Integrating Knowledge Management into QMS for Early Stage Companies

A Practical Approach for Improved Business Performance and Growth, Part 2

Lori Richter, Martin Lipa, and Nate Pofahl

REPRINT WITH PERMISSION ONLY

Knowledge management (KM) efforts are not undertaken for the sake of KM itself. They must be focused on providing effective management of knowledge to help employees do their best work for their organizations. KM is not only a regulatory expectation; if applied well, it also enhances business performance and employee engagement.

In BPI's April 2025 issue, the first half of this article introduced the basics of KM and quality-management systems (QMS). Herein, we conclude with case studies and practical strategies showing how early stage companies can establish scalable KM frameworks that encourage knowledge flow to ensure that the right information can reach the right people at the right time.

Getting Started with KM

KM is a *management science* — a means to analyze and improve business performance — and thus is less mature and more nebulous than practices such as quality risk management (QRM), organizational change management (OCM), and human performance improvement (HPI). KM concepts emerged in the 1990s as a means to improve business operations as knowledge work increased in complexity during the Information Age.

No definitive list of KM approaches, principles, or best practices exists. Considering the organizational models of most emerging biopharmaceutical companies (Figure 2 in Part 1), significant value can be achieved by applying some of the practices listed in the "Common Approaches" box in Part 1. The "KM Approaches" box here in Part 2 lists illustrative strategies tailored to enhance the business performance of emerging biopharmaceutical companies. Each of those approaches provides emerging companies with KM practices that can help to mitigate the loss of critical operational knowledge and decisions, reduce errors and mistakes in day-to-day work, and improve overall QMS effectiveness and business performance.

Below, we offer some preliminary case studies from emerging biopharmaceutical companies to suggest how others can

- build improved, KM-enhanced procedures
- drive continual improvement through a knowledge-sharing culture
- enhance tacit knowledge transfer for innovation and continual improvement.

Figure 4: Who–what–why design example form

4.0 PROCEDURE
4.1 [Section Title]
Procedure Intent: [Intent]

Step	Responsible	What is to be done	Reason
4.1.1	[Role X]	[Action]	[Reason for action]
4.1.2	[Role Y]	[Action]	[Reason for action]

Case Study Concepts

Based on expert opinions and experience with emerging companies, we have identified the following pilot efforts that represent preliminary case studies of KM implementation in progress. Studying them can bring valuable benefits and practical guidance to the emerging biopharmaceutical community. These early cases have progressed sufficiently to demonstrate the outcomes described below.

Building a KM-Focused Procedure: As discussed, a KM-enabled QMS can be a key driver of business performance. Fundamental knowledge flow in biopharmaceutical companies relies on processes for documenting knowledge in searchable repositories. The quality of knowledge involved is key to enabling good decision-making. One approach to increase the available knowledge for effective decision-making without increasing training time is to create quality-controlled procedures based on a "who–what–why" structure (Figure 4).

Each such document calls out who performs what steps ("Responsible" in Figure 4) to identify who may need training, where handoffs occur, and who needs to assess changes to a given process. Identifying handoffs is especially important for ensuring that procedures have an efficient, built-in

KM Approaches Tailored to the Operating Model of Emerging Biopharmaceutical Companies

Early Development Focus

For companies that are focused primarily on preclinical and early clinical trials, the small workforce's vision is short term to achieve registrational studies. The overarching knowledge-management (KM) strategy establishes a basic direction for that workforce: what the differentiating, critical knowledge for the organization is; what content-management systems will be used (and how they'll be configured); where the organization will embed continuous improvement after action reviews (e.g., at stage gates) and deploying decision trackers; and so on. Notably, a proactive strategy can help to enhance regulatory filings, improve an organization's ability to respond to agency questions, and ultimately increase the value of the company and its assets to potential licensing and other partnerships.

