clear evidence of *knowledge* appearing at the forefront of regulatory thinking. One need look no further than a glance of the glossary, where a definition for *knowledge management* is

included to recognize this. Perhaps the three year time gap between the publications of the ICH Q8 and Q9 documents and this ICH Q10 guideline, allowed the thought process to crystallise, and the role of *knowledge* and *knowledge management* to emerge.

While the complex question of "what is knowledge" may remain, for the first time we find a formal definition of what the international regulatory community considers *knowledge management* to be.

> *"**Knowledge management:** systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing process and components."*

It is interesting that in its knowledge management definition it is *"information"* that ICH Q10 aspires to manage, with no formal mention of experience, what would Einstein think! However, when you dive deeper into the document you can find fine examples of what is considered knowledge which infer the inclusion of experience and tacit knowledge through the use of the phrase *product and process understanding*, such as:

> *"Development activities, using scientific approaches provide knowledge for product and process understanding."*

In the section on *Process Performance and Product Quality Monitoring Systems*, we see; *"Provide knowledge to enhance process understanding, enrich the design space (where established), and enable innovative approaches to process validation."*

More significantly, rather than *science* being considered *knowledge*; Q10 suggests that scientific approaches *provide* knowledge, with knowledge rather than science being the key. Further sources of knowledge are identified in Q10 as:

- Prior knowledge (public domain, or internally documented)
- Pharmaceutical development studies
- Technology transfer activities
- Process validation studies over the product lifecycle
- Manufacturing experience
- Innovation
- Continual improvement
- Change management activities

With the last four of these sources, we are beginning to see an emergence of the value and role of tacit knowledge; however, it is interesting that prior knowledge as set out above appears to be limited to documented knowledge only.

Emphasizing the Ability to Capture and Transfer the Expanding Knowledge Base

In the section on *Management of Change in Product Ownership*, Q10 suggests that management should ensure the *"essential information is transferred."* While under the heading *Lifecycle Stage Goals*, the goal of technology transfer is described as:

> *"To transfer product and process knowledge between development and manufacturing….this knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement."*

Most critically, and indeed perhaps most challenging for industry, is the acknowledgement in the *commercial manufacturing* phase where Q10 refers to the body of knowledge continually expanding.

> *"The pharmaceutical quality system should assure that the desired product quality is routinely met, suitable process performance is achieved, the set of controls are appropriate, improvement opportunities are identified and evaluated, and the body of knowledge is continually expanded."*

Finally, ICH Q10 introduces a pharmaceutical quality system model, which identifies two enablers underpinning the elements:

- Quality risk management
- Knowledge management

One may wonder as *Quality Risk Management (QRM)* has a Q document of its own (Q9), why does *knowledge management* not have one? Perhaps, in 2002 the role of QRM was clear to the regulators, while the importance of *knowledge* and *knowledge management* emerged during the decade, and there is not yet enough clarity around the subject to tackle the task of issuing a guidance document on it.

6. Guidance for Industry Q8, Q9, and Q10 Questions and Answers (R4) – *November 2011*

The most recent publication from the ICH is found in the Q&A document published in 2011 and it clearly states that *knowledge management* is neither a system nor a new concept, but is always important regardless of the development approach and it enables the implementation of all of the concepts described in ICH Q8, Q9 and Q10. In states that in conjunction with quality risk management, knowledge management can facilitate the use of concepts such as prior

knowledge (including from other similar products), development of design space, control strategy, technology transfer, and continual improvement across the product life cycle.

It also outlines the expectation that as more complex information is generated by the variety of emerging appropriate approaches (e.g., QbD, Process Analytical Technology (PAT), real-time data generation, and control monitoring systems), it will be necessary to ensure that it is better *"captured, managed, and shared during product life-cycle."*

Q10 does not suggest an ideal way to manage knowledge or prescribe how to implement knowledge management but simply provides a framework. The Q&A document emphasizes that each company must decide how to manage knowledge, including the depth and extent of information assessment based on its specific needs.

It substantially expands on the list of potential sources of information for knowledge management, further evidencing the evolutionary nature of the important role that knowledge plays in the safety of drug products. The authors would recommend anyone assessing their KM program to review the potential sources of knowledge listed in this Q&A document for possible gaps.

While they conclude that there is no added regulatory requirement for a formal knowledge management system to be in place, they clearly state that it is expected that knowledge from different processes and systems will be appropriately utilized. No doubt we will see more inspection findings focusing on this aspect in the coming years.

7. EU GMP Guide Chapter 1 – Pharmaceutical Quality System – *January 2013*

EU GMP Guide Chapter 1 was specifically revised in 2013 to directly reflect the concepts and terminology described of ICH Q10. It contains only two references to knowledge and its management. It states that the pharmaceutical quality system should ensure that product and process knowledge is managed throughout all lifecycle stages, and that continual improvement is facilitated through the implementation of quality improvements appropriate to the current level of process and product knowledge.

However, Chapter 1 does highlight the importance of experience. In the section on GMP, it states that one of the basic requirements of GMP is that all manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications.

Conclusion

Let us finish our review by posing another question: Unless we really know (or agree) what knowledge is, can we effectively manage it? As the industry's understanding of the role and importance of *knowledge* continues to evolve a cautionary note from Stephen Hawking may provide some food for thought:

> *"The greatest enemy of knowledge is not ignorance, it is the illusion of knowledge*
>
> – Stephen Hawking

About the Authors

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Why Knowledge Management is Important to Roche

by Kate Waters

This article provides an overview of the steps on a journey to mature the knowledge management process including the overall business objectives, managing KM expectations, key initiatives and learnings, focusing on increasing awareness and understanding of the systems, processes and capabilities required to engrain KM into our culture.

Roche's 2009 acquisition of Genentech brought with it many opportunities resulting in an enhanced product pipeline and increasing product demand. However, it also raised new challenges as a result of the increased complexity of the network and in managing the consistency of interactions with multiple health authorities. Adding to this complexity, the changing demographics (aging baby boomers) and organizational optimizations help raise the awareness and needs for a knowledge management system,

Initial failure to operate as an integrated network (global function to/from site, site to site, person to person) coupled with a limited life cycle product focus, silos of information and a diverse range of "knowledge" solutions was limiting our competitive advantage. Co-incident with this was an increasing awareness of the wider pharmaceutical industry knowledge management initiatives and emerging technologies supporting knowledge man.

This is the context from which we have commenced our knowledge management journey. For Roche, Knowledge Management (KM) is a set of enabling capabilities and associated behaviors that support how knowledge is acquired, categorized, distributed and applied so that knowledge will grow and evolve over time. It provides timely access to relevant information, linked to experiences and scientific knowledge to enable better decision making at appropriate levels within the organization.

Managing the Myths

During the journey, we found ourselves continually managing some prevalent "myths" about knowledge management, they included:

1. ***Knowledge management is all about knowledge.*** Most people agree the benefits of more and better knowledge, the real question is: knowledge to what end? Knowledge management systems must start and end as

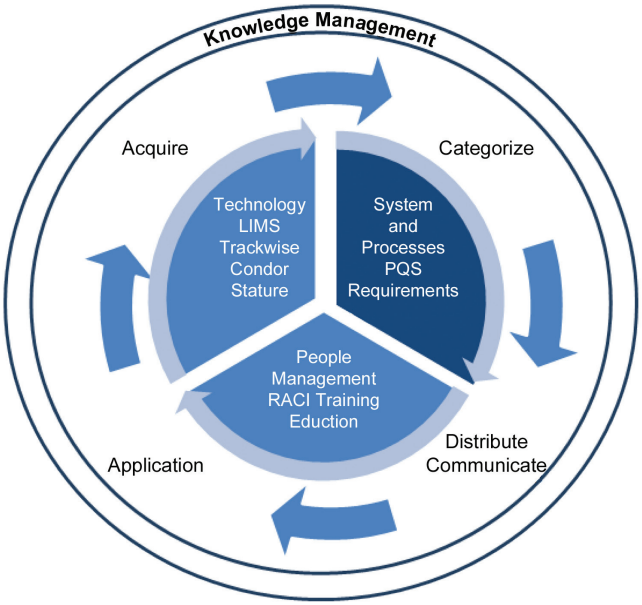

Figure 1. Roche knowledge management framework.

all other business initiatives do with a focus on delivering growth, improving operations and increasing profit margins.

2. ***Knowledge Management is all about technology.*** Technology can enable knowledge management, but it is much more important to consider, upfront, how it will be used. Clarity regarding the specific needs/problems the technology should address and also how it will integrate with existing technologies.

3. ***The goal of KM is to have a global search tool.*** Although we do need solutions designed to help the user search through large bodies of information, there are two key aspects of search technology that affect the user's success when seeking an answer: the search process and the relationship of the inquiry to the content. The search should be capable of detecting relevant sources, and then link and present the information based on the context of the inquiry.

4. ***The goal of KM is to create a document repository.*** Although document management is a goal, particularly where there is a problem finding critical information or there are redundant efforts to develop the same information. You must focus on the value and reliability of the information as much as on how the information is stored.

5. ***Knowledge management is about knowledge control.*** Knowledge management is not about maintaining a pristine database. It is about fostering an environment where people can ask questions like "does anybody know?" "What did we do when?" This means creating an open system that encourages relationship building and creating opportunities for personal interactions.

6. ***If you build it, they will use it.*** When done right, knowledge management transforms an organization. However, before you design your system, you need to consider how the system will be used, address concerns people will have about a new way of doing things. Your solution has to address the cultural attributes that encourage knowledge seeking and sharing.

The Starting Point

In deciding where to prioritize our initial KM efforts, we decided to address the systemic issues that aligned with noted general health authority concerns, i.e., areas related to submissions, inspections, recalls, product failures, and product supply shortage. From this review, the first area of robust knowledge management that we focused on was increasing our *process and product knowledge* across network. The goals of this initiative were to:

- Improve process capability and risk management
- Fully implement and leverage *product teams* (product stewards)
- Increase technical capabilities in the sites and global functions
- Fully implement and resource both of the ICH Q10 enablers, quality risk management and knowledge management
- Develop global inventory of product and process deliverables required by Quality System

The common feature of these efforts is that they facilitate decision-making processes and continuous improvement based on scientific understanding. We see these initiatives as key steps in our evolution to drive more proactive risk control and knowledge management.

