

The “Holy Grail” of a single cloud platform bringing your entire operation, organization and partners together in a compliance-embedded risk-aware and quality-ingrained BPM Platform is here.

CQRM XD **Quality Management**

CQRM XD: Next Generation All-In-One Governance, Risk, Compliance (GRC) & Quality Management System (QMS)

Xybion's CQRM XD Quality Management is a highly adaptable and technologically advanced Governance, Risk, Compliance (GRC) & Quality Management System (QMS) designed for today's digital world. 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, CQRM XD Quality Management automates compliance, risk & 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 CQRM XD Quality Management Difference

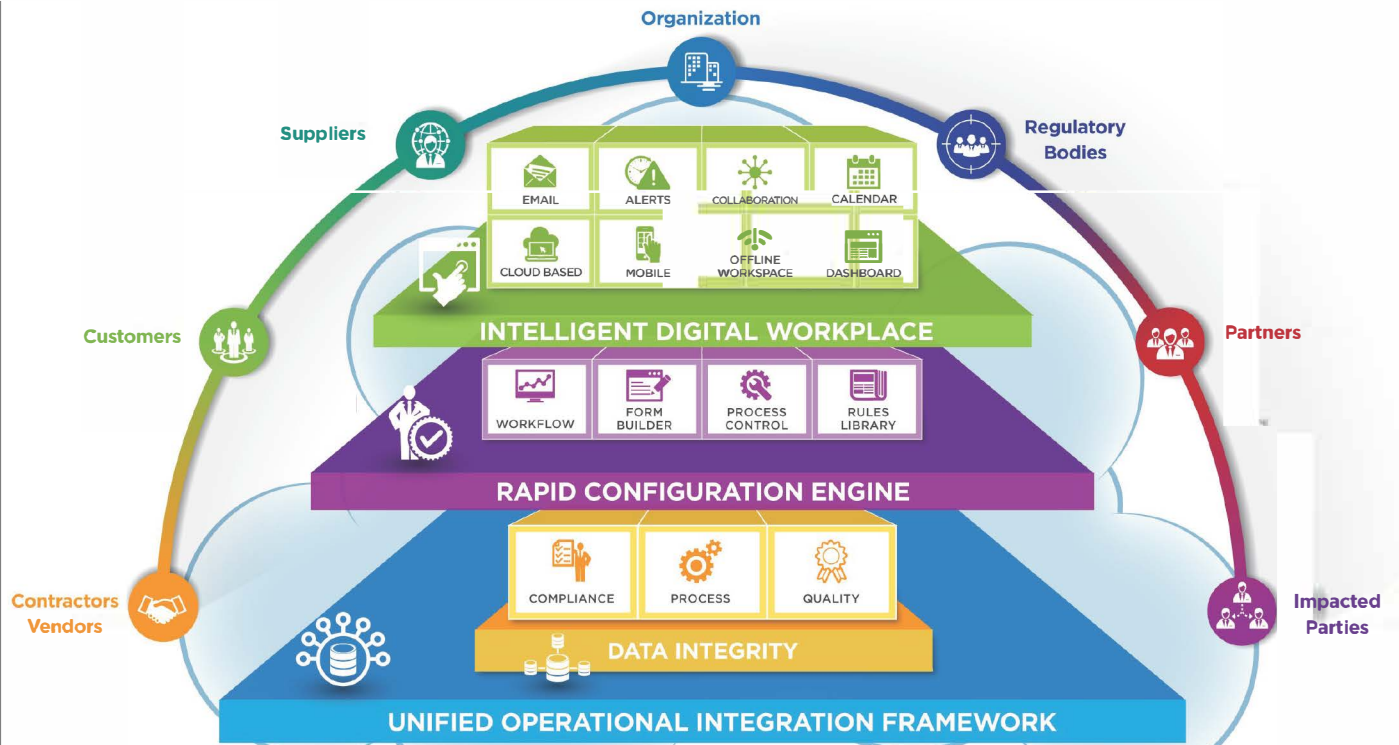
CQRM XD Quality Management is built on the Xybion "Digital Acceleration Platform," a new low-code technology stack that powers faster innovation, increased operational efficiency, and reduced cost. CQRM XD Quality Management was designed for regulated industries where high levels of regulations and strict evidence based documentation of activities are necessary for both compliance and/or for safety and liability management. The platform helps global organizations effectively automate, manage and control compliance and quality process flows, such as, risk management, corrective and preven-tive actions (CAPA), deficiency, non-conformance, customer complaints, audit management, training and competency-based learning management, incident management, Risk, Internal Control, and more.