Outsourcing Dependency

Companies based on a "virtual" model and/or outsourcing work to clinical research organizations (CROs) and contract development and manufacturing organizations (CDMOs) must ensure an understanding of critical product knowledge through a product-knowledge plan (see box below). That plan will define and embed knowledge-transfer and -sharing requirements for supply and quality agreements. The goal is to enhance partnerships through shared reflection processes (e.g., after-action reviews) to evaluate and improve communications, technology transfers, and so on.

Immature Information Technology Infrastructure

A simple, secure shared-folder structure acts as a knowledge repository. Decisions are documented informally, often in emails. Information technology (IT) systems are immature and are not integrated across operations. Such companies can create basic content-management guidance documents to tell employees what information goes where and deploy a standard decision-making process that captures contextual knowledge (e.g.. rationale, alternatives considered, knowns/unknowns at the time, and so on).

Compliance-Focused Quality Management System

The simplest quality-management system (QMS) might consist of just a few procedures and manual forms that are fit to meet most basic regulatory-compliance requirements. A company can enhance the effectiveness of such procedures by capturing important contextual knowledge (e.g., explaining why something is important, what to do if something goes wrong, and what assumptions can be made during change/risk assessment). Such context will help to establish a means to reflect and improve on processes over time (e.g., after-action reviews and communities of practice). Developing templates and using checklists for procedures with instructions for authors can ensure consistency and quality.

Compliance-Focused Training for Knowledge Transfer

At many emerging companies, knowledge transfer primarily takes place through compliance-focused training programs that rely on trainees reading and understanding standard operating procedures (SOPs). Compiling and organizing important domain-related knowledge — e.g., on a mechanism of action, a unit operation such as chromatography, or another topic — can be helpful in accelerating knowledge transfer (e.g., "platform" knowledge). Another key opportunity is knowledge transfer through team reflection, such as a briefings before initiating tasks that are new, unique, and/or difficult and after some time has passed since a task was last performed. To drive learning and continuous-improvement opportunities, after-action reviews also should be conducted after work is completed.

Experience-Focused Staffing

When a workforce has been hired for extensive industry experience and the ability to fill multiple skill sets in an organization, unexpected turnover can be a risk to business continuity. Consider how employees can navigate available knowledge assets when onboarding to shorten time to competency and the lower the risk of inefficiency. Train people on knowledge-sharing behaviors and connect them to existing KM approaches (e.g., how to conduct a prejob brief). Consider processes for offboarding that will capture and preserve mission-critical knowledge and other important know-how that are critical to business continuity.

notification processes and that the needs of subsequent users will be well understood. Procedure authors must not assume that users will understand each step and know both how to perform it and when to do so.

Documented procedures typically describe actions to be performed without explaining why ("Reason" in Figure 4). Including relevant contextual information — e.g., the importance of a step, the risks of incorrect execution (safety or regulatory impacts), and the rationale behind current practice — will facilitate effective troubleshooting and change assessments in the future. Users are more likely to skip a step, and authors may be more likely to remove/modify it, if they do not understand its value. Some steps are meant to address uncommon but high-risk scenarios or meet the needs of future users. Other

Product-Knowledge Plan Creation

Here are some questions to ask when creating a product-knowledge plan:

- What knowledge (both explicit and tacit) is most important, and where does it reside?
- Who are the teams and experts?
- Where do knowledge risks — e.g., retiring subject-matter experts (SMEs), knowledge held only by third parties, and so on — lie?
- How have we captured key decisions?
- What are product priorities, and how do we roadmap them?
- Into which processes should after-action reviews be built?
- What are our data-analytics and artificial-intelligence (AI) opportunities?
- What gaps must be addressed (e.g., expanding searches, merging repositories, and replacing high-risk SMEs)?
- How do we define roles, develop training, build partnerships, ensure communication, and so on?

Here are some ways to support knowledge-management (KM) principles and best practices:

- Build KM into the "flow" of every process.
- Consider this order of priority — people, processes, technologies, and governance.
- Leverage partnerships, simplify processes, and co-deploy technologies.
- Align business impacts with organizational objectives.
- Determine whether goals should be set from the top down or the bottom up.
- Differentiate between explicit and tacit knowledge.
- Start small and agile, then scale up/out.