The initiatives to date have provided a framework for our *product knowledge management* by cataloging explicit knowledge (documents), providing the starting point for metadata definition and making the deliverables available and searchable. This knowledge is specific for a single product, starting in late stage development and continuing through commercialization and operations activities. The main elements of the framework are:

1. Templates that identify required knowledge
2. Taxonomies to capture relevant information
3. Global access to the information

The creation and updating of the *product information* is identified at the time that the deliverables are generated with key review milestones during business process knowledge handover points. Key initiative examples include:

Perjeta Product History File Table of Contents			
Section (click to go to section)	**PQS Element Requirement (per GSP102)**	**Summary of Information/ Document Types (examples)**	**Contacts**
Product Information	[illegible]	Quality Target Profile Critical Quality Attributes (CQA/CCA) CQA Reports Critical Material Attributes (pCMA/CMA) Critical Process Parameters (CPPs) - CPP Reports Design Space Report (if applicable)	Belinda Briscoe - MSAT So-Yan Leung - QEV Malou Vega - PQS Mitch Lesiuk - VV QEV Glenn Smith - IMP QLP Kerstin Fabian - MN MSAT
	[illegible]	Development History Reports Product Specification Files (for IMPs)	
	[illegible]	Control Strategy / Control System	
	GSP102/sop028921 [g mol]	**Product Release Specifications**	
Process Validation	[illegible]	Validation Project Plans Key Performance Indicators **Process Characterization Protocols and Reports** Process Validation Protocols and Reports Scale Down and Scale Up Models (use and justification)	So-Yan Leung - IMP QEV Mitch Lesiuk - VV QEV Szu-Han Wang & Ming Tung - LS Cell Culture Chris Dowd - Purification Development
Method Validation	[illegible]	Validation of Analytical Methods Method Validation Master Plan and Report (MVMP) **Method Validation Protocols and Report**	Glenn Smith - IMP QLP
Tech Transfers	[illegible]	Technical Transfer Master Plan Site Specific Process Description Process Transfer Summary Report	Mitch Lesiuk - VV QEV Kerstin Fabian - MN MSAT
	[illegible]	Method Transfer Master Plan Transfer Protocols and Reports	
QRM	[illegible]	Product and Process Quality RIsk Management Reports	Mitch Lesiuk - VV QEV Kerstin Fabian - MN MSAT
Stability	[illegible]	**Stability Program and Reports**	Heather Raquist - Stability
Process Monitoring / APQR	[illegible]	**Manufacturing Process Specification**	Mitch Lesiuk - VV QEV Kerstin Fabian - MN MSAT Malou Vega - PQS Marissa Vidal - PTQ&P
	[illegible]	Process Monitoring Protocols and Reports	
	[illegible]	Post Approval Lifecycle Management (PALM, if applicable)	
	[illegible]	**Annual Product Quality Review (APQR)**	
Shipping Validation (optional) / Packaging Validation (optional)	[illegible]	Shipping Qualification Protocols and REports	Chris Renz - Shipping
Regulatory	[illegible]	**Product Registration**	Kieran O'Donoghue, Krista Terry & Najwa Watson

Figure 2. Example of a product history file structure.

- **Product History File (PHF):** a collation of product life cycle deliverables that provide a context for product data, information, and knowledge. The PHF provides the framework for a common terminology (e.g., metadata, thesaurus, taxonomy) supporting future KM initiatives. It focuses on critical deliverables as well as key process steps that can have most significant impact on product quality (e.g., CQA, CPV, analytics, technology transfers). A key element is the integration of knowledge transfer (handover) within existing business processes and teams.

- **Manufacturing Process Specifications (MPS):** the MPS is one-stop-shop for registration information providing enhanced visibility to the production network. The MPS provides a concise summary of the API and drug product manufacturing process to ensure consistency between regulatory documents, site-specific documentation, validation documents and release criteria. It assists in discrepancy management, executing process monitoring requirements, and enhance monitoring requirements (if applicable).

Other Product and Process Knowledge Initiatives

In parallel with the product history file and MPS development, other product and process knowledge initiatives were sponsored to start capturing *tacit knowledge*:

- **Product Quality Plan (PQP):** this initiative pairs the Product Strategic Plan with risk management to identify and critical product quality risks. It provides product quality oversight and product quality health indicators required for better business acumen. The goal is to provide better visibility, communicate risk mitigation controls and reduce firefighting. It also provides archiving of product information and knowledge by leveraging existing product documents (e.g., annual product reviews, audits, issue logs) and align other product initiatives (e.g., PHF and MPS) with QRM to manage risks and maximize resource utilization. Results and risks will be reviewed through a governing body, the Product Review Committee (PRC).

In addition, other global initiatives have commenced which address capturing portions of operational data:

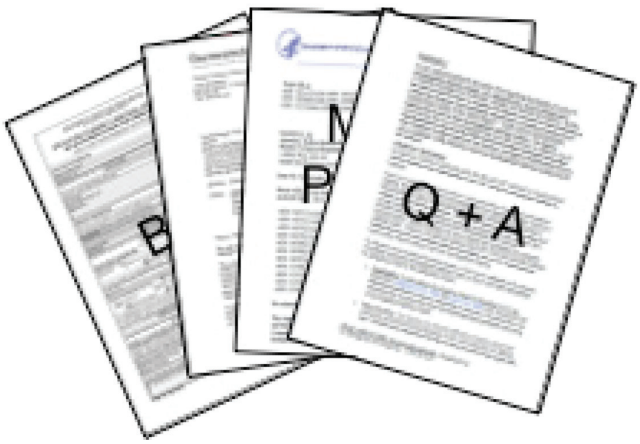

Figure 3. Manufacturing Process Specification (MPS).

- **Process Monitoring:** as part of the integration, harmonized requirements for process and product monitoring were defined (e.g. CPP, KPIs, CQAs, and other attributes to be monitored). The requirements include data collection, methods for establishing limits, trending rules, escalation, and reporting. A governance framework establishes a review board to provide for a proactive and collaborative forum to review process and product data (end to end) by subject matter experts to review for potential trend violations necessary to identify, prevent, and resolve quality impacting events in a timely manner.

What have we learned on our journey so far…

There will be resource contention from sites and functions; it is therefore crucial to ensure alignment within and between organizations on overall priorities. This is critical for buy in and effective execution. Having consistent leader sponsorship and management oversight will help resolve potentially conflicting initiatives and priorities. The knowledge teams are working hard to counteract any perception that KM creates more work, as well as capture and share user testimonials.

The ability to identify and integrate critical knowledge handovers into ongoing IT roadmaps and project portfolios facilitates the evolution and adoption of the KM program(s). For example, clarifying business process knowledge handover requirements for CMC and technology transfers projects.

Focusing KM Efforts on Developing an Overall KM Roadmap

The roadmap provides the opportunity to simplify complex and redundant IT architecture and eliminate individual data marts and warehouses with disjointed information. The KM solutions must keep users needs in mind as solution are identified.

The KM initiatives also provide opportunities for organizational change, and therefore require a strong governance framework in place. This includes strong sponsorship at all levels – leadership, global functions, sites and users.

To successfully build awareness of the KM program, the bottom line requires that you communicate, communicate, communicate.

Start, Act, Learn, Strategize

In summary, today there are now many active KM initiatives within Roche. These are driven by the business to better share processes and knowledge within specific user communities either at the functional, departmental or at team level. They serve a variety of business drivers to reduce rework, increase efficiency, and enable better decision making by engaging user communities, harmonizing business processes and providing repositories and/or tools for information sharing and collaboration.

A key theme for knowledge management at Roche has been in developing communities of practice and portals (Wikis, SharePoint, Google Sites) for ease of access, sharing documents and capturing team decisions. Some of these initial initiatives have now transitioned to the next phase of establishing relevant metadata and providing search capabilities across function/department repositories.

To successfully build awareness of the KM program, the bottom line requires that you communicate, communicate, communicate.

We commenced our program with a specific focus on *product and process knowledge* driven by business imperatives and as we continue our journey we now recognize the need to integrate and focus these efforts. We must now capture our individual and organizational learning to establish an overall *knowledge management strategy* to best suit the business going forward; to focus and align the communities, the technologies, the business processes and the content to fully realize our competitive advantage.

About the Author

Kathleen (Kate) Waters leads Genentech's Global Quality Systems Validation and Manufacturing Operations group, responsible for defining and realizing the quality management systems strategy for manufacturing systems qualification, process development, cleaning and process validation, process monitoring and trending, systems maintenance, clean utilities and manufacturing controls. In addition, she is currently co-leading the development of the product and process knowledge management program. Waters has been at Genentech for more than 22 years, having held positions in engineering, operations and quality. Waters frequently leads or collaborates on global initiatives, ensuring cross-functional engagement, and incorporating industry best practices. In addition to ISPE, Waters is a member of PDA, the Society of Women Engineers (SWE), the International Society of Automation (ISA), and the Process Automation Roundtable (PAR). She can be reached by email: waters@gene.com.

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The 80/20 Rule of Knowledge

by Nuala Calnan

This article explores the academic research and presents some recent concepts in the field of knowledge management, in particular in regard to the value of the tacit knowledge that is "locked" within our organizations.

> *"Knowledge derives from minds at work*[1]
>
> – Davenport and Prusak (1994)

Were you surprised to read in the *Case Study of the Evolution of Knowledge Management at Merck* article[2] that the majority of organizational knowledge, approximately 80%, is understood to be tacit knowledge, while only 20% of the available knowledge is explicit? This resonated strongly with me as a researcher currently exploring the role of knowledge in addressing the challenges and opportunities for the pharmaceutical industry when implementing the *science- and risk-based approaches* espoused within the ICH quality guidelines ICH Q8 – Q11.

I took the opportunity therefore to ask about the impact of this realization on the Merck KM strategy development, during the interview conducted with Marty Lipa and Dr. Michael Thien for this supplement.[3] Lipa noted that they learned this first principle of knowledge management from their colleagues in the American Productivity and Quality Center (APQC), and admitted that initially he did not believe it himself until they undertook some knowledge-mapping activities in the early phases of their KM project. These mapping exercises highlighted that barriers to knowledge flow did indeed exist and arose specifically when they did not have sufficient access to *tacit* knowledge.

A recent white paper[4] published by Coveo (Feb 2014) expands on this 80/20 ratio when it discusses the concept of the long tail of enterprise knowledge. Built on the long tail theory developed by Chris Anderson in his 2004 *Wired* magazine article and subsequent book, Diane Berry of Coveo applies the long tail theory to knowledge "based on human interaction with information residing among systems, repositories, people and situations unknown to the user." Coveo depict this concept visually in the figure below, succinctly showing the 80/20 divide and providing "an overview of the long tail of systems, business problems and organizational knowledge."