Xybion's CQRM XD Quality Management is a comprehensive quality management and compliance software solution that delivers Enterprise Quality and Compliance Management. The platform provides powerful cloud-based capabilities that facilitate organizational compliance with regulatory guidelines such as ISO 9001, ISO 13485, ISO 17025, 15014001, GxP, 21 CFR Part 11, financial reporting and governance regulations (SOX, CA Bill 198), and other industry standards and risk-based regulations. The solution is designed for maximum flexibility and is easily adapted to your organization's unique business processes. Additionally, CQRM XD Quality Management provides the capability to manage all types of stakeholders and their contacts, organizations and locations; including customers, partners, external contractors, governing bodies, and various internal groups.



Finally, a Digital Cloud Platform for highly regulated industries that doesn't force you to go back in time technologically... nor change the way you operate.

Xybion's Digital Acceleration Platform: Simplify & Unify



CQRМ XD Quality Management is the industry's only QMS that integrates the three core principles of a "Digital Acceleration Platform".

The Platform is based on Xybion's XD platform and incorporates: Unified Operational Integration Framework, Rapid Configuration Engine and Intelligent Digital Workplace:

Unified Operational Integration Framework

The foundation of the Digital Acceleration Platform is the "Unified Operational Ecosystem." It is ONE system that combines operational applications, quality management and compliance. Intelligence regarding quality and compliance is applied to business processes as they happen, instead of being done retroactively by siloed applications. CQRМ XD Quality Management 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. By ensuring ingrained quality and embedded compliance, it greatly simplifies IT architectures and releases resources back to the business. Core innovation activities are done with "quality ingrained" and "compliance embedded," enabling projects to be completed faster while adhering to all relevant regulations and providing the documentation you need to prove it.

Rapid Configuration Engine

CQRМ XD Quality Management is built on Xybion's

highly configurable, low-code technology stack which facilitates "configurations" vs. "customizations." This Rapid Configuration Engine solves the "Last Mile" problem, where the only way to fully align applications to the company's needs is to develop client specific customizations. By providing customizations as configurations, Xybion delivers customizations within days as opposed to weeks.

Not only do you get up and running in record time, the entire quality ecosystem is tailored to your unique needs today and is adaptable to your changing needs tomorrow. In addition, The Rapid Configuration Engine eliminates the high cost inherent of customizing traditional QMS, and the manual workarounds typically needed while you wait for those customizations to be delivered.

Intelligent Digital Workplace

CQRМ XD Quality Management facilitates an Intelligent Digital Workplace that enables team members to collaborate via the cloud, with full calendar, alerts, chat, and email capabilities. It provides this Intelligent Digital Workplace to your entire team - both internal team members and external partners and processes.

This workplace provides unparalleled productivity to your people. The Intelligent Digital Workplace extends to people who work for third parties, integrating them into the larger project team and connecting them to the collaboration and additional task management functions of the platform.

Modular Functionality for Maximum Flexibility



CQRM XD Quality Management - Embedded Enterprise Content Management

CQRM XD Quality Management has a powerful Enterprise Content Management (ECM) system integrated with the process management and workflow engines built in the XD Platform. It has all the features and functions inherent to any best of breed content management system. The XD platform's query system supports 100% search capability for every word and workflow, while the embedded ECM allows rapid creation of any report based on selected meta data or search words. Built-in analytics allows for rapid creation of customized dashboards that enable you to manage workflows, know where each document is in its life-cycle, and understand who has control over the document at any time. Dealing with an external audit or Inspection questions is a simple affair... It allows you to quickly render any document classified by type, department, creator, data content, etc., along with full audit trail.