—Source: Lipa MJ. Operationalizing Knowledge Management. PDA/FDA Joint Regulatory Conference: September 2024.

Figure 5: Example charter; CMC = chemistry, manufacturing, and controls; GXP = good-practice framework; KM = knowledge management; PV = pharmacovigilance; QA = quality assurance; SOP = standard operating procedure; WI = work instructions

Meeting Team Members	
Required	Biometrics; clinical safety (PV), development, operations, and QA; CMC and QA, regulatory, quality systems
Optional/Ad Hoc	Document owners (subject-matter experts, SMEs), finance, legal, information technology (IT)

Meeting Objective	Communication Guidelines
Ensure that important/high-risk procedures are documented and appropriate for the functions that need to follow them. Make learning available to enable consistent performance of procedures and adherence to standards. Develop and maintain KM strategies to ensure that information is appropriately controlled and available to people who need it.	Facilitator to send agenda before the meeting date Team members expected to send a delegate if they are not able to participate Agenda and minutes

In Scope	Out of Scope
New/revised (major) SOPs, WIs, forms Training-needs assessments; identify topics, approve annual GXP training Computerized system enhancements Lessons learned	Specific work instructions not used cross-functionally Simple document updates Corporate policies Safety training

Commitment	Cadence
1–3 hours/month	1–2 times/month

steps have been implemented to address risks that no longer exist due to other process or system changes, so including "why" in documented procedures provides just-in-time contextual knowledge that otherwise might take years for future individuals to collect. The "why" helps users now and will benefit future authors when a document undergoes revision.

Thus, a "who–what–why" design helps to ensure right-the-first-time operations by maintaining a history of decisions and their rationales. That is vital for regulatory compliance, process improvement, and preserving knowledge over time. Well-written, clearly explained procedures will reduce the need for training and help users to identify opportunities for improvement. Clear procedures that are easy to follow provide a standard way of performing work and reduce unnecessary corrections and decision-making. Processes must be designed with users in mind to reduce variability by ensuring consistency in operations. Clear procedures lessen cognitive overload, freeing users to focus on important and complex steps and allowing them to apply their mental capacity toward identifying future improvements.

One pilot benefit (leading outcome) from a current project is the removal of redundant steps once the "why" is understood for documented procedures. Additional stakeholder (who) reviews have resulted in well-written steps that users can follow easily. Expected business outcomes (lagging outcomes) include a reduction in cost and increase in speed through right-the-first-time execution and improved troubleshooting when employees can understand why steps are performed (e.g., reduced cost and cycle time, reduced waste and deviations).

Encouraging a Knowledge-Sharing Culture: Documenting why process steps exist and are important is one way to share knowledge, but that is one-way communication. Sharing is best when it is multidirectional. A knowledge-sharing culture openly shares information for the benefit of peers and the organization at large. Situationally aware employees seek to learn from others in a reflective environment.

Beginning with staff onboarding, a knowledge-sharing culture must be fostered continually. Qualified personnel are a minimum QMS requirement. Assigning procedural documents for employees to read is a common training and qualification strategy for early stage pharmaceutical companies. However, "death by a thousand SOPs" is not enjoyable for new employees; more importantly, such approaches create missed opportunities for organizations to learn.

Instead of assigning procedures in a training curriculum, leverage the power of modern electronic documentation systems. Collect and group procedures for the teams that use them and/or the processes that they support. Assign an instructor lead or on-the-job training checklist by which a trainer, coach, or manager can direct employees to applicable collections and walk them through the important or unique parts of each procedure. Such processes ensure that employees receive only the knowledge they will need to perform their roles and responsibilities, which minimizes deviations and fosters consistent practices across teams and departments.

Instructor-led training ensures that learning is right-sized for learners, helps to identify information that may not be clear to new employees, and allows them to share their previous experiences in return. Such two-way communication can benefit a company by focusing training time on what learners need while creating opportunities for the organization to learn from newly hired staff. Trainers then can take lessons thus learned and share them with others across the company for initiating potential process improvements.