> *"Into every act of knowing there enters a passionate contribution of the person knowing what is being known, this coefficient is no mere imperfection but a vital component of his knowledge.*
>
> – Michael Polyani, Personal Knowledge (1958)

Where do you think the answers to the high value problems your organization lie? For example, when seeking true root causes in cases of quality defect investigations, customer complaints, process deviation reviews or worse still, repeat process deviations reviews? In the "head" where 20% of the

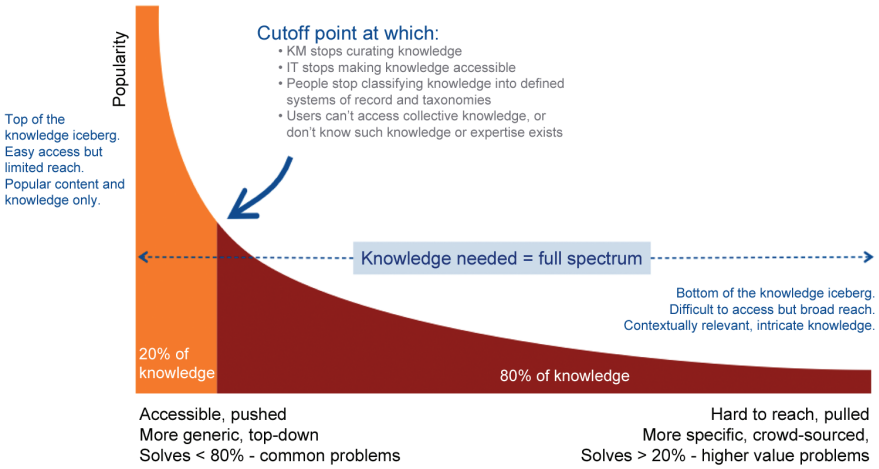


Figure 1. Coveo long tail of knowledge concept.

knowledge typically solves 80% of the problems or in the long "tail" where 80% of the hard-to-reach, intricate knowledge holds the key to 20% of the "higher value" problems?

Understanding the Differences between Explicit and Tacit Knowledge

Before we discuss the relevance of the work of Ikujiro Nonaka, in the areas of both knowledge creation and knowledge emergence for the pharmaceutical industry, let us first draw upon the definitions provided for *tacit and explicit* knowledge included in his 2001 book on knowledge emergence.[5]

> *"**Explicit** knowledge can be expressed in words and numbers and shared in the form of data, scientific formulae, specifications manuals and the like. This kind of knowledge can be readily transmitted across individuals formally and systematically.*
>
> ***Tacit** knowledge on the other hand, is highly personal and hard to formalize, making it difficult to communicate or share with others. Subjective insights, intuitions, and hunches fall into this categoryof knowledge. Difficult to verbalize, such tacit knowledge is deeply rooted in an indivual's action and experience as well as in the ideals, values or emotions he or she embraces."*

However, Michael E.D. Koenig, an acknowledged expert and author in the area of knowledge, in a May 2012 post on KM World[6] raises the issue that this two way split of knowledge categories is oversimplified. He introduces an additional category which he calls *implicit* knowledge, defined as:

> "*Implicit* knowledge is information or knowledge that is not set out in tangible form, but could be made explicit..."

In his post, he points to the danger of approaching knowledge as a dichotomy between explicit and tacit as it then becomes easy *"to think overly simplistically in terms of explicit knowledge, which calls for **"collecting"** KM methodologies, and tacit knowledge, which calls for **"connecting"** KM methodologies, and to overlook the fact that, in many cases, what may be needed is to **convert** implicit tacit knowledge to explicit knowledge."* I like this idea of collecting, connecting and converting as it gets to the heart of an important and fundemental knowledge concept; knowledge is dynamic not static.

Indeed Nonaka's own renowned SECI process,[7] while based on a two way categorization of knowledge, in fact embodies this "dynamic" nature of *knowledge conversion* as a spiral, elevating knowledge **value** throughout the conversion process from tacit to explicit and back again. It is important to understand the intrinsic value that tacit, explicit and even implicit knowledge have in their own right. The goal is not to transform the 80/20 ratio by moving all forms of knowledge into explicit formats, but rather to create new knowledge and greater understanding as the conversion spirals through the different forms and the knowledge base expands.

The SECI Process

Nonaka introduced the SECI model in a 1994 article,[8] in response to traditional management models that focused on how to *control* information flow and processing within organizations. The SECI process seeks to provide a con-

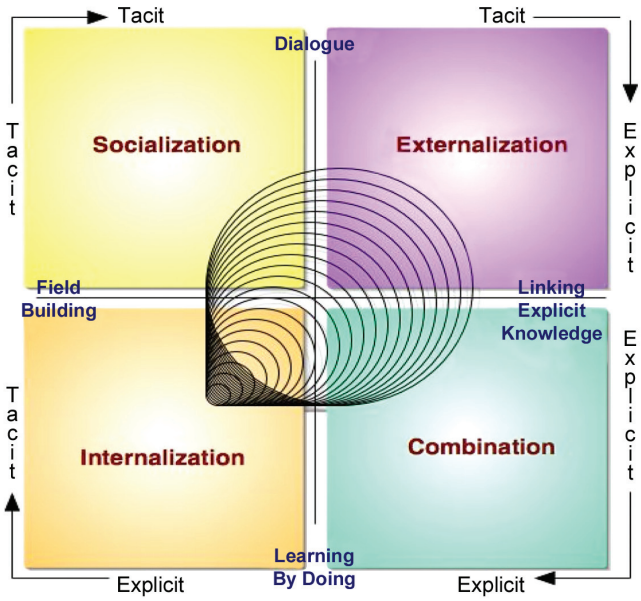


Figure 2. The SECI Process.[8]

ceptual framework for the continuous and "self transcending" process of knowledge creation. This dynamic nature of knowledge is key to Nonaka's thinking and he goes on to outline what knowledge management should achieve:

> *"What "knowledge management" should achieve is not a static management of information or existing knowledge, but a dynamic management of the process of creating knowledge out of knowledge."*[9]

The four stages of the SECI process show how through **Socialization** (from tacit to tacit), tacit knowledge can be shared or transferred between individuals and groups as peer- to- peer or expert- to- peer within an organization (i.e., connecting). In addition, when this concept is applied externally it facilitates knowledge accumulation through supplier, customer and other stakeholder (clinicians, regulators, competitors) dialogues.

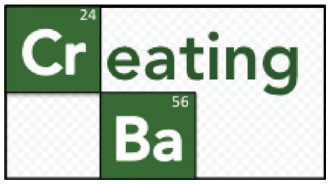
Externalization (from tacit to explicit) is the process of articulating tacit knowledge into explicit knowledge that facilitates the crystallization and translation of knowledge (i.e., converting) into readily available forms, which allows that knowledge to be shared by others and ultimately becomes the basis for *new* knowledge. Active (indeed *proactive*) listening and open non- judgmental forums for dialogue are essential to this process.

Combination (from explicit to explicit) is the process of converging existing explicit knowledge into more complex and systematic new explicit knowledge. Knowledge is collected (internal and external acquisition), exchanged (disseminated) and combined to create new knowledge *and* to make it more accessible. This process may happen in meetings (real and virtual), team based projects, social media platforms (intranet, online forums), industry workshops and presentations. Nowadays, integration and access will likely be through online repositories, knowledge databases and search platforms.

Internalization (from explicit to tacit) describes the process of embodying explicit knowledge and is closely related to "learning by doing." Knowledge that has been acquired or created is now shared cross functionally throughout the organization. This may involve rolling out new knowledge through pilot projects or prototyping. It is the "in-the-field" element of converting explicit back to tacit in order to embed and enhance the skills and understanding of those using the knowledge.

The SECI process, taken together describes a dynamic spiral where knowledge created is "organizationally amplified" as the conversion occurs from the level of the individual right up through communities of practice, cross functional teams, departmental, divisional to organizational boundaries. This dynamic amplification process directly facilitates the *emergent* properties of knowledge, which has real resonance for the pharmaceutical industry as new knowledge emerges "each batch, each day." Indeed, there is an increasing trend in recent academic literature that acknowledges these emergent properties of knowledge as being a vital source of creative *capability and strategic flexibility* of organizations, exceeding the traditionally held views of knowledge simply as "a source of competitive advantage."

Perhaps most importantly though, Nonaka recognizes that knowledge creation is a delicate process, which requires a nurturing environment or "enabling context" provided through the support and "care" of management. This is the hard bit. Providing technology for people to search and connect through, even in the presence of an overarching knowledge strategy, will not enable effective knowledge creation. Nonaka et al[10] describe this enabling context as ***"Ba"*** (based on a Japanese word roughly translated as "place"). Describing "ba" as "a shared space that fosters emerging relationships" which can be physical, virtual or mental and will most likely be a combination of all three.



Knowledge is shared, created and amplified through interactions with others.

"Ba" is the "knowledge space" where such interactions take place.

An amusing example of the SECI tacit- explicit knowledge creation and transfer process might be the relationship between Walter White and his protégé Jesse Pinkman in the recent Breaking Bad TV series. His ability to convey his expert tacit knowledge on the "black art" of the synthetic chemistry crystallization process to his unqualified assistant, who in turn systematically produced explicit batch documentation, SOPs and lab manuals to become an expert himself are a case in point.

Whatever your cultural touchstones, knowledge without context is just information. To be in a position to capture and exploit emerging knowledge and continuously create new knowledge, your KM strategy must ensure due care is paid to providing and nurturing this "enabling context."

Knowledge in Action

Ultimately, what makes knowledge valuable is the capacity it provides to take action. Davenport and Prusak state in their *working knowledge* book, "knowledge can and should be evaluated by the decisions or actions to which it leads."[12] Better knowledge enables smarter decisions. When we look

at the details behind quality defects highlighted in regulatory warning letters or review reasons given for product recalls – what is evident is the poor quality of the decision making that led to the deficiency. Taking incidences of willful fraud to one side, what we see time and again are examples of good people making bad decisions. As an industry, what we should strive for is a situation where good people, working collaboratively are enabled to evaluate, generate and validate good decisions that are beneficial to the patients who rely on the medicines we produce.

Caveat Emptor (Buyer Beware)

A few words of caution that this article should at least mention. First, do not underestimate the necessity to facilitate the evolving nature of knowledge. Your experts (both internally and externally) must be prepared to evolve too as the body of knowledge expands and evolves. Expertise which refuses to examine itself ceases to be real knowledge and instead, as Davenport and Prusak succinctly put it, "When knowledge stops evolving, it turns into opinion or dogma." In an age when outsourced activities, right across the pharmaceutical product lifecycle, have never been greater it is critical that any contractual arrangements take account of this evolutionary nature of knowledge. These arrangements should facilitate regular sharing, transfer and engagement to assure the ongoing ability to make good decisions resides with the ultimate decision maker – the entity regulated as being responsible.

