Labwise® XD

Integrated Document Management For Effective Governance and Quality

Key Benefits:

- **Improve access & 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**

Xybion Corporation
105 College Rd East
Princeton, NJ 08540
sales@xybion.com
www.xybion.com

Direct: (609) 512-5790
Fax: (609) 482-3823
Toll Free: (844) 291-4430

Document Management

Labwise® XD DMS is a full-featured document management system that in-cludes built-in best practices for 21 CFR Part 11, ISO and quality processes, as well as governance processes such as SOX. As a flexible document management system, Lab Wise OMS empowers knowledge workers to configure the repository to meet the specific needs of your company without customization. The OMS is highly configurable and seamlessly integrates with all Labwise® XD modules.

Effective corporate governance requires good document control. Although many global organizations have purchased document management systems, many have failed to adapt them to facilitate governance

Labwise® XD DMS Features:

- 21 CFR PART 11 COMPLIANT
- SEAMLESS INTEGRATION WITH LABWISE QUALITY
- EASE OF DOCUMENT METADATA MANAGEMENT
- FILE FORMAT NEUTRAL
- POWERFUL DOCUMENT WORKFLOW CAPABILITY
- COMPREHENSIVE REPORTING
- SECURE, CENTRALIZED REPOSITORY
- COLLABORATIVE DOCUMENT LIFECYCLE PROCESS
- ADVANCED SEARCH & RETRIEVAL CAPABILITY
- SEAMLESS INTEGRATION WITH DESKTOP APPLICATIONS

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Validation-Ready Services & Documentation

Labwise® XD 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 on-going operational support.

FEATURES	DESCRIPTION
COMPREHENSIVE LIBRARY SERVICES	
Check-in/Check-Out	Controlled secure access, full versioning capabilities, document history
Full Text Search & Retrieval	Supports full text search and retrieval within document content
Visual Status Indicators	Document status at a glance
Automatic PDF Conversion	Flexibility to specify automatic PDF conversion for documents
BUILT-IN DOCUMENT CONTROL BEST PRACTICES	
Document Hyperlinks	Embed internal document hyperlinks to support key regulatory processes requiring internal document links
Document Taxonomy	Flexible file and document class taxonomy to facilitate document behavior and searching
Support for Controlled & Uncontrolled Documents	Allow users to specify if documents are controlled or uncontrolled for good corporate governance
Comprehensive Document Security	Granular security for each type of activity (editor, etc.) can be applied to groups or individuals down to a specific document level
Configurable Document Properties	Easily configure document attributes to facilitate search & retrieval and document accessibility
21CFR PART 11 COMPLIANCE	
Audit Trail	Comprehensive audit trails in compliance with 21 CFR Part 1.10(e). Audit trails are accessible at any time
Dual ID/Password; Non-Biometric e-Sigs	Supports the use of e-signatures comprised of a secure user ID/ password combination in accordance with 21 CFR Part 11.2000(a)(1)
Time Out Security Expiration	Session terminates after a user-specified number of minutes to prevent unauthorized access during a period of inactivity, in accordance with 21 CFR Part 11.3000(d)
Password Controls	Enforces the uniqueness of each user ID and password combination for authentication in accordance with 21 CFR Part 11.00 (a)
Full Electronic Signature	Electronic records include full signature manifestation. Fields include: printed name of signer, time/date stamp, and meaning of signature in accordance with 21 CFR Part 11.50 (a)

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