A QMS will work best if it is designed and improved in collaboration with consideration of a company's specific business needs. Authors of quality-controlled documents can benefit from a cross-functional forum to collect

feedback and identify potential stakeholders. Cross-functional KM teams (Figure 5) provide forums for sharing and discussing the results of improvements. Ideally, such teams meet frequently to share updates, discuss stakeholder feedback, and assess potential learning needs. Team members are encouraged then to report updates to their teams and collect feedback from procedure authors. A standard meeting with a supporting agenda can ensure that people have time to meet, that all participants learn the organization's needs, and that procedure authors have a forum in which they can share feedback (for parallelism).

Pilot benefits (leading outcomes) in a case-study project include a 50% reduction in the number of training assignments after removing the majority of read-and-understand assignments and replacing those with manager-led onboarding checklists. Surveys of new employees after onboarding have demonstrated increased satisfaction with onboarding processes, and managers appreciate having a systematic approach to reviewing role-critical information with new employees. Last-minute requests to assign procedures as training have dropped to zero because such requirements are discussed early in onboarding.

Expected business outcomes (lagging outcomes) are twofold: The time that it takes to bring new employees to competency is shortened, resulting in increased productivity and improved employee engagement. And such processing is sped up using clear steps that can be understood by users, thus decreasing cycle times, with continuous improvement of baseline processes.

Tacit Knowledge Transfer for Innovation and Continuous Improvement: Controlled documents and training should not be the sole repository for organizational knowledge and its transfer. Steps that are critical to product quality should be documented in controlled procedures, but such information can be stored in other places as well. An integrated training program leverages formal training elements as discussed above with just-in-time learning to ensure that employees receive the knowledge to perform their responsibilities when they need it. Organizations also have access to a number of cloud-based tools that employees are accustomed to outside of work. For example, Google Suite and Microsoft Office online tools (see the box above) make it easy to document knowledge, control editing rights, and connect different knowledge repositories with simple drag-and-drop website-development tools.

For example, process-flow diagrams and checklists can be enhanced and made readily available by posting them on an internal website. Elements of such documents can be made engaging by adding hyperlinks to detailed steps or videos on the current known ways to perform given activities and/or controlled procedures to which employees must adhere. Best-practice videos and instructions are great just-in-time learning tools that encourage knowledge sharing. Companies can recognize and reward people who create new videos for the internal website. Such sites help to connect people to knowledge and integrate different knowledge repositories into one convenient location.

Such repositories are not just for large organizations. Small companies can benefit from documenting standard work in easily accessible locations. It is common for such organizations to have a single person who is responsible for several standard processes. Documenting what is done helps those individuals remember what is to be done and when — especially if such tasks are infrequent — and can be a significant time saver when that person becomes unavailable (whether on leave or having moved on). Backup individuals can use documented information to perform needed procedures. That saves time by preventing the need to struggle through a process someone rarely performs, and it can prevent or reduce training before the primary employee leaves. Finally, if a procedure does need to become a controlled document as a company matures, the process is tested already and can be transferred quickly into a formal quality system.

Current pilot benefits (leading outcomes) include decreased hands-on time for managing quality records with work processes documented on Google sites, including links to prebuilt reports in the quality system. Hands-on time also is decreased, with frequently asked questions (FAQs) answered through video and step-by-step guides. Document change-control requests increasingly are made right the first time thanks to an online checklist with links to current templates.

Expected business outcomes (lagging outcomes) include increased efficiency and speed through ease of access to troubleshooting information and rapid problem resolution (thus reducing cost and cycle time). Employees are brought to competency quickly through easy access to information (leading to increased productivity and improved employee engagement).

Using Available Cloud Tools

Learn how to create a **Google** site online at https://support.google.com/sites/answer/6372878?hl=en.

Learn how to create a **SharePoint** site at https://support.microsoft.com/en-us/office/create-a-site-in-sharepoint-4d1e11bf-8ddc-499d-b889-2b48d10b1ce8.