> *"If you are "renting" knowledge, make sure you take steps to retain it*
>
> – Davenport & Prusak (1998)

Second, while the power of unlocking the knowledge currently held as tacit knowledge holds much opportunity for the pharmaceutical industry (one which has long overvalued explicit knowledge at the expense of "know how"), it must be **filtered before use** to remove any negative cognitive biases and the impact of heuristics. These may be rules of thumb or intuitions based on the experiences of the individual that inform their decision-making. On many occasions, these heuristics provide the grit that underpin these decisions – or as some might say the "gut feeling." However, research has shown[13] that an individual's cognitive biases can have a negative impact on judgment and the way they make decisions. At DIT, the *Pharmaceutical Regulatory Science Team* have an ongoing research program on the area of heuristics and have come across an interesting recent paper (2012) in the *Journal of Knowledge Management* that examines this very relationship between an individual's tacit knowledge and the bounded awareness in managerial decision-making.[14] The authors revisit the 1986 Challenger Disaster to review the impact of biases (referred to as bounded awareness) within the technical and scientific management teams on the ill -fated launch decision. They draw the conclusion that:

> *"Managers' dependence upon their existing tacit knowledge and the bounds on their awareness influence each other in a cycle of positive reinforcement."*

For anyone who has ever participated in a routine investigation or reviewed a process CAPA, the paper makes for chilling reading on the potential implications of not backing up each decision with sound science and appropriate risk management approaches.

An Ounce of Prevention is Worth a Pound of Cure

In conclusion, I share with you an experience from the podium of IVT's Validation Week (March 2014), where I facilitated an audience interaction session on the subject of *continued process verification*. I asked a question to the audience, of approximately 50 attendees, how many organizations routinely engage with their production line operators to encourage them to provide proactive feedback on process performance, as per the recommendation on page 15 of the FDA Process Validation Guidance (2011):

> *"Production line operators and quality unit staff should be encouraged to provide feedback on process performance."*[15]

In a show of hands there were less than five who indicated they routinely seek out this source of tacit knowledge when evaluating the capability or stability of the process. In the discussion that followed, it emerged that many more organizations do engage with their operators in the event of a deviation arising or during an investigation, unfortunately this after the fact.

Is this an example of our "bounded awareness"? Where we actively fail to engage a group with real tacit knowledge on potential sources of variation or on the effectiveness of recent change controls, when we could still prevent a deviation or discrepancy arising? Instead, we wait until we are in a corrective active situation and expect to gain enlightenment when the fear of blame might obscure open, non-judgmental communication and disable the "ba."

Finally, as my own area of research is also examining the role of excellence philosophies in the delivery of en-

hance quality products, Leading Quality Indicators (LQI) are a cause close to my heart. I leave you with some food for thought, examine your own quality metrics dashboard and instead of looking at how many CAPAs you closed last month (a measure of how busy someone in QA was) see if you can determine what percentage of your CAPAs are preventative actions and what percentage are corrective actions (one measure of the effectiveness of your pharmaceutical quality system). Next, consider acting on this knowledge to implement a new 80/20 rule, a target for PA/CA.

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About the Author

Nuala Calnan has more than 20 years of experience in the pharmaceutical industry with a strong technical background in new facility design, commissioning, start-up and regulatory consultancy. She graduated in 1991 with a BSc Eng degree from the Dublin Institute of Technology and received her MBA in 2002 from the Open University in the UK. A longtime member of ISPE, Calnan was on the author team for the ASTM E2500-07 Guide and has contributed to several the ISPE Science- and Risk-Based Approach industry guides. Her new challenge is to complete a PhD on the implementation of the recent ICH Q8 – Q11 regulatory guidelines and her research focus includes knowledge management and operational excellence. She has authored several papers and contributed to a recent book on *Leading Operational Excellence in the Pharmaceutical Industry*.

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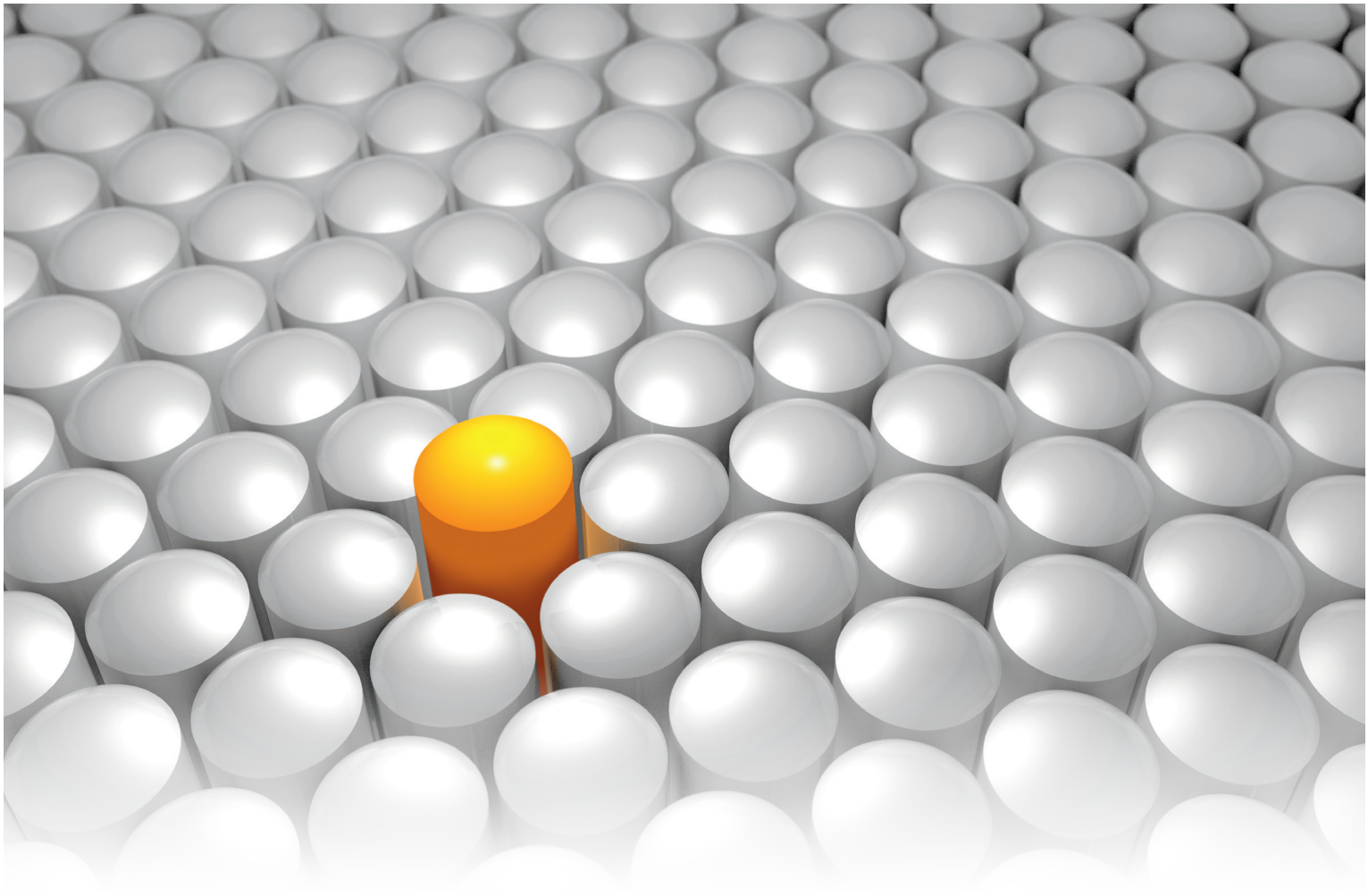

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The Role of Taxonomies in a Knowledge Management Solution

by Evelyn L. Kent

This article discusses how taxonomies can help organizations turn content into usable information.

What is Taxonomy Anyway?

Put simply, taxonomy is a way of describing a particular world in a hierarchical way. We will look at some of the key definitions a little later in this article, but in the context of knowledge management solutions, taxonomies are important because they let organizations turn content into usable information.

Traditionally, people have applied taxonomic classification to documents, articles or books to help users consistently retrieve information. Today, however, organizations find that valuable information also resides in e-mails, memos, unclassified reports, field notes, blog posts, hand-written documents and across social media, but that information is notoriously difficult to find with keyword searches. Consequently, the need to find information has moved beyond Dewey Decimal-like systems, that have to be applied in a manual process, to computer-based *auto-classification* systems. Such systems help organize and retrieve content as well understand what is in the content, much like an index at the back of a book.

Pharmaceutical companies are using taxonomic-driven classification to help with drug production in two primary ways. They are classifying years of existing research documents to connect pieces of meaningful information. The resulting insights can inform all stages of the drug development process, from improving the development of molecules to identifying appropriate experiments during animal and pre-clinical studies and designing clinical trials by uncovering connections among disparate and scattered documents. Pharmaceutical manufacturers also can use taxonomies to reduce manufacturing defects and costly production delays related to investigations plagued by missing or outdated information. One pharmaceutical industry client has recently estimated that it will save close to $30 million over five years by improving the quality of the available information in just one of their manufacturing areas by reducing human errors and enhancing decision capability.

> *"Taxonomies help pull meaningful information from content through text analytics, which turns text into data through the use of machines and software.*

What can Taxonomies do?

Taxonomies help pull meaningful information from content through *text analytics*, which turns text into data through the use of machines and software. At its core, text analytics involves breaking a stream of text into meaningful words or phrases, but "meaningful" is a relative term.

Taxonomies, ontologies and other classification schemes give organizations an opportunity to do this by allowing them to define what is meaningful to their particular line of business. A news company might define a "drug maker" as a criminal, whereas a pharmaceutical company would likely define that as a wholly different thing.

Because taxonomies use *synonyms*, users can tell their

Classification Schemes

Some helpful definitions; *(Be careful! In practice, people may use these terms interchangeably.)*

A **taxonomy** is a way of describing a particular world in a hierarchical way. Most people were probably first exposed to taxonomies as children in school, where they would have studied how animals and plants are sorted in the scientific world. Some may even recall mnemonic devices we used to remember the highest-to-lowest rankings of the taxonomy:

Levels of Classification: *Kingdom, Phylum, Class, Order, Family, Genus, Species.* For example, a lion is a feline (Family) which is a mammal (Class), which is an animal (Kingdom). Each level of the taxonomy helps define the one above it, as well as the one below it. Taxonomies can be used to define many types of worlds.

