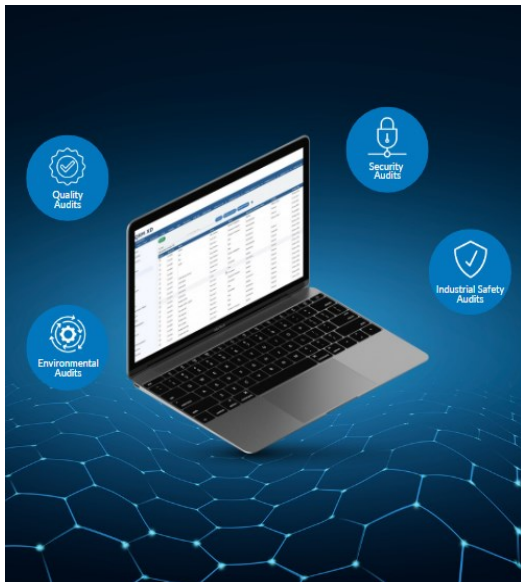


Xybion® QMS

Xybion QMS is a powerful cloud-based software that facilitates organizational compliance with regulatory guidelines and ensures products and processes meet the highest standards, such as ISO standards, GxP, 21 CFR Part 11, financial reporting, governance regulations, and many more.

Xybion QMS: The All-In-One Digital Quality Management System



Xybion QMS software streamlines your quality management processes so they are easily tailored to your specific operating style and business needs.

Quality Management System

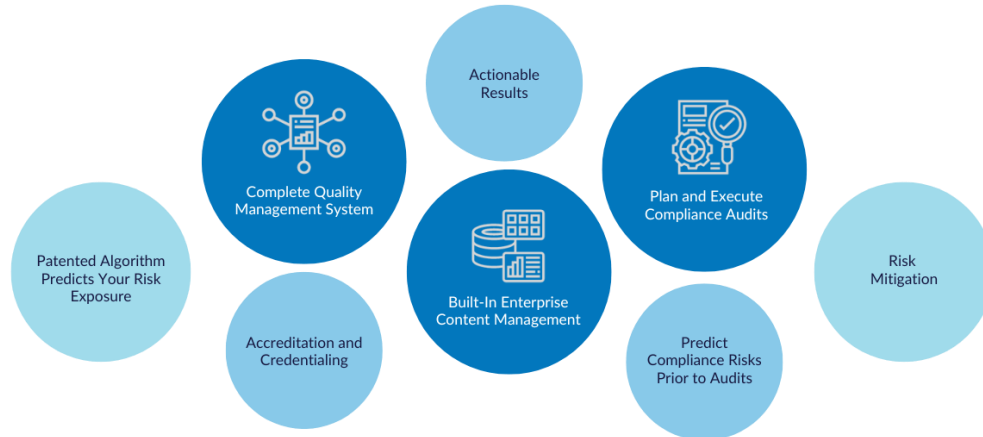
Xybion QMS is a highly adaptable and technologically advanced Quality Management System (QMS), designed for today's digital world. Xybion QMS is purpose-built with embedded quality and compliance. This next-generation platform ensures compliance, risk, and quality in complex, highly regulated industries.

Easily tailored to your specific operating style and business needs, Xybion QMS automates compliance, risk, and quality management, while ensuring that organizations maintain a seamless workflow connecting internal organizations with external partners, vendors, and regulators in highly regulated work environments.

The Xybion QMS Difference

Xybion QMS was designed for regulated industries where high regulations and strict evidence-based documentation of activities are necessary for compliance or safety and liability management. The platform helps global organizations effectively automate, manage, and control compliance and quality process flows, such as Corrective and Preventive Actions (CAPA) deficiency, Nonconformances, Audit Management, Complaints Management, Change Management, Document Management, Incident Management, Competency Management, Internal Controls, Programs and Objectives, IT Governance and Quality Management. Xybion QMS is a comprehensive quality management software solution that delivers enterprise quality and management. The platform provides powerful cloud-based capabilities that facilitate 21 CFR Part 11 compatibility. The solution is designed for maximum flexibility and is easily adapted to any organization's unique business processes. Additionally, Xybion QMS can manage all stakeholders and their contacts, organizations, and locations, including customers, partners, external contractors, governing bodies, and various internal groups. Xybion QMS can automate workflows, manage content, and integrate into existing technology environments, as well as granularly control and secure the activities of the different user roles within the system. It reduces IT support costs due to system consolidation and application landscape simplification. Also, it ensures compliance through its built-in features to support regulatory compliance with IACUC, AALAC, GLP, 21 CFR Part 11, and internal training requirements.