Alleviating the Growing Pains

Knowledge flows easily when a small organization is just starting up. "Dams" to that flow begin to form as companies grow, specialize, and outsource. Implementing a KM-enabling QMS can help to ensure that knowledge moves to where it is needed when it is needed. A key strategy for successful QMS development is to install a system chosen to meet an organization's actual needs rather than a standard "cookie-cutter" QMS. KM can help to improve QMS performance and provide a means to drive quality culture and deliver significant financial benefits.

As our preliminary case studies illustrate above, significant value can be captured through targeted low-effort, high-impact actions. The immediate value will not be on the scale of a large, commercially focused corporation with a global footprint and thousands of employees. But the results will help emerging companies to operate more efficiently by reducing errors and other waste. These efforts can help to attract key talent and to increase the value position for a company overall.

In addition to the pilot programs that we have observed, some other low-effort KM strategies can be implemented easily by small biopharmaceutical companies:

- after-action reviews and lessons learned from key events
- communities of practice that help people to connect
- standardized and centralized decision trackers that connect people to knowledge
- off-boarding checklists ensuring that knowledge is retained when people leave an organization.

Additional actions require more effort but offer greater results to help companies adopt KM practices. Tracking metrics can show how KM efforts are supporting the business. It helps to educate employees on the value of KM and why it is worth their investment in time for both reflection and documentation of procedures. Refer back to the "KM Approaches" box in Part 1 for more details.

Installing KM's fundamental principles and practices might be easier in small companies than in large ones. Emerging organizations often are more nimble and ready to experiment, and their (often relatively young) management might understand new systems and tools that must be installed on the way to commercialization. Implementation can be based on a systems-thinking mindset and strong long-term vision to ensures that knowledge will be documented and flow effortlessly, enabling deployment of cutting-edge technologies with less effort than would be required at a large corporation. A scalable KM framework that strengthens a company's QMS will drive compliance, efficiency, and innovation as the organization matures.

By capturing tacit and explicit knowledge, standardizing processes, and documenting decisions, emerging biopharmaceutical companies can reduce variability, enhance decision-making, and foster a culture of continuous improvement. Enabling QMS robustness by integrating KM practices positions new companies to achieve strategic goals and sustain long-term success. Such efforts enhance the overall value to society through helping to foster a large percentage of the clinical pipeline and bring new therapies to market.

Lori Richter *(lrichter@alxoncology.com) is senior director of the GxP quality management system, and* ***Nate Pofahl*** *(npofahl@alxoncology.com) is director of GxP learning and document management at ALX Oncology, 323 Allerton Avenue, South San Francisco, CA 94080; 1-650-466-7125; https://alxoncology.com. Corresponding author* ***Martin Lipa*** *(martin.lipa@prst.ie) is an industry and regulatory advisor with the Pharmaceutical Regulatory Science Team in Dublin, Ireland, and formerly executive director of knowledge management at Merck and Co.*

To share this in PDF or professionally printed form, contact informa@wrightsmedia.com.

BioProcess International

It's noisy out there! *BioProcess International's* custom-publishing programs give you a way to stand out from the crowd.

Custom Publishing

Put your science to work. Publishing as part of BPI's main scientific issues and featured reports gives you access to our powerful print and digital platforms, putting you in front of sought-after prospects and reinforcing your position with existing clients.

Custom Reports

Custom Publishing programs include:

- Two to 24 pages (or more) — your choice!
- Access to BPI branding and templates
- Source tracking
- Turn-key editorial, design, and production services
- Full reprint and posting rights



Supplier Side Articles



Contacts:

Hanieh Ahmadian	hanieh.ahmadian@informa.com
Linda Cole	linda.cole@informa.com
Faizan Haider	faizan.haider@informa.com
Perri Lucatello	perri.lucatello@informa.com
Martha Phillips	martha.phillips@informa.com
Alexander Zenonos	alexander.zenonos2@informa.com

For more information, download our media kit.