CQRM XD Quality Management - Embedded Business Process Management

As a purpose-built, cloud-based enterprise process-driven quality & compliance management platform, CQRM XD Quality Management utilizes a case management functionality that is built on top of a robust Business Process Management (BPM) engine and other integrated document and quality, compliance, risk and governance capabilities. CQRM XD Quality Management is designed to facilitate detailed and consistent BPM for regulated industries and commercial enterprises. The platform incorporates adaptable BPM capabilities and out-of-

the-box compliance, quality, risk and governance features that allow organizations to manage various data collection, cases, issues, actions, follow-up, complaints, audits, checklists, events, ethics and compliance, and many other business activities.

CQRM XD Quality Management - Leveraging Proactive Workflows

CQRM XD Quality Management delivers a foundational set of consistent workflow processes that enable proactive management of tasks and activities particularly helpful in Corrective Actions / Preventive Actions in a timely manner. Managers can create and store action plans in a library for reuse saving valuable time in planning actions.

Additionally, CQRM XD Quality Management has intuitive, powerful configuration options for building workflows, forms and rules in accordance with your business process which help in monitoring 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 their portfolio.

CQRM XD Quality Management is unique in its ability to be quickly configured at module, submodule, workflow, screen and field levels. The full platform can automate work-flows, manage content, integrate into existing technology environments, as well as granularly control and secure the activities of the different user roles within the system.

CQRM XD Quality Management is Modular - Deploy Only What You Need, When You Need it.

CQRM XD Quality Management 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 to any organization's unique quality and compliance processes.

CQRM XD Quality Management is modular platform architecture allows you to deploy ONLY the functionality that you need TODAY yet remain positioned to scale and rapidly ramp up new functionality as needed without disrupting existing business operations. CQRM XD Quality Management provides "One Platform" and "One Solution" to meet your immediate business demands, and the dexterity to drive each step of your organization's strategic roadmap.

Future-Proof Your Technology Investments

Meeting Your Needs Today AND in the Future

Many traditional QMS solutions include hard-coded modules that are operational-focused and only allow a certain level of configurability. These solutions quickly hit roadblocks when developing more complicated and site-specific requirements. Many also focus on the individual "topics" of Quality (Audit, CAPA, etc.) rather than the end-to-end process of business and compliance management. However, CQRM XD Quality Management provides companies the ability to quickly and efficiently implement quality and compliance programs and solutions that fit their organizational needs across many areas of focus.

CQRM XD Quality Management 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. CQRM XD Quality Management delivers immediate value without expensive customization, minimizing 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 a modular low-code application development, so clients can easily deploy the functionality they need and quickly adapt the QMS to their unique business processes.

In this way, CQRM XD Quality Management can scale rapidly with the company's growth and improve process efficiency. Also, as the company grows commercially, the GRC modules help to manage the risks associated with in-house and external distribution models, including changing regulations, promotional compliance and much more.

And lastly, no other solution can provide your organization with a modern low code technology stack that leverages the core principles of a Digital Acceleration Platform; Unified Operational Integration Framework, Rapid Configuration Engine and Intelligent Digital Workplace.

Xybion – Your Expert Partner

Leveraging our extensive global experience working with companies of all sizes, we offer deep domain knowledge of FDA regulations and have a long track record of helping clients build effective compliance and risk mitigation strategies and solutions.

Since 1977 Xybion has provided software, services and consulting for global corporations operating in highly regulated industries. Our unique solutions focus on

Xybion Corporation

105 College Rd East Princeton, NJ 08540

Direct: (609) 512-5790 Toll Free: (844) 291-4430

www.xybion.com

The CQRM XD Quality Management Suite of Modules Includes:

- Enterprise Governance, Risk & Compliance (eGRC) Management
- Business Process Management
- Electronic Document Management
- Enterprise Asset and Content Management
- Risk Management
- Audit
- Program and Objectives Management
- Corrective Actions/Preventive Actions (CAPA)
- Non-Compliance
- Customer Complaints
- Business Process & Compliance Intelligence
- Competency-Based Learning Management
- Employee Training

CQRM XD Quality Management is a Total Compliance, Risk and Quality System for today's digital connected world that meets the needs of organizations in highly regulated industries Today AND in the Future... growing, adapting and changing as you change or your ecosystem changes.

regulatory compliance, GRC, quality management, GxP, Total Regulated Laboratory and R&D Process management, integrated preclinical lab management, content migration and systems validation. Xybion specializes in helping companies improve their over-all compliance processes and provides a complete view into organizational risk across global organizational models.

Fax: (609) 482-3823