Transform Your Quality Management



Next Generation Compliance, Quality and Risk Management Solutions for a Global Pharmaceutical Manufacturer

A global pharmaceutical manufacturer was looking for a QMS solution that integrates with their R&D labs. Unable to find it from their current QMS provider and other QMS systems on the market, they chose Xybion for its robust, all-in-one digital quality management system software. The global pharmaceutical manufacturer had a siloed and paper-based quality management approach, making preparing for inspections more challenging. The company also comprises three significant divisions across the United States and Europe, each with its own quality management process, leading to process gaps and making it more difficult for internal auditors to prepare for regulatory inspections.

The global pharmaceutical manufacturer partnered with Xybion to launch a user-friendly web-based quality management system (QMS) and be able to provide solutions to:

- Streamline quality management processes by eliminating disconnected systems within siloed working environments
- Enable to deploy only the functionality they need to ensure quality and compliance
- Help reduce manual data entry errors via automated processes
- Ensure 21 CFR Part 11 compliance on electronic records and signatures

Xybion team effectively delivered a web-based, multilingual, validated quality management solution thus enabling the pharmaceutical manufacturer to improve compliance and efficiency for their internal processes.

Unified Operational Integration Framework

Xybion QMS ensures process fidelity, data integrity, and chain of custody protection across your organization. This unified operational ecosystem provides the functional breadth and depth companies need for highly regulated industries. Xybion QMS fully integrates with all quality assurance systems found in R&D, pharmaceutical, and all regulated laboratories. Ensuring intrinsic quality and embedded compliance, it dramatically simplifies IT architecture and releases resources back to the business.

Rapid Configuration Engine

Xybion QMS is built to facilitate configurations vs. customizations. This rapid configuration engine solves the last-mile problem, where the only way to align applications to the company's needs entirely is to develop client-specific customizations. Xybion delivers customizations within days instead of weeks by providing customizations as configurations. In addition, the rapid configuration engine cuts the high cost inherent in customizing traditional QMS and the manual workarounds needed while you wait for those customizations to be delivered.

Intelligent Digital Workplace

Xybion QMS promotes an intelligent digital workplace that enables team members to collaborate via the cloud, with a full calendar, alerts, and email capabilities. It provides this intelligent digital workplace to your entire team, internal team members, external partners, and processes. The intelligent digital workplace extends to people who work for third parties and connecting them to the platform's collaboration and additional task management functions.

Modular Functionality for Maximum Flexibility



Xybion QMS - Embedded Enterprise Content Management

Xybion QMS has a powerful enterprise content management (ECM) system integrated with the process management and workflow engines built into the platform. It has all the features and functions inherent to any content management system. Xybion QMS query system supports 100% search capability for every word and workflow. At the same time, the embedded ECM allows the fast creation of any report based on selected metadata or search words. Built-in analytics allow for rapid creation of customized dashboards that enable you to manage workflows, know where each document is in its life cycle, and understand who controls it at any time. Dealing with external audit or inspection questions is a simple affair. It lets you quickly render any document classified by type, department, creator, data content, etc., along with a full audit trail.

Xybion QMS - Total Quality Management Software for Every Laboratory

Xybion QMS software streamlines your quality management processes so they are easily tailored to your specific operating style and business needs. Deploy only the functionality you need today without disrupting your business operations.

Xybion QMS is designed for maximum flexibility and easy adoption of any organization's unique quality and compliance processes. Proactively mitigates your risk exposure for proactive management of tasks and activities, which is particularly helpful in CAPA.

Xybion QMS - Always Be Audit-Ready

Built-in analytics allow for rapidly creating customized dashboards that enable you to manage workflows and know where each document is in its lifecycle. It will help you in audits and inspections where you can render any document with a full audit trail.

Xybion QMS - Leveraging Proactive Workflows

Xybion QMS delivers a foundational set of consistent workflow processes that enable proactive management of tasks and activities, particularly helpful in corrective and preventive actions (CAPA) on time. Managers can create and store action plans in a library for reuse, saving valuable time in planning actions.

Additionally, Xybion QMS offers intuitive, powerful configuration options for building workflows, forms, and rules according to your business processes, which help monitor various performance objectives. Pick-select fields, form design, business rules on fields, flow, and notifications are all configurable. The search and reporting capabilities allow the organization to report on the various benchmarking information across its portfolio. Xybion QMS is unique in its ability to be quickly configured at module, submodule, workflow, screen, and field levels. The entire platform can automate workflows, manage content, integrate into existing technology environments, and granularly control and secure the activities of different user roles within the system.

