REGULATORY FOCUS

# Seeing the Bigger Audit Picture with an Enterprise Quality Management System

**By K.R. Karu**

If you ever want to watch a lively debate, bring together three groups—Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) auditors—and tell them to find common ground for their processes so they can coexist in the same system. They will look at one another's processes and find things that are totally foreign, and conclude that they cannot do it. You know what? They are right.

GLP auditors are responsible for assuring the quality of preclinical laboratory and animal testing. The format used is well defined by US Food and Drug Administration (FDA) regulations, with the hierarchy consisting of a Master Schedule entry, which may have one or many audits. The audits may have one or more findings. The findings then may have one or many related Corrective and Preventative Actions (CAPAs).

GCP auditors do something entirely different: they audit human clinical studies, meaning they are auditing the practice of medicine. Their hierarchy begins with a program that may have multiple clinical studies that need to be audited for accuracy and adherence to the study protocols. These audits can also have related findings and CAPAs.

Finally, GMP auditors confirm that written processes and standard operating procedures (SOPs) are being followed throughout small-scale manufacturing for clinical trials as well as commercial manufacturing. By the time product is finally manufactured, the recipe is well defined and GMP auditors ensure it is consistently followed. Multiple auditing groups, including GMP, compliance, supplier, purchasing and others also have the added responsibility of auditing suppliers, vendors and other third-party, contracted entities that support the manufacturing and distribution process.

Due to the distinct differences between one audit process and the next, an audit group should not be asked to unnaturally conform to one universal process. A comprehensive and effective enterprise quality management system (EQMS) does not force these three distinct groups to accept a "one size fits all" process; rather, it allows each audit hierarchy and process to be configured to meet the specific needs and requirements of

each unique audit group, while sharing common data fields, so across-the-board analysis can be accomplished.

A standard process can be established for related CAPAs, supplier information and other quality data to avoid duplicating efforts and repeating issues that have already been remedied. The benefit of putting these processes in a single system is that it creates a closed loop from early development through mass production.

In many companies, when one functional group (preclinical to clinical to commercial manufacturing) finishes its part of the product development process, the next group takes over with little or no vision into what was done previously. Likewise, the preceding group does not learn what happens next in the life cycle. With a shared system, three groups that are ultimately related in the product development lifecycle cease acting tribally. While the audit processes differ, there is some overlap in product names, materials used, locations, etc. In addition, as part of the hierarchy, most audit processes have potential findings and CAPAs related to the audits and, to a certain extent, these can be shared across groups. The findings of one group should be evaluated by the next to ensure similar mistakes are not made. CAPAs can apply to more than one functional area, especially when the root cause of a problem is process-, material- or equipment-related.

## Handling Outsourcing Complexities

Another factor that complicates all audit processes is outsourcing. Today, much of the work of bringing a product to market and producing it in a commercial setting is outsourced to contract laboratory organizations (CLOs), clinical research organizations (CROs) and contract manufacturers. Pharmaceutical companies have to audit the work of these contractors, since the pharmaceutical company must assume responsibility for the development and manufacturing of its products.

Auditors need to audit the audits performed in all three functional areas when contracting these services, as well as ensure the contractors adhere to their contracts and quality agreements. Thus, outsourcing introduces a new group of auditors to an already complicated dynamic. When a decision is made to use a supplier for GLP, GCP or GMP processes, pharmaceutical companies must evaluate these contractors' science, business practices, facilities, validation practices, legal practices and agreements and compliance with multiple regulations, including environmental health and safety. Most of these evaluations are performed by separate auditing groups from both quality and business groups within the different functional areas; it is not uncommon to have one set of auditors from a company leaving a site while another set is walking in.

This duplication of effort is expensive and time-consuming for both the auditing company and the third party being audited. A centralized auditing system that encompasses the different processes and different business functional areas creates efficiencies—not only visibility throughout the lifecycle, but also continuity in processes.

Rather than every audit group checking basic contractor background information, this information now can be shared. A central profile of a contractor or supplier's qualification should be one of the first steps in a consolidated EQMS auditing process and frees the specialized auditors to concentrate on their areas of expertise, while permitting updates to the central profile or expedited issuance of findings and CAPAs if a change in corporate standards is noticed.

## Managing Global Impacts

One more dimension impacts auditing—geography. The pharmaceutical industry is globalized, with preclinical and clinical studies occurring worldwide. Materials used in finished products can come from multiple sources in multiple countries.

If a company has regional or in-country auditing groups, sharing information becomes even more critical. An issue found in one region can affect the whole supply chain. If a supplier in one region cannot deliver or has quality issues, is there an approved supplier elsewhere providing the same goods and services at the required level of quality? In a centralized EQMS, these situations can easily be tracked and managed.

Centralizing your various auditing functions in an EQMS raises the level of trust in systems and processes across your company's management team. Dashboarding and

reporting from a centralized system increase visibility of issues and transparency across the organization. Critical decisions and actions can be taken sooner in the process.

An EQMS also helps to ensure a safer product. No longer are potential problems hidden in point solutions with little or no visibility of these issues—an EQMS allows management to "connect the dots." Individual, seemingly unrelated issues detected in various auditing processes alone may not seem out of the ordinary, but looking across functions, such issues may indicate a potential problem.

Finally, a global auditing process centralized in an EQMS creates measurable cost savings and efficiencies. IT and individual business units no longer have to support multiple point solutions. As an exercise, perform an inventory of systems currently used for the various auditing functions. From a business perspective, do these point solutions contain information that other functional areas might find useful? Do they collect redundant information? Consolidating multiple systems and creating easily consumed information from the data jointly collected will provide efficiencies to all auditing groups and management.

**Author**
**K.R. Karu** is an industry solution director for Sparta Systems, a leading quality management and compliance software supplier. Karu has worked in the global life sciences industry for 30 years, and is a member of the Parenteral Drug Association and the International Society for Pharmaceutical Engineering and a participant in the Good Automated Manufacturing Practice Forum.