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WHITEPAPER

DEVELOPING EFFECTIVE PROCEDURES

BY JEFF HALL & LISA HAWKINS

Developing Effective Procedures

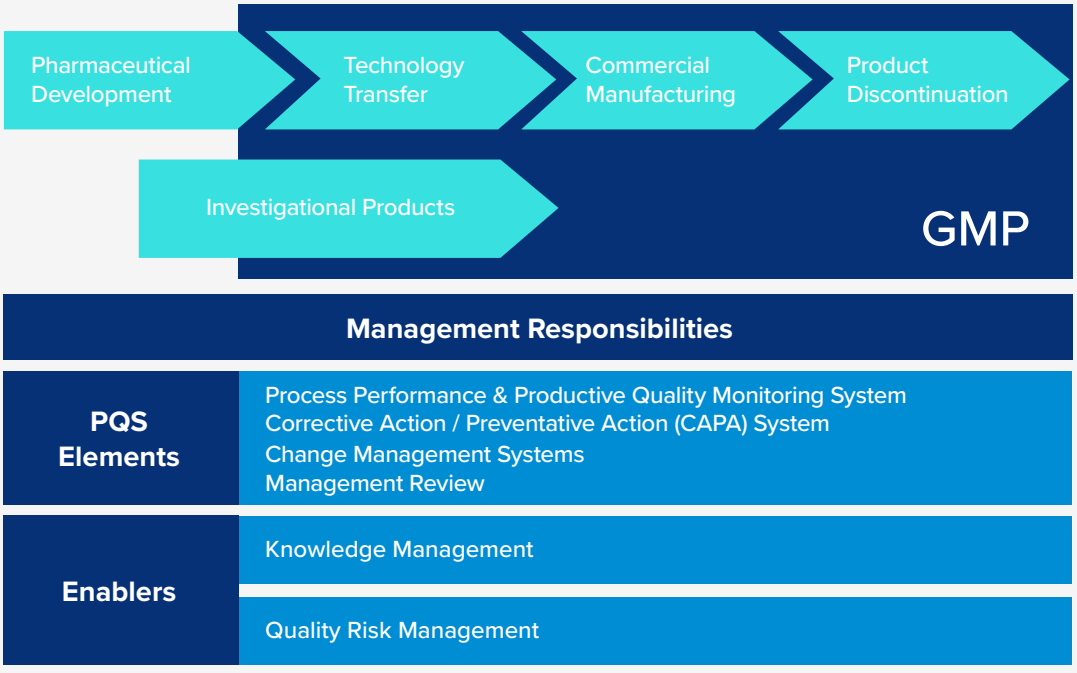
Needing to develop or update your procedures? Are you sitting at your computer starting to write procedures for every subject discussed in regulations and standards, addressing each statement with a procedural step? Put the procedure template away. The first step to writing effective procedures is in understanding WHY you are writing that procedure.

As everyone knows, a QMS/GMP/SOP controlled document system is made up of a certain set of procedures that get the job done, right? Let's challenge that idea. An effective documentation system is not a series of procedures: it is a process by which the organization will maintain a state of control that ensures patient safety by manufacturing products that are safe and efficacious. This doesn't happen because of procedures. Procedures are functional tools of a controlled process but are not the entirety of a control system.

Before fingers are ever put to a keyboard to start writing a procedure, the organization should evaluate its place in the product lifecycle, the type of product it is manufacturing, and the resources it has available to implement effective procedural controls. An organization with fewer than 50 people will end up with a different system than a multi-site organization with 50 people in one group. The path to get there, however, can be the same regardless of the organization.

We recommend a structured approach to understanding what your controls should be based on a foundation of three key processes: Change Management, Risk Management, and Knowledge Management. This is not to say that the remainder of the elements from ICH Q10 are not critical. They will be integrated as the structure is built. The elements and enablers and their role in product lifecycle are shown below.

