



Xybion integrates the key processes required for companies operating in heavily regulated industries with the existing systems leveraging the current IT infrastructure. As with all of the Xybion solutions, Labwise XD Quality Management is available as a hosted, web and onsite solution environment. The Quality Management system is designed with maximum flexibility to adapt to an organization's unique quality needs and business rules.

## Quality Management

Labwise XD Quality Management provides a flexible and scalable solution to manage quality issues and initiatives. Our comprehensive, integrated quality management software helps companies comply with key industry regulations, such as ISO 9001, ISO 14001 GxP, FDA 21 CFR Part 11, financial reporting and governance regulations (SOX, CA Bill 198) and other industry standards and risk-based regulations.

### Quality Management

- CAPA
- Audit management
- Incident management
- Nonconformance
- Complaint management
- Change management

### Visibility and Collaboration

- Training & learning management
- Document management
- Business intelligence

## Integrated Approach to Quality Management

### Key Benefits:

- Improve access and accuracy of information
- Lower total cost of ownership
- Reduced time spent searching for documents
- Rapid development
- Increased worker productivity
- Improved collaboration
- Supports controlled & uncontrolled documents
- No expensive customization

### Governance and Risk

- Risk Management
- IT Governance
- Programs and objectives

### Scalable Compliance Management

- Suppliers & customers
- Equipment & products
- Solution builder



## Validation-Ready Services and Documentation

- Labwise XD Quality Management audit is designed exclusively for deployment in highly regulated software environments.
- Because intended use varies from one company to another, we deliver a practical validation toolkit which includes a complete set of pre-written validation protocols including IQ, OQ, and PQ Operational test scripts to ensure production readiness and accelerate validation.
- The validation methodology follows the latest GAMP guidance and principles of software validation.
- Our experienced professional services team can help you streamline your validation effort and reduce time-to-compliance and ongoing operational support.



## A Complete Quality, Risk & Compliance Solution

### Enterprise Class technology

Xybion's Labwise XD Quality Management System combines leading edge technology, advanced workflow and analytics that will help your organization ensure consistency and compliance across a broad spectrum of key business processes such as quality, governance, risk, and collaboration management. Unlike point solutions that may focus on one specific quality management function, Labwise XD Quality Management system facilitates the integration and management of disparate, but related mission critical functions across the enterprise mitigating risk, increasing productivity and lowering the total cost of ownership. Xybion offers technology to connect the Quality Management system with other key enterprise activities, such as asset management, research and development, and document management.

### Services and Business Consulting

To support global departments, Xybion's suite of enterprise technology is backed by an experienced professional team with the knowledge and expertise to ensure the Labwise XD Quality Management system meets the organization's requirements.

Xybion can deliver the following services to complement your quality management initiatives:

- Industry staffing services to support technology and processes
- Governance, risk, and compliance consulting
- Information and document management consulting
- Integration and migration services
- Technology implementation
- Systems and process validation
- Project management
- Strategy consulting

