The OpenText Quality Management System

Ensure High Product Quality and Maintain Compliance in All Your Critical Processes

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 and your company. The result: you suddenly find yourself out of compliance with standards and procedures.

The Quality Management System for Life Sciences helps you achieve the highest product 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 documents such as SOPs. Manage CAPAs, NCPs, Deviations, Audits, and other quality systems in a single, integrated solution that is easily accessible from any web browser. 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.

How OpenText Helps you Manage Your Quality Systems

The OpenText Quality Management System (QMS) solution lets you quickly and easily track and manage all your different quality systems. CAPAs, NCPs, Deviations, Audits, and other information can be easily accessed via the web-based interface from anywhere in the organization or anywhere in the world.

KEY BENEFITS:

- Manage multiple quality systems centrally
- Help ensure compliance with internal and external regulations
- Real-time dashboards highlight the status of all ongoing tasks
- 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

Collaborative 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 new 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.

Quality Management System Benefits

With the 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, 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. ■

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