ICH Q10 Pharmaceutical Quality System



The proposed roadmap requires stepping back to the basic structure of these three systems (Knowledge Management, Change Management, Risk Management) and how they integrate with each other before editing or creating procedures. The primary goal is to create a thoughtful structure of processes and procedures that interact appropriately where procedure adherence does not become an administrative task. The resulting system ensures efficient product realization, establishes a state of control, and facilitates continual improvement. A cross-functional team can be used to determine process owners and the purpose of the process (why do we need a CAPA process? Hint: "because FDA says so" is not the correct answer here).

QUALITY RISK MANAGEMENT

Regulatory authorities have been evaluating drugs, devices, and other products and the companies that make them using a risk-based approach for many years and have had an expectation that the companies themselves are approaching their system control using a Quality Risk Management methodology (ICH Q9). Companies that function only in a basic compliant state (i.e., all procedures and processes are based only on 21 CFR 210/211 Current Good Manufacturing Practice for Finished Pharmaceuticals) will be missing this key element as risk itself is never mentioned directly in the regulations. Therefore, using all available knowledge regarding risk management is key to building a good foundation. ICH Q9 Quality Risk Management (QRM) should be used to incorporate risk management into all aspects of the QMS and other GMP functions.

Quality Risk Management is the foundation of an effective process documentation system. Multiple processes and procedures provide input into and are informed by the risk management process. Risk Assessment is a single part of the process and should be used as required but does not represent thorough risk management. A recent project to create a thorough Quality Risk Management system resulted in the integration of the process in over 40 separate procedures.

One part of QRM that is often missed is the need for critical processes, such as change management and deviation/CAPA management. Critical changes or issues must be reviewed against the product or process originating risk assessment to determine if a previously implemented mitigation has failed, may fail, a new failure mode has been identified, or that a change may introduce a new risk or remove a previously implemented mitigation.

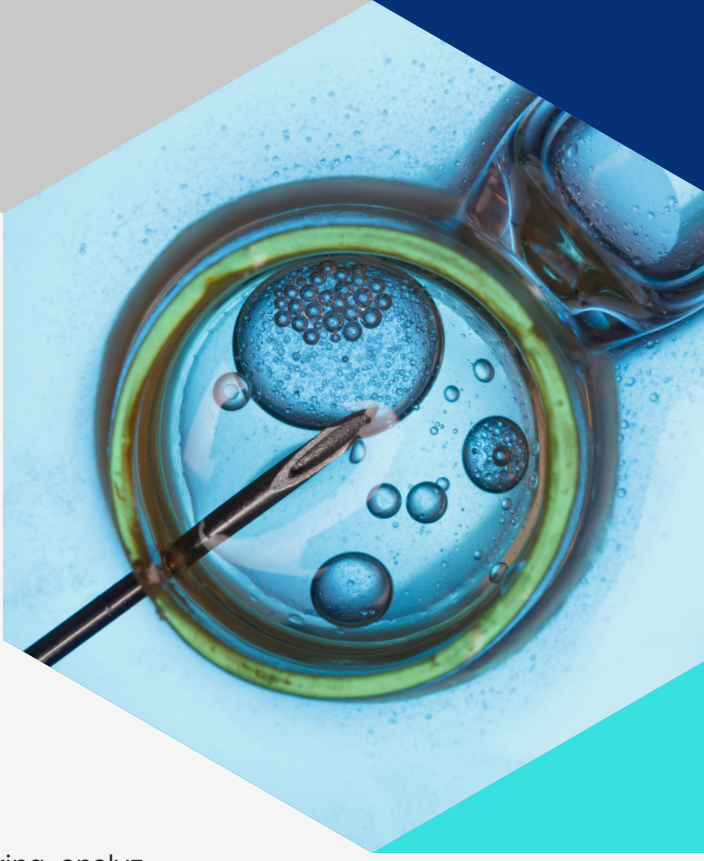
CHANGE MANAGEMENT

The Change Management System is a primary driver in meeting the intent of ensuring control of product quality, safety, and efficacy. Knowledge Management processes coordinate with Change Management to ensure that the controlled processes are appropriately delivered to the user. If the documentation system is structured using a sound approach, Change Management also ensures ICH Guidelines and local regulatory requirements are met.