An **ontology** is similar to a taxonomy, but it is not only hierarchical. Ontologies provide more context for classification, e.g., a lion might be an animal, but it also might be the name of a sports team, and the home for that sports team might be Detroit, Michigan. Mapping how things are related to one another helps define them.

A **controlled vocabulary** is a key concept related to taxonomies, ontologies, and classification schemes. Controlled vocabularies are used in thesauri, taxonomies, and other knowledge organization systems.

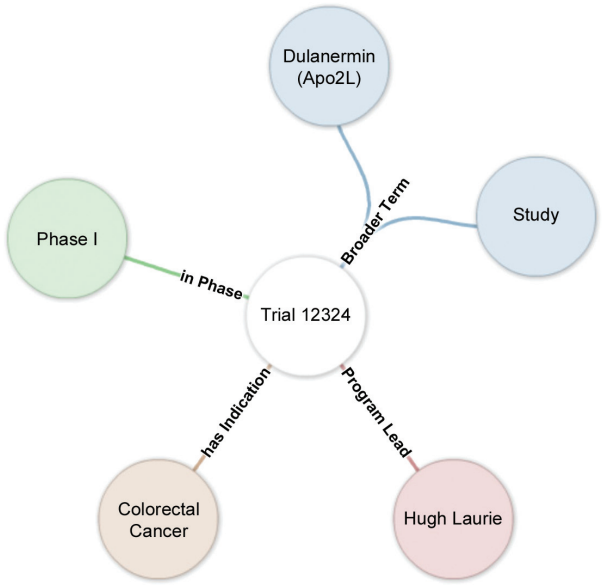


Figure 1. Example of a Pharmaceutical Industry Ontology.

A **thesauri** is another term that refers to a component of a good classification scheme. Thesauri promote consistent use of terminology to enable successful term classification, indexing, and knowledge organization. They generally include a hierarchy and synonyms – a list of terms that are also used to refer to a particular term or concept, e.g., the term H1N1 also will have a listing for swine flu, since it is widely known by both names.

systems to look for terms that are related to a key term without a person having to direct that search. For example, a taxonomy of pharmaceuticals might direct its classifier to find content about H1N1 when a searcher types "swine flu." In this way, the computer understands a link that the user might not think to look for or might not understand even exists.

Once a document is classified, it can be labeled with metadata describing the core concepts found in the text. This can then be stored for later recall by search engines such as the Google Search Appliance and Solr. SharePoint users can add the classification results to their farms to bolster SharePoint's native abilities and add deeper taxonomy relationships. This keeps information better organized and makes it more *findable* for the user. Most importantly, it also removes the burden of applying terms by the user, making metadata more consistent.

Taxonomies and auto-classification help organize and examine information for use in a variety of ways. They look through volumes of content in a fraction of the time that humans would, and they apply more consistent metadata to it. They drive discovery of links between documents and reveal patterns within text, and they save knowledge workers time in searching for and recreating content.

About the Author

Evelyn L. Kent is a content strategist at Smartlogic, creating content strategy and messaging around Smartlogic's software, which performs text analytics and improves enterprise search using metadata derived from taxonomy-driven auto-classification. She came to Smartlogic from McClatchy-Tribune (MCT), where, as principal ontologist, she built a multifaceted ontology to classify two million news stories a year. She has 15 years of experience in content strategy, creation and delivery.

Knowledge Management in the Product Lifecycle – An Overview of PQLI Knowledge Resources

by Chris Potter, PhD

This article summarizes the ISPE guide resources that can be used by practitioners to understand where and how in the product lifecycle knowledge management can be applied.

Product Quality Lifecycle Implementation® (PQLI®) is ISPE's global industry initiative for a practical approach to implementation of International Conference on Harmonization (ICH) guidance Q8(R2), pharmaceutical development; Q9, quality risk management; Q10, pharmaceutical quality system; and Q11, development and manufacture of drug substances.

Since its commencement in 2007, PQLI has sought to describe practical applications of the ICH quality guidance that underwrite the ICH quality vision. PQLI is about the many "hows" relating to the "what" of ICH guidance and demonstrates there are many right ways, not just one way, to successfully implement ICH guidance in a global environment and throughout the lifecycle of a product. The primary focus is on science- and risk-based approaches to product realization and manufacture and has welcomed contributions from all scientists, engineers, regulators, and industry leaders committed to supporting these principles.

> *"Within PQLI, ISPE has established multi-disciplinary, multi-national teams in support of these strategic themes, addressing them from the perspectives of both small molecules (chemically derived) and biotechnology."* [1]

See more at: http://www.ispe.org/pqli-resources.

Within the context of the pharmaceutical quality system outlined in ICH Q10, *Knowledge Management (KM)* is positioned as one of two key enablers, along with quality risk management, necessary for the effective and successful operation of a pharmaceutical quality system across the product lifecycle. This article summarizes the resources that are already available, including ISPE guides and discussion papers, from the product quality lifecycle implementation guide series that can be used by practitioners to understand where and how in the product lifecycle knowledge management can be applied.

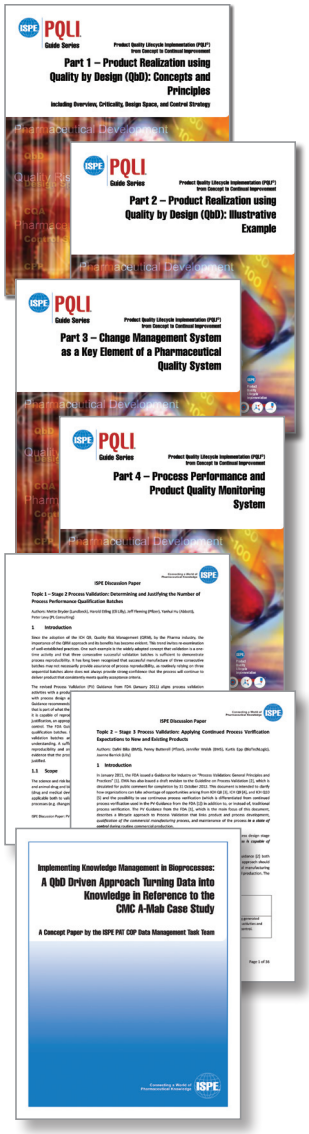
Knowledge Management in the Product Lifecycle

ISPE has to date published four Parts[2-5] of a Guide series, Product Quality Lifecycle Implementation (PQLI), and two further discussion papers,[6,7] which are specifically related to process validation in line with the 2011 US FDA guidance on process validation.[8] In addition to these, the ISPE PAT COP released in 2012 a concept paper[9] on knowledge management in bioprocesses that deals directly with the issue of turning data into knowledge. It used the CMC A-Mab case study10 as a basis for this concept paper. These guides and articles are summarized below:

ISPE PQLI Guide Series:

- *Part 1 – Product Realization using QbD, Concepts and Principles*
  - Overview

  - Criticality
  - Design Space
  - Control Strategy
- *Part 2 – Product Realization using QbD, Illustrative Example, Drug product and small molecule drug substance*
- *Part 3 – Change Management System as a Key Element of a Pharmaceutical Quality System*
- *Part 4 – Process Performance and Product Quality Monitoring System*



Process Validation Discussion Papers:

- *Topic 1 – Stage 2 Process Validation:* Determining and Justifying the Number of Process Performance Qualification Batches
- *Topic 2 – Stage 3 Process Validation:* Applying Continued Process Verification Expectations to New and Existing Products

CMC A-Mab Case Study – ISPE Concept Paper:

- *Implementing Knowledge in Bioprocesses:* A QbD Driven Approach Turning Data into Knowledge in Reference to the CMC A-Mab Case Study

The initial PQLI Guides, Parts 1 and 2 describe in detail the **"QbD flow"** and provide many examples of where knowledge management is applied. The **"QbD flow"** is illustrated in Part 1 and is reproduced below as Figure 1. This shows the importance of knowledge management to achieve product realization in a *feed forward* manner.

In another flow diagram taken from Part 1 given here as Figure 2, the importance of the cumulative nature and re-use of knowledge is illustrated, for example to support continual improvement opportunities during the commercial manufacturing phase of the lifecycle. The role of *feedback* is shown relating to how continual improvement opportunities feedback to facilitate examination of the knowledge currently available, regarding the product and process understanding, from development studies, technology transfer, process validation and routine manufacture.

A Bioprocessing Example of Knowledge Management

This *feedback/feed forward* concept was further developed by the ISPE PAT COP, working on the concept paper for bioprocessing. While the framework presented was developed for the A-Mab case study, the concepts relating to KM may be useful. The need for KM and the use of *prior knowledge* was discussed as follows:

> ***Need for Knowledge Management***
> *Where does prior knowledge, as laid down in the A-Mab Case Study, come from? To design new product/processes we should use the information which is already available. There is a lot of information in manufacturing data of commercial products; this information can be used in development, if it is available in a structured form. Knowledge management allows providing knowledge from other products on a science-based foundation. In extrapolation of the A-Mab Case Study, the Task Team suggests a roadmap for continual improvement and elements how knowledge management can be supported*[9]

Figure 3 shows vertically in the first column some elements of the **"QbD flow"**, this evolution being from product understanding through process understanding into manufacturing. In other columns labeled "Information Management", "Knowledge Management," and "Interfaces" current availability of suitable tools is estimated as required

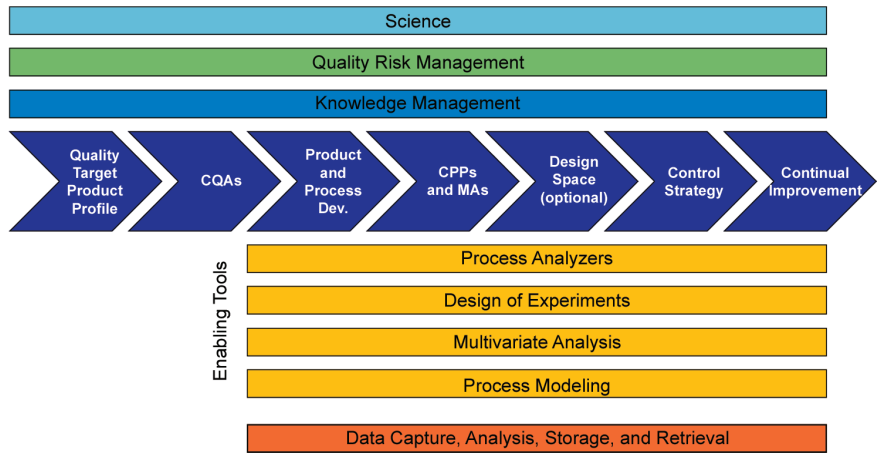


Figure 1. QbD Approach showing overarching principles and some enabling tools.

