Why QMS-OT?

Complete Solution

- Seamlessly integrated with OpenText ECM, providing a closed loop quality process.

Flexible and Scalable

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

Regulatory Compliance

- Built to assist companies in meeting regulatory requirements

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.

Xybion's Quality Management System 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 preventative actions (CAPA), audits, training, and regulated document management.

Key Features & Benefits:

- Fully integrated with OpenText ECM Suite, reducing support costs and user training requirements.
- Prebuilt and custom workflows for audits, CAPA, compliance 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).

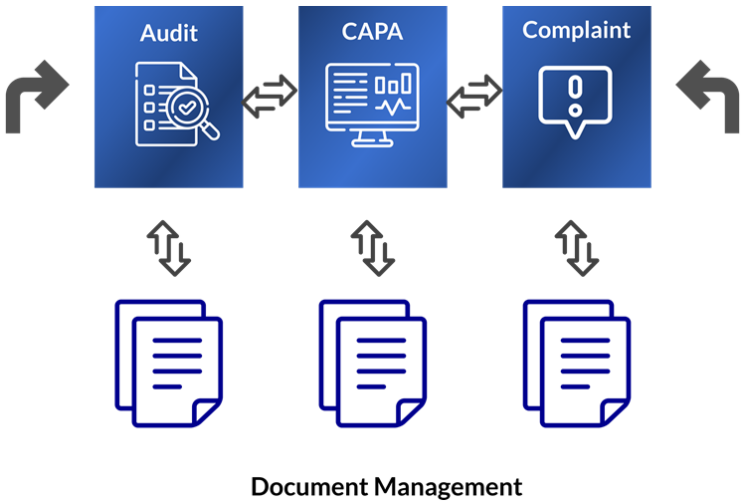

Figure 1. Xybion's QMS-OT platform enables organizations to manage key business processes required for robust quality programs, including audits, CAPAs, and customer complaints.

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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 a 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.

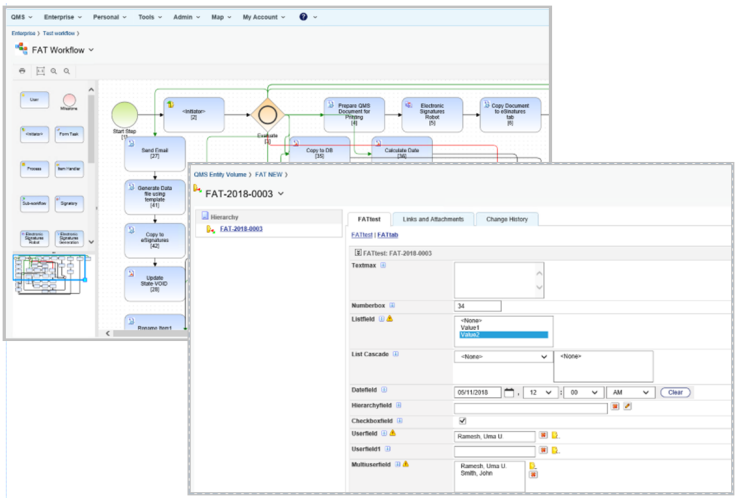

Figure 2. QMS-OT enables an organization to manage and control regulated documents throughout their lifecycles. Documents that are needed for audits, CAPA, training, etc. can be created, reviewed, approved, edited, and maintained within the Quality Management System repository. This functionality can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

About Xybion

Xybion is a leading SaaS company dedicated to providing life sciences and health systems companies with innovative software solutions to accelerate the transformation of today's inventions into tomorrow's approved medicines, devices, and diagnostic tests designed to save lives and keep employees safe. Our intelligent cloud platform and software solutions help companies accelerate digital transformation of processes, speed up innovation, optimize operations, reduce compliance risks, and achieve significant cost savings.

Xybion is serving over 160 customers in 29 countries including all the top 20 global biopharmaceutical companies. Xybion's global scale and expertise brings employees around the world to help companies in life sciences, health systems, research institutions, and governments. We help companies digitally transform their regulated business operations. Our unique solutions focus on employee health and safety, integrated preclinical lab management, early-stage drug discovery, digital lab solutions, regulatory compliance, GRC, quality management, predictive compliance, content management, and systems validation.

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