Xybion QMS Provides One Platform and One Solution - Deploy Only What You Need

Xybion QMS consists of a suite of modularized components which can be added to a core implementation as the organization's needs grow and change. Our solution is designed for maximum flexibility and easy adoption of any organization's unique quality and compliance processes.

Xybion QMS is a modular platform architecture that allows you to deploy only the functionality you need today, yet remain positioned to scale and rapidly ramp up new functionality without disrupting existing business operations. Xybion QMS provides one platform and one solution to meet your immediate business demands and the agility to drive each step of your organization's strategic roadmap.

Achieve Total Compliance with Xybion QMS Modules

Xybion QMS Modules:

- CAPA Management
- Audit Management
- Complaint Management
- Change Management
- Document Management
- Nonconformances
- Incident Management
- Competency Management
- Internal Controls
- Programs and Objectives
- IT Governance
- Quality Management

Xybion QMS: Total Quality and Compliance Suite

Xybion QMS is purpose-built with embedded quality and compliance; this next-generation platform ensures compliance, risk, and quality in complex and highly regulated industries. Easily tailored to your specific operating style and business needs, Xybion QMS automates compliance, risk, and quality management while ensuring that organizations maintain a seamless workflow connecting internal organizations with external partners, vendors, and regulators in highly regulated work environments. Xybion QMS helps global organizations automate, manage, and control compliance and quality process flow through its modules.

Xybion QMS: CAPA Management Module

Corrective and Preventive Action (CAPA) can be daunting for quality-minded organizations. Xybion QMS makes managing CAPAs easy with a comprehensive CAPA workflow embedded in the enterprise quality management solution. The CAPA solution is integrated with all other core quality management processes. The CAPA management module is offered as a stand-alone solution or integrated with other quality management processes.

Xybion QMS: Audit Management Module

Effectively managing audits is essential to any quality management program. Good audit management helps to proactively ensure quality by measuring and improving processes, procedures, and marketed services and

products. Xybion QMS Audit Management module ensures quality adherence throughout the entire value chain. It contains a comprehensive audit management module to help reduce risks and maintain customer satisfaction.

Xybion QMS: Complaint Management Module

Customer complaints present unique challenges to manufacturers across multiple industry sectors. By nature, customer complaints represent dissatisfaction with either product quality or performance in a post-distribution environment. Xybion QMS Complaint Management module is designed as part of an integrated GRC suite to efficiently document, manage, and control customer complaints in compliance with current regulatory guidelines and best practices.

Xybion QMS: Change Management Module

Effective change management is essential to achieve regulatory compliance and good corporate governance. Xybion QMS Change Management module empowers organizations to consistently follow best practices to initiate a change request, follow a risk-based approach to assess change impacts, create action plans, obtain appropriate approvals and signoffs, and provide communication and collaboration throughout the change cycle.

Xybion QMS: Document Management Module

Many document management systems require you to adapt your business processes to fit the software. Xybion believes this should be the other way around – the software should be adaptable to your business processes. Xybion QMS Document Management module fully supports the way YOU work. Key platform features are highly configurable to help you holistically manage compliance-related information across an organization's entire value chain.

Xybion QMS: Nonconformances Module

It is critical to have an effective strategy for nonconformances and to develop Corrective and Preventive Actions (CAPAs) to prevent repeat occurrences. Xybion QMS Nonconformance module allows you to effectively automate and manage the nonconformance process in compliance with regulatory guidelines. This module provides management of nonconformances through automated, web-based tools for handling materials, methods, components, and products.

Total Quality Management Software For Your Laboratory

Xybion QMS: Incident Management Module

Xybion QMS Incident Management module provides a complete incident management solution to help you consistently and appropriately manage incidents. The secure, cloud-based platform offers enterprise collaboration and communication to manage incidents appropriately and comply with internal procedures and outside regulatory requirements.

Xybion QMS: Competency Management Module

Xybion QMS offers a comprehensive training and competency management software module as a part of its Xybion QMS software suite. The cloud-based software helps you comply with requirements for electronic signature, electronic records, and software validation, such as 21 CFR Part 11 from the FDA.

Xybion QMS: Internal Controls Module

Xybion QMS Internal Controls module can manage your control environment, risk assessment, control activities, information and communication, and ongoing monitoring in compliance with your company's business objectives, within a single platform.

