

### Integrated Document Management for Effective Governance and Quality

Workforce competency and training management software provides secure end-to-end training records management with fully compliant audit trails. Grant access rights with simplicity. Ensure the validity and integrity of your training records while maintaining clear visibility of training needs. Easily store and access training content, records,



Labwise XD DMS is a full-featured document management system that includes 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, Labwise DMS empowers knowledge workers to configure the repository to meet the specific needs of your company without customization. The DMS is highly configurable and seamlessly integrates with all Labwise XD modules.

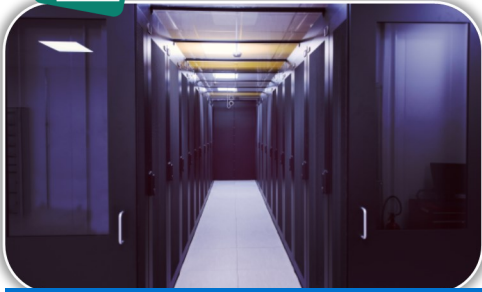
### Key Benefits:

- 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

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 and quality processes. Labwise DMS is a secure, web-based Document Management System that delivers compliance without customization.

### 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
- Advance search and retrieval capability
- Seamless integration with desktop applications



## 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
<b>COMPREHENSIVE LIBRARY SERVICES</b>	
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 Flexible file and document class taxonomy to facilitate document behavior and searching Allow users to specify if documents are controlled or uncontrolled for good corporate governance
Document Taxonomy	Granular security for each type of activity (editor, etc.) can be applied to groups or individuals down to a specific document level
Support for Controlled & Uncontrolled Documents	Easily configure document attributes to facilitate search, retrieval and document accessibility
Comprehensive Document Security	
Configurable Document Properties	

## 21 CFR PART 11 COMPLIANCE Audit Trail

Dual ID/Password; Non-Biometric e-Signatures	Comprehensive audit trails in compliance with 21 CFR Part 1.10 (e) Audit trails are accessible any time Supports the use of e-Signatures comprised of a secure user ID/ password combination in accordance with 21 CFR Part 11.2000 (a)(1) Session terminates after a user specified no. of minutes to prevent unauthorized access during a period of inactivity in accordance with 21 CFR Part 11.3000 (d)
Time Out Security Expiration	Enforces the uniqueness of each user ID & password combination for authentication in accordance with 21 CFR Part 11.00 (a)
Password Controls	Electronic records include full signature manifestation. Fields include: printed name of signer, time/ date of stamp, and meaning of signature in accordance with 21 CFR Part 11.50 (a)
Full Electronic Signatures	

