Ensure High Quality and Maintain Compliance in Clinical Trials

The OpenText Clinical Trial Quality Management System

“Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.”

- WILLIAM A. FOSTER

Adhering to a high standard of quality in processes, products, and functions throughout a Life Sciences organization is a complicated and highly dynamic responsibility. Lack of visibility into your quality systems can lead to issues being overlooked or mishandled. Deviations from quality standards quickly affect the bottom-line performance of your organization. The result: you suddenly find yourself out of compliance with standards and procedures. Regulatory agencies (FDA, EMA), standards organizations (ICH) and industry consortia, such as Transcelerate, are actively seeking to harmonize best practices to ensure quality and consistency across the clinical trial process. In doing so, these organizations also hope to reduce the cost and time to bring potentially life-saving medications to the market.

The Clinical Trial Quality Management System helps you achieve the highest quality while maintaining compliance across all your key processes and systems. Move away from error-prone, paper-based systems and automate your manual review and approval methods, reducing the risk of non-compliance. OpenText offers electronic forms and workflows that let you automate the entire process of creation, review, and approval of quality and clinical trial documents, such as SOPs, protocols, CRFs, informed consent, and consolidate the appropriate documents into an electronic trial master file (eTMF). Manage CAPAs, NCPs, deviations, audits, and other quality processes in a single, integrated solution that is easily accessible from any web browser or device. Generate on-demand reports that provide up-to-the-minute details and visual indicators on the status of all quality tasks, processes, and documents. Detailed, 21 CFR Part 11-compliant audit trails, easy retrieval of information, and electronic signatures ensure you’ll have all the information required to respond to any inquiries.

**KEY BENEFITS**

- Manage multiple quality processes centrally
- Help ensure compliance with internal and external regulations
- Real-time dashboards highlight the status of all ongoing tasks
- Pre-built, customizable electronic forms make data entry easy and efficient for end users
- Completely electronic; eliminates paper processes and reduces human error
- Drag-and-drop workflow builder maps any quality process
- 21 CFR Part 11-compliant
- Configurable reports let users track key quality metrics in real-time
- Audit trails show all actions and events
- Web-based, easy deployment
“Quality” is defined as the absence of errors that matter.

Many groups, such as ICH, CTTI, and others, are working toward improving the quality of clinical trial process for a variety of reasons. Primary among them are protection of patients and obtaining reliable results and meaningful information from the trial. Life Sciences companies are additionally concerned with reducing the costs and time to market for their products. What defines a sufficient clinical trial quality program?

The FDA outlines the requirements for an adequate and well-controlled clinical trial in 21 CFR Part 314. Sponsors are mandated to document and demonstrate the following:

- Study design permits a valid comparison with a control to provide a quantitative assessment of drug effect
- Method of selection of subjects provides adequate assurance that they have the disease or condition being studied
- Method of assigning patients to treatment and control groups minimizes bias and assures comparability of the groups
- Adequate measures are taken to minimize bias
- Methods of assessment of subjects’ response are well-defined and reliable

Further, in its guidance to industry, the FDA recommends a quality risk management approach to clinical trials. As such, the study protocol should be considered blueprint for quality and the following steps should be taken:

- A risk assessment should be performed to identify and evaluate risks to critical study data and processes
- A monitoring plan with appropriate metrics should be designed and implemented to address important and likely risks identified during risk assessment.

How OpenText Enables Clinical Trial Quality

The OpenText Clinical Trial Quality Management System (ctQMS) lets you quickly and easily track and manage all your different quality processes starting from study design to closeout. CAPAs, non-conformities, deviations, audits, and other information can be easily accessed via the web-based interface from anywhere in the organization or anywhere in the world.

Workspaces allow you to manage each quality system individually yet maintain visibility across all quality systems in one central location. OpenText ensures security, which lets you control access to the different workspaces, ensuring users only see the information required for their respective roles or job title.

Electronic forms make creation of quality records quick and easy. Any type of form can be recreated electronically, removing the need for paper forms. The form is filled out in the browser, saved, and then automatically routed for review, processing, and approval. Any subsequent changes are captured in the version history and audit trails.

The workflow functionality in the QMS allows users to model any quality process via configuration, negating the need to re-validate the entire application. The graphical workflow builder lets you drag icons representing different tasks and roles onto the palette. You then quickly connect the tasks in the proper sequence, either sequentially or in parallel. Automated decision steps can be put in the process, speeding review, along with electronic signature requests.

At the completion of the quality process, all information is stored in the repository where it is indexed and fully searchable. Past quality records are easily retrieved and viewed online. A number of standard reports are provided, and custom reports can be created. Reports can be retrieved in real time, or run on scheduled intervals.

A key component of any quality program is continuous improvement. The ability to use analytics to define, measure, and refine processes along the value chain is critical to maximizing efficiencies and reducing errors. The OpenText platform has powerful integrated analytics tools to help you gain timely insight and streamline processes.

Quality Management System Applications

With the Clinical Trial Quality Management System, you can increase visibility into all of your quality processes in real time:

- Remove paper and automate manual review and approval processes. This reduces opportunities for errors in data entry and routing of paper forms.
- Find all quality information in one location, quickly and easily. With all information easily accessible via a web browser—not sitting in binders or a file cabinet—you can quickly access any quality information from anywhere in the organization.
- Ensure compliance with internal and external regulations. By automating your quality systems, you are assured information gets to the right person at the right time and is acted upon within the specified time requirement. Incidents of non-compliance are reduced.
- Detailed reports, dashboards, version control on all documents, and audit trails for any activity gives you the information you need to prove compliance at any point in the quality process.
Summary

Coordinating and streamlining quality programs across the enterprise, while maintaining regulatory compliance, are primary among the challenges that Life Sciences organizations face today. The opportunity to cut costs and reduce dependency on paper and manual processes is of enormous benefit. In the Life Sciences industry, one of the key factors in maintaining regulatory compliance is the management and control of key documents that are subject to various regulations. All aspects of a quality system generate regulated documents, such as policies, standard operating procedures (SOPs), work instructions, investigation reports, audit reports, training reports and validation documentation.

Our ctQMS enables your organization to manage and control clinical trial documents throughout their lifecycles. Documents that are needed for audits, CAPA, training and so on can be created, reviewed, approved, edited and maintained within the Quality Management repository. This functionality can be built into the workflows for both audits and CAPA. Regulated documents are maintained in full compliance with the FDA’s 21 CFR Part 11, including the ability to render and electronically sign approved documents. Thus, the OpenText ctQMS offers companies the software infrastructure to remain compliant, reduce costs of records management, and establish best practice through collaboration before, during, and after the clinical trial process.