Xybion QMS: Programs and Objectives Module

Leading companies use software to set measurable objectives, record data to measure against those objectives, and report on compliance status. With Xybion QMS Programs and Objectives module, you can set your company, department, or unit-wide objectives and tie those objectives to applicable programs such as environmental, health & safety, and quality programs.

Xybion QMS: IT Governance Module

In today's challenging technology and business environment, IT systems drive or highly influence many compliance processes. To help you manage your IT governance, Xybion provides a complete IT Governance software solution as part of its Xybion QMS software suite, available in the cloud or on-premise.

Xybion QMS: Quality Management Module

Xybion QMS Quality Management module provides one platform and one solution to meet your immediate business demands, unique business needs, and the agility to drive each step of your organization's strategic roadmap.

Compliance Builder

Compliance Builder with real-time monitoring is a unique software offering that helps companies enable 21 CFR Part 11 compliance and ensure data integrity by monitoring and securing data from file systems, databases, lab and manufacturing equipment. Compliance Builder integrates directly with your R&D operations to effectively monitor real-time compliance. FDA-regulated companies can leverage the most advanced real-time compliance monitoring system for a holistic risk mitigation approach across all instruments, files, and databases.

Compliance Risk Predictor

Compliance Risk Predictor helps life sciences companies conduct quantitative assessments of business risks. The patented solution improves a company's ability to understand current compliance status, know business risks and prioritize actions. Understanding higher visibility and prioritized actions make teams more productive and reduce costs.

Xybion Accreditation

Xybion Accreditation is a leading digital workplace solution providing end-to-end process management to automate and simplify the complex process of accreditation, recognition, and auditing programs, including the medical device single audit program. Xybion Accreditation helps to manage required certifications and accreditation efficiently with complete security and data integrity.

Third-Party Risk Management

Xybion's cloud platform for the digital transformation of Third-Party Risk Management utilizes a single low-code platform with built-in governance, risk, compliance, quality, and enterprise content management. An integrated Third-Party Risk Management platform can make processes more efficient, reduce operations costs, and reduce noncompliance costs and business risks.

Validation Management

Xybion's Validation Management software is a total quality and compliance management software that allows companies to create a unified process for creating, managing, and executing all validation activities across multiple sites and countries and numerous regulatory guidelines as necessary.

Future-Proof Your Technology Investments

Meeting Your Needs Today and in the Future

Traditional QMS solutions include hard-coded, operational-focused modules that allow a certain configuration level. These solutions quickly hit roadblocks when developing more complicated and site-specific requirements. Many also focus on the particular topics of quality (Audit, CAPA, etc) rather than the end-to-end business and compliance management process. However, Xybion QMS allows companies to quickly and efficiently implement quality and compliance programs and solutions that fit their organizational needs across many focus areas.

Xybion QMS provides a single, out-of-the-box, yet highly configurable solution to holistically manage quality and compliance processes and information across an organization's entire value chain. Xybion QMS delivers immediate value without expensive customization, minimizing the total cost of ownership over time. Xybion's holistic approach towards product lifecycle, including pre-clinical activities, clinical data, GRC, and data integrity, are all maintained with modular low-code application development, so clients can easily deploy the functionality they need and quickly adapt the QMS to their unique business processes. This way, Xybion QMS can scale rapidly with the company's growth and improve process efficiency. Also, as the company grows commercially, the GRC modules help manage the risks associated with in-house and external distribution models, including changing regulations, promotional compliance, etc. Our innovative system is designed to meet your current needs and adapt to your future needs. With Xybion QMS, you can rest assured that you use a reliable and efficient quality management system that will help streamline your processes and improve your overall success. Book a demo of Xybion QMS to begin holistically managing and automating your quality processes that support your business's commitment to quality.

Xybion QMS Distinct Top Advantages:

- Increase visibility
- Better business decisions
- Always be audit-ready
- Enhance Security
- Deploy only what you need
- Supports regulatory compliance
- Integrate into existing technology environments
- Achieve better compliance
- Leverage existing workflows
- Proactively mitigates risk exposure
- Proprietary patented AI algorithm fully

Xybion QMS is the all-in-one digital quality management system for today's digitally connected world that meets the needs of organizations in highly regulated industries today and in the future. Experience our commitment to providing solutions for maximum flexibility and easy adoption of your organization's unique quality and compliance processes.

About Xybion

Xybion is a leading SaaS company dedicated to providing life sciences and health system 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.

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.

Xybion is serving over 160 customers in 29 countries including all the top 20 global biopharmaceutical