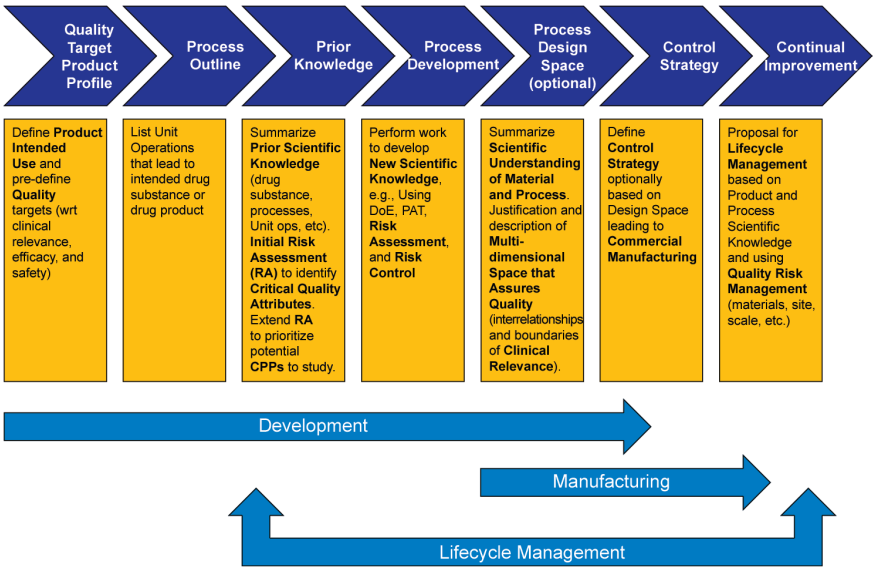


Figure 2. Conceptual application of QbD through a product's lifecycle.

to perform an activity given by a cell. From this Figure it can be seen that some tools in the "collect" and "store" data columns are available, however, there are still requirements for many tools under the "Knowledge Management" and "Interface" columns.

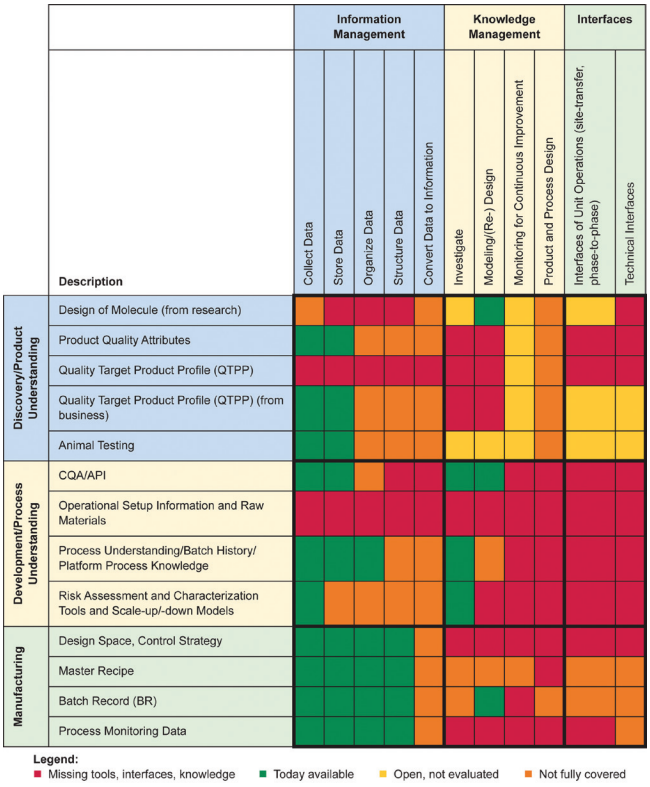


Figure 3. Availabiltyof information and knowledge management tools throughout the bioprocess lifecycle.

This concept paper includes illustrations of *feed forward* and *feedback* of knowledge and provides a structured approach for linking information and knowledge management through the bioprocess lifecycle

The Role of Quality Risk Management as a Source of New Knowledge

The pharmaceutical development process is iterative in nature and this is outlined in some detail in PQLI Guide Part 1. Figure 4, taken from the guide, highlights the central role that Quality Risk Management (QRM) plays in the establishment of both process and formulation understanding. Each step of formulation and process development is underpinned and informed by the outcomes from quality risk management activities. Prior knowledge informs all steps of QRM through the combination of the experience and tacit knowledge of each of the *Subject Matter Experts (SMEs)* involved. New knowledge is generated from the outputs from each risk exercise and from subsequent development studies conducted to increase understanding and hence reduce risk.

Knowledge Driving Continual Improvement

Another PQLI resource worthy of review when preparing a knowledge management strategy, specifically in regard to continual improvement activities as discussed in Figure 2 above, is an article published in the *Journal of Pharmaceutical Innovation (JPI)* in 2009 on the Application of Science- and Risk-based Approaches to Existing Products.[11] In the article, the PQLI team presented their findings with respect to the business, technical, risk and regulatory processes necessary when applying science- and risk-based approaches to continual improvement projects of existing marketed products. This article stresses the need to review all prior knowledge before embarking on new studies. More insights can be gained from the three excellent case studies that are included showing three different approaches to continual improvement.

Process Performance and Product Quality Monitoring as a Source of Knowledge

June 2013 saw the publication of the fourth guide in the PQLI series on Process Performance and Product Quality Monitoring System (PP&PQMS). The guide provides "how to" guidance, examples of technical and scientific methodologies and supporting management processes recommended when establishing and implementing a PP&PQM system in

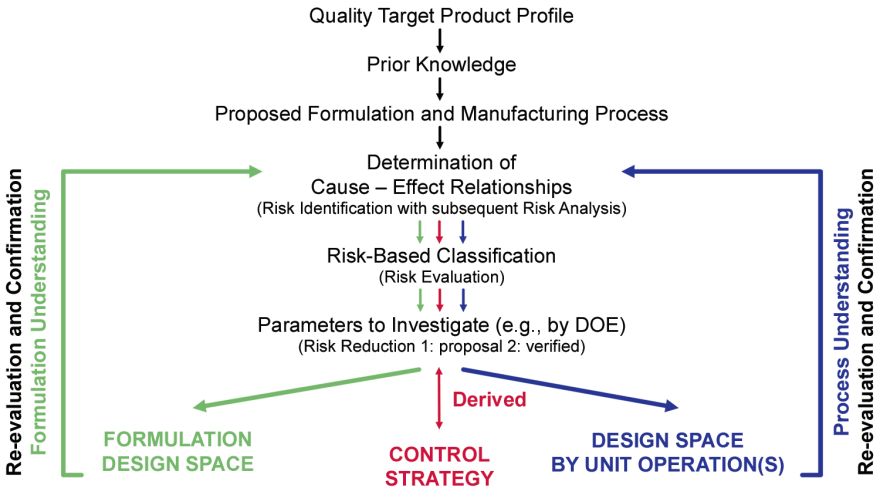


Figure 4. Iterative approach to drug product development.[13]

line with the requirements of ICH Q10.

This guide deals with various aspects of the knowledge hierarchy, from analysis of data, through the review and dissemination of information up to the management of the knowledge regarding both the performance of processes and the ongoing and routine review of product quality. The output from these reviews could lead to opportunities to drive continual improvement. Section 3.7 deals directly with how to *provide knowledge to enhance process understanding* and outlines how information related to products, manufacturing processes and components should be systematically acquired, analyzed, stored, and disseminated as part of knowledge management. Sources of such information include:

- Development studies
- Product quality review
- Output from a PP&PQMS
- Prior knowledge of similar products and process
- Literature
- Regulatory interactions
- Knowledge from troubleshooting exercises and continual improvement activities
- Current output of risk management exercise on product and process, and on the control strategy

The guide asserts that this information should be captured within the organization's knowledge management system that should not only enable review of commercial manufacturing data, but also facilitate re-evaluation of the risk assessments for product/process. It points out that the review should allow optimization of a quality attribute or parameter criticality classification and continual improvement of the control strategy. In addition to availability of this knowledge within the commercial manufacturing environment, the guide recommends that it also should be fed back into the pharmaceutical development/technology transfer groups. This can now serve as prior knowledge that can help to assess risks and facilitate better classification of CQAs and CPPs for future products. It recommends that knowledge should be managed:

- Within a single product across its lifecycle
- Across products that are similar and operate using the same technology or formulation platform, and
- Across multiple sites

On a cautionary note, the guide reminds us that the effectiveness of these approaches to knowledge management rely on maintaining knowledge elements or risk management exercises as current.

The Role of Quality Stewards as a Focal Point of Knowledge

The concept of quality stewardship is dealt with comprehensively in section 4 of the PP&PQMS guide. The guide acknowledges that role of a *quality steward* can involve accountabilities and responsibilities being delegated in different ways across different disciplines in different companies and indeed names for this role may vary for those charged with oversight of responsibility for one, or a series of products, such as:

- Product quality stewards
- Product design owners
- Product quality leaders

Although varying in scope of responsibilities and organizational affiliation from company to company a major feature of this role is to serve as a focus for knowledge management throughout the product lifecycle.

