MS-OT

Quality Management for OpenText

Why QMS-OT?

Complete Solution

Seamlessly integrated with Open Text ECM, providing a closed loop quality process.

Flexible and Scalable

Offers pre-built workflows that are configured to suit your organizations specific business rules. Customized workflows are also available.

Regulatory Compliance

Built for Purpose to assist companies in meeting regulatory requirements

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Xybion's Quality Management System solution for OpenText (QMS-OT) gives life science organizations, including pharmaceutical, medical device, biotechnology, and diagnostic companies, a flexible and extensible solution to manage quality issues and initiatives. With out-of-the-box integration to OpenText LiveLink® Enterprise Content Server, you'll gain efficiencies and save on support costs by leveraging your existing investment.

The Xybion QMS-OT platform offers a turnkey solution for a variety of business critical processes required for life science organizations, including Corrective and Preventive Actions (CAPA), Audits, Training and Regulated Document Management.

Key Features & Benefits:

- Fully integrated with Open Text ECM Suite, reducing support costs and user training requirements.
- Pre-built and custom workflows for Audit, CAPA, Compliant Management, and more.
- Automate the process of capturing, monitoring, and manage key quality issues and initiatives across the organization.
- Compliant with the electronic records provisions of the U.S. Food and Drug Administration's (FDA) 21 CFR Part 11, while addressing the needs for Pharmaceutical Good Manufacturing Practice (21 CFR 210 and 211), Biological Good Manufacturing Practice (21 CFR 600--680) and Medical Device Quality System Regulations (21 CFR 820).

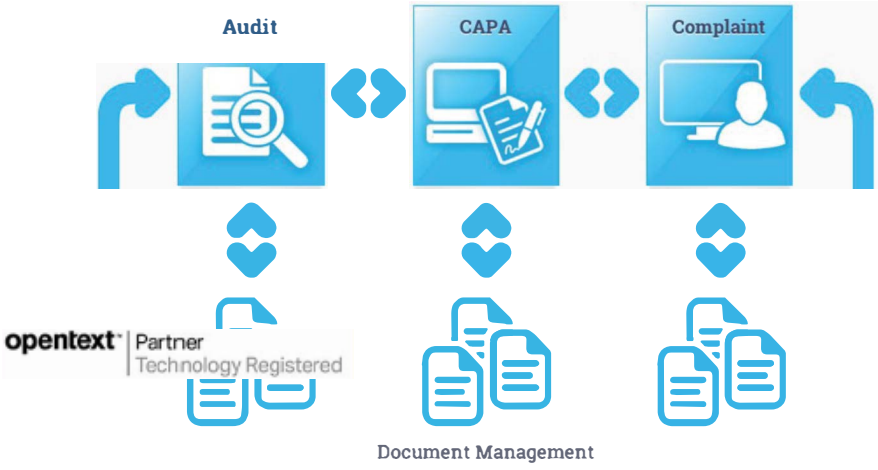

Figure 1. *Xybion's QMS-OT platform enables organizations to manage key business processes required for robust quality programs, including Audits, CAPAs, and Customer Complaints.*

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CAPA Management

Life science organizations are required to capture, track and report on event discrepancies of various types. CAPA allows the capturing, tracking and reporting of various quality issues, including observations, complaints, adverse events, deviations, non-conformances and audit findings. There are four main phases within CAPA: Incident Phase, Investigation Phase, Planning Phase and Execution Phase.

Configurable forms are used to capture and present data and information throughout the process, and configurable workflows are used to integrate the various CAPA phases, along with the other processes, such as Audit, Training, and Regulated Document Management. CAPA allows the unique identification of incoming sources of product and quality data. It facilitates investigation and analysis to allow comprehensive corrective and preventative action plans to be put in place and tracked to conclusion. Verification and validation of the specific actions or remedies are also specified and tracked in CAPA.

Comprehensive Auditing

Audits are a key tool used for life science organizations to assure that quality initiatives are in compliance with established quality requirements and to determine the effectiveness of the overall quality system. Audits can be applied to various entities, including external suppliers, vendors, internal departments, individual processes and systems.

The Quality Management System audit capability allows users to create audit templates that can then be used to prepare for specific audits. Audits flow through a typical workflow, including audit initiation, planning, scheduling, execution, reporting, and follow-ups. When an Auditor generates an Audit from an Audit Template, the Audit becomes available for execution. As the Audit is executed, the Auditor completes each section of the audit form until all areas are completed. Once the Audit is completed, it is closed, at which point the Audit becomes an Audit Record. Audit findings or observations can then be used to generate a CAPA. Follow-up activities are scheduled and tracked as needed.

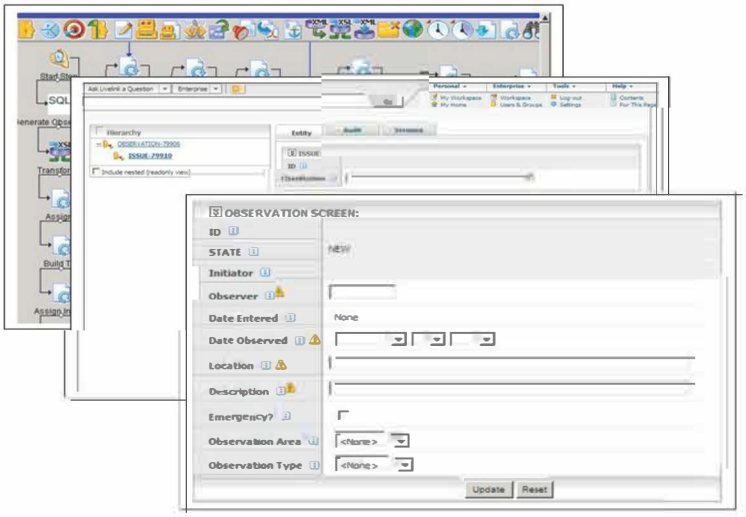

Figure 2. QMS-OT enables an organization to manage and control regulated documents throughout their lifecycles. Documents that are needed for audits, CAPA, training, etc. can be created, reviewed, approved, edited and maintained within the Quality Management System repository. This functionality can 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.

Regulated Document Management

In the life science 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.

Did You Know?

- Xybion has over 20 years of experience helping clients streamline compliance and mitigate risk.
- Our team of professional extensive global experience and works with companies of all sizes from multiple industries.
- We offer deep domain knowledge of FDA regulations and has a long track record of helping clients build effective risk mitigation strategies.

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