The Change Management process should be developed to ensure that the change reviewers can clearly understand the impact of each change on the entirety of the process, risk, and other systems (e.g., Production and Process Control). This process, and its controls, need to be considered more than the administrative function of change management. As a part of overall Change Management, the Document Management process can have a significant impact on document accuracy, ensuring that the number of procedures does not become overwhelming by helping to find ways to combine where possible, and ensuring the elements listed above are met.

When evaluating this system's structure, alignment should include agreement on the definition of a change and what occurrences require a formal change process (e.g., routine maintenance that uses like for like parts does not require change management but a change in a critical part to a new non-like for like part would require evaluation or changes made to processes at early clinical phase manufacturing may require a less formal structure).

Further, the system should require preapproval of the change before implementation, including risk evaluation that is required to tie into the originating or most current risk management documentation for certain critical changes. Additionally, the process should require that the change does not remove a change previously made to address a CAPA or regulatory commitment or audit observation without justification of how the new change will not negate the effectivity of the commitment or interfere with intended risk mitigations. (Note: revision control is a great tool for identifying if a change is the result of a CAPA, audit finding, etc.) The system must include the requirement to reassess overall risk if the required change identifies a risk that has not previously been identified through other risk management activities.



KNOWLEDGE MANAGEMENT SYSTEM

Knowledge Management is a systematic approach to acquiring, analyzing, storing, and disseminating information related to product, manufacturing processes, and components and is a key enabler in ICH Q10. Knowledge Management ensures that process and process knowledge is managed throughout the product lifecycle. Knowledge Management is more than a formal training and education program, it is an integrated part of developing the information used in all lifecycle stages and to comply with regulations and requirements.

Knowledge Management also is important to Change Management activities. The initial determination of the documentation structure provides a foundation for the knowledge that the organization has identified. The procedures and documents written for the critical QMS processes are a key element of Knowledge Management, but they are only one part. Review of early phase development data, product quality information, change management information, discrepancy handing, audit management, adverse events, and other key QMS processes all provide input into a well-structured Knowledge Management System.

CONSTRUCTING THE PROCEDURE SYSTEM

Once the process framework has been developed, rather than creating the Tier 1 Quality Manual first, it will be left for last in this initial plan. Critical Tier 2 processes (as defined in the QRM/KM/CM structure) will be created/modified in a risk-based order that highlights when and where control is needed. Procedures appropriate to those processes will be developed. Next, remaining “non-critical” Tier 2 processes will be addressed with appropriate procedures developed. Finally, the Quality Manual is written against the actual QMS processes defined in the procedures reducing the amount of detail it contains that may contradict the other procedures. Tier 3 process documents can be generated throughout the process so long as the controlling process and its documents have been implemented.

Procedures should be seen as functional tools in the same way analytical instruments are tools. These procedures will be process driven not subject driven (e.g., audit management processes rather than internal/external/regulatory audits). This will reduce the overall number of procedures that define specific functions and create a purposeful flow between procedures that have relationships (e.g., CAPA, Nonconforming Materials, and Deviation Management). By changing the document generation process to refining tools including their relationships to each other, there is less confusion between procedures. The procedure itself is not the endpoint: the endpoint is robust documentation of a process that provides the proper level of Knowledge Management and process control throughout the product lifecycle and the organization.

ABOUT THE AUTHORS

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Jeff Hall is an Associate Director in Human Performance services with over 30 years of experience with implementing programs to support the start-up, operation, and maintenance of process systems and equipment. He has over 20 years of experience managing projects of up to $125M and leading groups of people ranging from one to over 25 persons. Jeff has an MBA and is an expert in Training Development and Project Management. He uses the skills in these two areas to manage project costs and efficiency. He has used this approach to create focused, effective, and efficient organizations and successful project implementation. He is experienced in auditing, developing programs, and leading projects in GMP, GLP, and GCP environments.

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