The guide points out that an extensive amount of knowledge and expertise in all areas of manufacturing and quality is required throughout the long term and iterative process of pharmaceutical development, technology transfer, and commercial manufacturing. At a given point in the product lifecycle, different technical and business functions are more involved than others in order to achieve project milestones and solve problems specific to that lifecycle stage of the product. Therefore, it can be particularly challenging for an organization to retain and document all the key information pertaining to the process and the product from its initial design phase to product discontinuation. Performance issues can be indicated by:

"QbD Step" in Product Lifecycle[1]	Examples of Prior Knowledge	Knowledge Use	PQLI Reference
Product Lifecycle Stage from ICH Q10 – Pharmaceutical Development			
Generate Quality Target Product Profile (QTPP)	• Research phase • Patient needs and clinical studies • Safety studies • Biopharmaceutics • Preformulation studies	• Drive product and process development • Establish CQAs	• Part 1, section 3 and 3.1 • Part 2, section 2.2.1
Process Outline	• Company knowledge, e.g., platform technologies • Literature • Innovation	• Establish CQAs	• Part 1,section 3 and 3.2 • Part 2, section 2.2.4 for drug product. • Part 2, section 3.2 and 3.2.1 for drug substance
Propose initial list of critical quality attributes (CQAs) of drug product and tentative acceptance criteria where possible. Use these to derive CQAs for small molecule drug substance.	• QTPP • Company knowledge • Pharmacopoeia • ICH Guidelines, e.g. Q6A and B, 3, and 5 series • Molecule and process research studies	• Standards to be achieved during pharmaceutical development	• Part 1, section 3.4 • Part 1, Topic II, Criticality especially section 7.3.3 with exemplification • Part 2, section 2.2.2 for drug product • Part 2, section 3.2.1 for drug substance
For large molecules, use research studies to develop the molecule to propose CQAs. Prioritize CQAs using quality risk management (QRM) exercise	• Knowledge above and from subject matter experts (SMEs)used in QRM exercise	• Prioritize CQAs to study	Refer to A-Mab case study section 2.5 as an example for a biotech molecule
Identify and prioritize using QRM potential critical process parameters (CPPs) and material attributes (MAs) to study	• Proposed CQAs and acceptance criteria • Company knowledge from platform technologies, other related products and manufacturing • SME knowledge • Literature	• Prioritize CPPs and MAs to study, and design of study	• Part 1, section 3.5 • Part 2, section 2.2.5 and 2.2.6 for drug product • Part 2, section 3.2.3, 3.2.4, 3.2.5 for drug substance
Conduct iterative studies' using QRM: • Design of experiments (DoEs) • Science	• Use SME's experience and knowledge, literature and company knowledge to design DoE studies - Number of factors - Ranges	• Process and process knowledge • Finalize CQAs • Propose CQA acceptance criteria for technology transfer and process validation • Propose control strategy (and design space)	
Assignment of criticality	• Use SME's experience and knowledge and company knowledge and strategy in a QRM exercise to assign criticality		• Part 1, section 3.5.7 • Part 1. Topic II, Criticality, especially section 7.3.4 • Part 2, section 2.2.6 (end) for drug product
Propose design space (Optional)	• Finalized CQAs and acceptance criteria • Algorithm(s) from studies • Knowledge from studies	• Propose "flexible regulatory approaches" • Use as an element (s) in control strategy	• Part 1, section 3.6 • Part 1, Topic III, Design Space with exemplification • Part 2, section 2.2.8 for drug product • Part 2, sections 3.2.3, 3.2.4, 3.2.5 for drug substance
Propose control strategy using QRM	• Algorithm(s) from studies • Knowledge from studies • GMP requirements • Regulatory guidelines • ICH Q&As and Points to Consider • Company strategy	• Overall process risk assessment • Drive implementation into manufacturing • Process validation strategy	• Part 1, section 3.7 • Part 1, Topic IV, Control Strategy with exemplification • Part 2, section 2.2.9 for drug product, sections 3.2.3, 3.2.4 3.2.5 for drug substance • Part 2, section 4 for a thorough discussion of drug substance and drug product • Part 3, section 3.2
Product Lifecycle Stage from ICH Q10 – Technology Transfer			
Technology transfer	• Output from all development studies • Company knowledge from other products	• Overall process risk assessment • Drive implementation into manufacturing • Control strategy • Process validation strategy • Batch release strategy • Continual improvement	• Part 2,section 5.2, 5.3, 5.4 and 5.5
Product Lifecycle Stage from ICH Q10 – Commercial Manufacturing			
Process validation	• Output from all development and technology transfer studies • Regulatory requirements	• Establishment of a process performance and product quality monitoring system	• Part 2, section 5.7 • Process validation discussion papers
Routine manufacture	• Output from all development, technology transfer studies and process validation studies • Root cause analysis from troubleshooting exercises	• Establishment of a process performance and product quality monitoring system • Continual improvement opportunities • Change management	• Part 2, section 6, Continual Improvement • Part 3, particularly section, Change Management System • Part 4, sections 3 and 4
[1] From PQLI QbD Flowcharts given in Figures 1 and 2.			

Table A. References to Use and Generation of knowledge in PQLI Guide Series and Discussion Papers.

- Monitoring results or product complaints
- Investigations and remediation process
- Major changes and presumed impact
- Regulatory strategy
- Supply chain considerations

These performance issues form the *knowledge history* that extends through a long period of time, and possible organizational and ownership changes. Large organizations with a rich pipeline, where multiple products may be at the same stages of the development and lifecycle, are particularly challenged by their ability to manage the knowledge base effectively, in order to maintain continual oversight and consistent decision-making. The concept of the role of quality steward came about to assist organizations manage this complex process.

The concept is equally applicable to:

- Small organizations with a relatively small pool of knowledge
- Generic organizations
- Innovator organizations with large portfolios of existing, marketed products
- Organizations with a diverse supply chain extending across many suppliers, sites, and countries

A summary of the principles of quality stewardship is given in Figure 5, which shows at the top of the box on the left the high level role. The bullets show examples of elements impacting product quality with the arrows linking to the diagram of the ICH Q10 pharmaceutical quality system model.

A Road Map to the PQLI Resources – Prior Knowledge to New Knowledge

A detailed review of all four of the PQLI Guides and the two process validation discussion papers has been conducted to examine applications of *prior knowledge* and the generation of *new knowledge* through the product lifecyce. In Table A, activities in the **"QbD flow"** have been mapped to the four stages in the product lifecycle as per ICH Q10 pharmaceutical quality system. For each "QbD step," examples of *prior knowledge* used and how *new knowledge* generated in that step provide the foundations for activities undertaken in subsequent steps are given. The last column provides the reference to the location of the knowledge resources in PQLI Guide series and discussion papers.

Conclusion

This article has set out to highlight resources that are available within the published PQLI Guide series and related articles. A roadmap of the detailed references mapped onto the ICH Q10 has been developed and is included. PQLI teams continue to develop guidance in this area and progress on new guides planned is available on the website. For those charged with the responsibility for the knowledge manage-

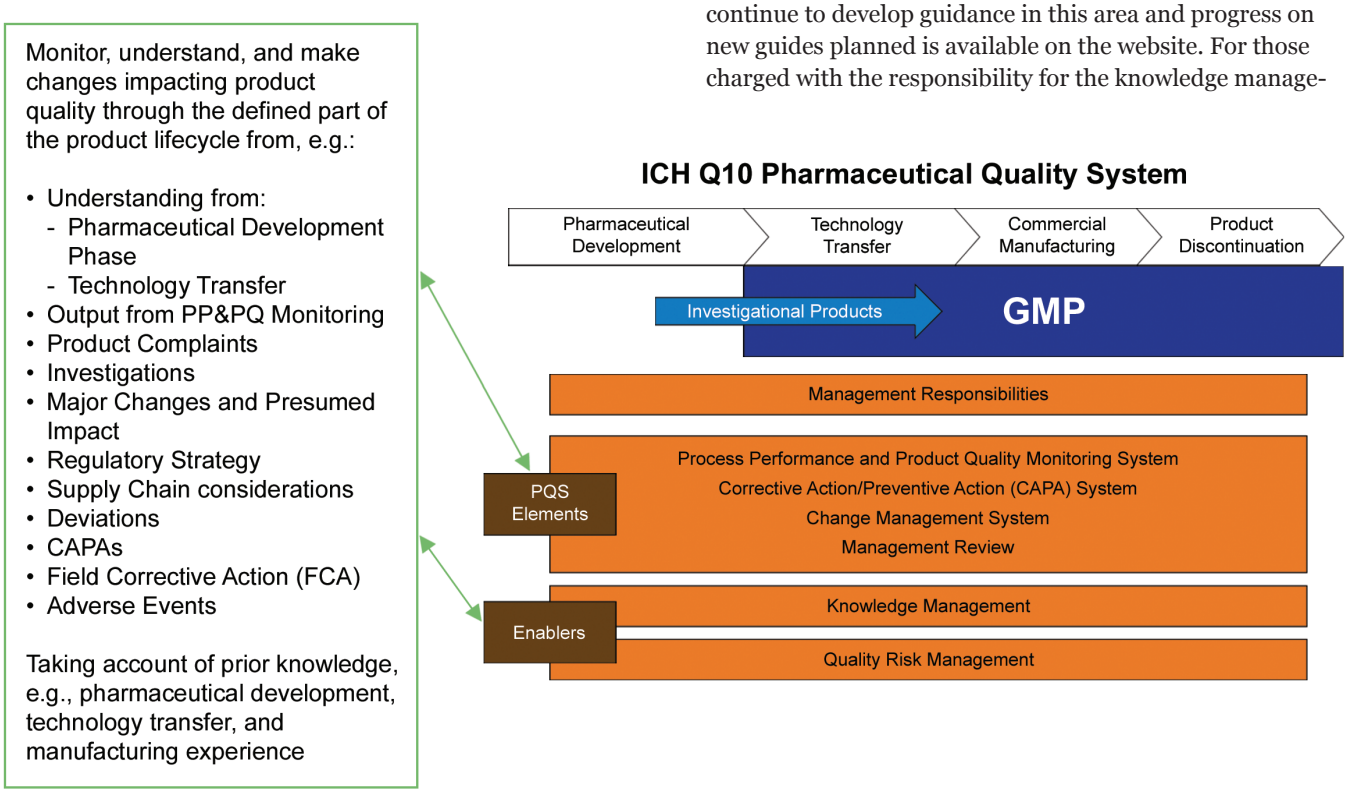


Figure 5. Principle of quality stewardship.

ment within an organization, keeping a watching brief on the developments of this group will add real value.

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About the Author

Chris Potter graduated from the University of Exeter with a degree in chemistry and completed a PhD at Imperial College London University in organic chemistry. He started work at Beecham Research Laboratories, and moved to Sterling-Winthrop to take management positions in both pharmaceutical and analytical development. During this period, he worked on both ethical and over-the-counter drug development. For the later period of his career, Potter moved to ICI Pharmaceuticals, later Zeneca, then AstraZeneca where he had a senior positions as manager of Analytical Development and R&D QA and CMC Project Management Group with responsibility in both the UK and US. He finished his career as Director of External Pharmaceutical Programmes. Potter retired at the end of October 2007 and is now performing part-time CMC consultancy work. He is currently an ISPE Advisor working as project manager for PQLI and several programs within the PQLI portfolio such as quality metrics and breakthrough therapy. Potter was a member of EFPIA's ad hoc Quality Group from 1996 to 2007, and during this period was EFPIA topic leader for ICHQ6A, Specifications for New Drug Substances and New Drug Products, and ICH Q4B, Regulatory Acceptance of Pharmacopoeial Interchangeability. Potter led EFPIA's PAT Topic Group, which produced a Mock P2 to promote discussion and understanding regarding how ICH topics Q8 and ICH Q9 could be implemented. He can be contacted by email: c.j.potter@btinternet.com.

For additional information on the ISPE Product Quality Lifecycle Implementation (PQLI) initiative, please visit www.ispe.org/pqli-resources.

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Knowledge Management in the Context of Process Knowledge

by Alice Redmond and Tim Howard

This article explores knowledge management in the context of pharmaceutical process knowledge, where the industry is now and what the future holds.

It is widely acknowledge that pharmaceutical manufacture is a knowledge-intensive process, and consequently, it depends on scientific, technological and organizational innovation in the way that information is generated, managed and analyzed. Currently, many organizations have diverse information silos that reflect the different scientific disciplines, the phases of the drug R&D process (discovery, development and clinical), commercial manufacture as well as the different organizations collaborating in the field. These silos can lead to inefficacy, rework, mis-communication and a lack of common understanding as to what is important and why.

Aligning the Silo's

Fundamentally, Knowledge Management, (KM) as a concept and a term arose approximately two decades ago. Quite simply it means holistically organizing a body of information and knowledge. Early on in the knowledge management crusade, Davenport (1994) developed the still widely quoted definition:

> *"Knowledge management is the process of capturing, distributing, and effectively using knowledge."*

This definition has the virtue of being simple and to the point. A few years later, a second definition of KM, by Duhon, 1998 is the most frequently cited in the literature for KM across all industries:

> *"Knowledge management is a discipline that promotes an integrated approach to identifying, capturing, evaluating, retrieving, and sharing all of an enterprise's information assets. These assets may include databases, documents, policies, procedures, and previously un-captured expertise and experience in individual workers."*

As you have seen in the *From Science to Knowledge* article in this supplement on the evolution of the regulatory persective on knowledge the regulatory foundation for process knowledge in the pharmaceutical industry started in earnest in 2005 with the first revision of ICH Q8. This coined the phase "process knowledge" and sets the regulatory expectation for the documentation of process information. ICH Q10 details this explicitly in the following definition:

> *"**Knowledge management:** systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing process and components."*

ICH Q10 then suggests that scientific approaches provide knowledge with knowledge rather than science being paramount. ICH Q10 identifies the following types of process knowledge:

- Prior knowledge
- Pharmaceutical development studies
- Technology transfer
- Process validation studies
- Manufacturing records and experiences
- Process and operational Innovation
- Outputs from change management
- Continual improvement

Clearly, the classification of knowledge given above includes both "tacit" and "explicit" knowledge types, with a definite leaning toward "tacit" knowledge. ICH Q10 defines *product and process understanding*, such as:

> *"Development activities, using scientific approaches provide knowledge for product and process understanding" and process performance and product quality monitoring systems, "provide knowledge to enhance process understanding, enrich the design space (where established), and enable innovative approaches to process validation."*

When considering all of the scientific, technical and quality-related aspects of each stage of a product's lifecycle, it appears obvious that knowledge management was specifically called out in ICH Q10 as an enabler to the success of the overall Pharmaceutical Quality System (PQS) implementation. During the development phase of a pharmaceutical product, large amounts of data are generated in the form of developmental studies, process design, equipment capability, clinical evaluation, process optimization studies, method development, risk assessments, etc. These sources of knowledge are then drawn upon to establish the design space, process parameters and quality attributes used in commercial manufacturing. Essentially, the extensive knowledge gained during development facilitates the establishment and implementation of the process control strategy, operational controls and assurances of quality relied upon during commercial manufacture. Without a system to gather, distribute and utilize the data generated during development, the product lifecycle ceases to progress and the subsequent technology transfer and commercial manufacture phases will be overwhelmed with quality and regulatory issues if the drug application gains approved in the first place.

A critical element of an effective pharmaceutical knowledge management system, i.e., one that meets the intent of the ICH Q10 guidance, is *information acquisition*. It is crucial that tacit knowledge (knowledge that is "in the head") is converted to explicit knowledge (knowledge that is documented and able to be disseminated). This requires that knowledge management is incorporated in the "way of working" by utilizing logical standardized procedures which have a foundation in how process knowledge is used. Key to this is ensuring that common understanding and definitions exist across the lifecycle to facilitate this. While alignment of terms may never be "harmonized" within the industry, there is a definite convergence with the regulatory requirements and glossaries outlined in ICH Q8 and ICH Q10.

Where is the industry now and where does it need to go?

Process knowledge has almost been the "invisible man" or at least one that is well-disguised! Indeed, process knowledge has only been formally collated, according to the recommendations of ICH Q8(R2), by the majority of the industry in the past decade. Even at that, it all too often tends to be a loose collection of registration documentation, batch data, QC results, trending data in a series of excel sheets and copies of completed checksheets or other related records. More significant, has been the rarity of encountering *process knowledge* documentation that was methodically passed from one phase of the lifecycle to the next and made available to support the decision makers in the commercial manufacturing phase.

When considering a roadmap for *process knowledge* going forward, you should:

- Define the requirements for documenting process knowledge information, including minimum requirements for the type of data, information and knowledge to obtain for specific processes.
- Assign responsibilities for knowledge management (for example, who is responsible for acquiring and documenting the data at each stage of the lifecycle).
- Ensure the assignment of responsibility for data management is adopted from the outset and includes the company and all of its partners involved in the development of the product. The mentality should be, when in doubt, document. The acquired information may have relevance in another stage of the product lifecycle.
- Store acquired information in a secure manner (e.g., document management system, controlled database, etc.)

Knowledge dissemination is both an art and a science."

An Art and A Science

Knowledge dissemination is both an art and a science. How can a company manage the distribution of information from the development phase right through to the commercial manufacturing phase, with the potential of multiple sites, partners and companies in a global context? Furthermore, how can they capture and retain the "tacit" knowledge gained throughout the lifecycle.

The art is to have a process that can be customized to a given organization, individual product or group of products and having the mindset to implement a structured documentation process from the start of development: with the assumption that this product may succeed to commercial manufacture and the knowledge will be needed. The *science* is figuring out the *"voice of the product,"* what are the critical process parameters that yield the critical quality attributes that confer the product the efficacy to improve quality of life. The science is also about building the PQS to support the product without further complicating the process or adding time to product development. Developing a series of structured workflows and tools for *information acquistion* that can be implemented throughout the project lifecycle will aid the execution of this.

Acquired information then needs to be communicated effectively internally (and potentially externally). Document or content management systems, libraries, databases, etc., are all systems that are capable of controlling and promoting access to specific information. Management should advocate effective communication of information and empower employees to share information in an open and effective manner. Retaining knowledge only in a tacit form should be discouraged by management.

> *"A successful knowledge management program requires a culture of continuous learning and sharing.*

What is the key to knowledge utilization?

Since knowledge management and enhanced process understanding are a regulatory expectation and critical to enable continuous improvement, pharmaceutical companies must make a concerted effort to collect all relevant scientific, technical and quality data and information, store this data and information in secure environments (physical or electronic), communicate and provide access to all levels of the organization in order to facilitate the *utilization* of this data and information to enable knowledge creation.

A successful knowledge management program requires a culture of continuous learning and sharing. This goes well beyond managing data or documents via an IT tool, or creating a library of information. However, a good IT tool or information repository can provide tremendous access to knowledge and help foster the culture desired. When selecting a tool or set of tools for knowledge management, the criteria below should be considered:

- The tool and interface need to be user friendly and easy to navigate such that the information desired is readily accessible.
- The mechanisms for filing, archiving and tagging information should facilitate ease of intelligent search and retrieval.
- It should allow users to seek, share, and subscribe to knowledge items with relative ease. *Knowledge seeking* occurs when a person has a need for information and is able to readily find it. *Knowledge sharing* is when a person makes knowledge available to others. *Knowledge subscribing* is the act of passively monitoring activity within an identified area or subject matter area (i.e, a process shift supervisor may subscribe to knowledge management topics for unit ops under his purview or products manufactured at his facility). Those subscribing to content are notified when new knowledge is shared, or have the pertinent information "pushed" to them.
- The tool should be appropriate for the organizational level at which the knowledge is to be shared. In some cases the knowledge sharing is most critical person- to-person within a shift. In other instances the sharing is most critical between product stewards sharing information site to site. Other examples include shift-to-shift, production area to production area, and function-to-function sharing of knowledge.
- Finally, the tool should readily facilitate the archiving of data that has been superseded or no longer relevant so that active content is always relevant to users.

In reality, the level of complexity of the knowledge management tool required may vary at different points of the lifecycle. When process knowledge is being managed from product development, through scale up, to full-scale production, a complex solution may likely be the best option for knowledge management. When process performance information is being maintained and shared shift- to- shift, a much simpler tool may be most appropriate – perhaps not an IT based tool at all, but a white board that is reviewed at shift turn over. In each case, the aspects above should be considered when an appropriate knowledge management tool is selected.

Documented process knowledge is a not only a regulatory expectation, but an operational and financial prerequisite.”

When a given IT tool is implemented, even when a simple white board based tool is employed, a common language must be established and understood by all users. The development of a standard language or taxonomy, should be established for process units, process steps, process parameters, classification of deviations, abnormal event classifications, product information, components, etc. For example, when information about two bioreactor contamination events are resident in a knowledge management system, the reference to the contamination event should use the same coding or language. In addition, the reference to the unit operation should use the same coding or language. Furthermore, the search for infomation when investigating a potential future contamination event of a bioreactor should readily yield the information from the previous events. A common language, taxonomy or coding system is critical for this functionality.

How do we know what we don’t know?

Documented process knowledge is a not only a regulatory expectation, but an operational and financial prerequisite. The harnessing of process knowledge from development to operations has not been effectively embraced by the industry to date, particularly when it comes to capturing *“tacit”* knowledge. The old question comes to mind *“how do we know what we don’t know?”*

The development of a *knowledge management system* for process knowledge, complete with the assignment of responsibilities, is critical to the business and this needs to be supported by a PQS that is appropriate for the lifecycle phase in question.

Innovation is a key component of ICH Q10, so the door is open to justify your implementation choice; from the simplicity of a whiteboard to the complexity of a unique identifier based knowledge management system. Picking the tool is the easy part, setting the foundation for a common language and agreeing the roles and responsibilities for the implementation is what we need to develop a succinct and logical execution approach to.

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