

## Affordable electronic signatures and compliance management

### DocuShare Compliance Module

The DocuShare Compliance Module is an ideal solution for any organization seeking to provide control over electronic documents and their associated business processes. Built upon the DocuShare Enterprise Content Management platform, the Compliance Module extends core DocuShare functionality and allows companies to achieve regulatory compliance with the technical provisions of 21 CFR Part 11, HIPAA, Sarbanes Oxley and more.

#### The Problem

Many organizations have become accustomed to managing their controlled content manually. While this may seem simple in theory, it can quickly become chaotic in even a small- to medium-sized company. Examples include:

*You're getting ready to issue your company's quarterly financials. As usual, after the CEO approved the first version there were a few last-minute adjustments. Did the CEO review and approve the updates?*

*During an FDA inspection, the inspector asks to see your cleaning and maintenance procedures. While reading a cleaning procedure she sees a reference to version 1.2 of the routine maintenance procedure for the equipment. However when she looks for that procedure in the maintenance binder, she finds v1.1 which is stamped as the "latest effective version". Which is the correct procedure?*

*You're compiling patient billing records to send out for statistical analysis. How do you know that all identifying information has been removed?*

Unanswered questions like these quickly lead to costly inefficiencies, not to mention the legal consequences of a regulatory citation or legal action.

The DocuShare Compliance Module provides an easy-to-use, integrated



environment for automating these processes and managing them electronically.

#### The advantages of the Compliance Module

The DocuShare Compliance Module enables companies to reengineer manual and ineffective processes with structured lifecycles and workflows. These lifecycles promote consistency and will significantly reduce the time employees spend securing, administering and sharing controlled content.

By using the DocuShare Compliance Module, you can easily control changes based on security, and quickly track when and why changes were made to controlled content. This helps organizations comply with internal and external regulations.

The DocuShare Compliance Module can reduce mistakes, operating costs, wasted time, confusion and delays, while enhancing the process of delivering services and products to market.

The DocuShare Compliance Module enables:

- ◆ Compliance with 21 CFR Part 11 electronic records management, manufacturing conventions, OSHA guidance, ISO 9000 quality guidelines and more
- ◆ Effective management of controlled content such as standard operating procedures, marketing materials, financial reports, product documentation and material safety data sheets
- ◆ Automatic global publishing of read-only renditions of approved content
- ◆ The ability to establish when and why someone has come in contact with content
- ◆ The ability to ensure content legitimacy
- ◆ The ability to track and manage attempts to inappropriately handle documents
- ◆ A quick response to internal auditors and regulatory agencies
- ◆ The ability to enforce accurate approvals and signatures



## Key Features

The Compliance Module supplements existing DocuShare functionality with:

### Easy to use Web interface

DocuShare requires little or no training; you can easily access available content.

### Automatic notification and tracking

Assure auditors and regulators they have current and accurate information.

### Secure and easily accessible centralized repository

Ensure that controlled documents are accessible from one location for review and approval.

### Electronic signatures (21 CFR Part 11 compliant)

Meet regulatory requirements for electronic approval signatures - no need to print and sign.

A signature page is rendered with each controlled document, showing all attached signatures.

The Compliance Module's electronic signature functionality cryptographically links each signature to its source document.

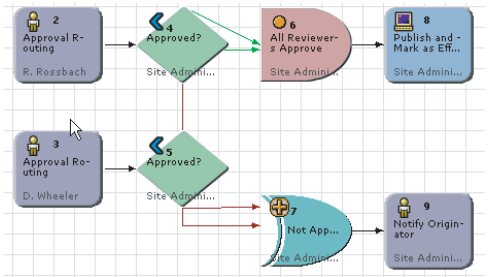
The Compliance Module's electronic signature functionality requires the DocuShare user to supply username & password in order to electronically sign a document.

User	Operation	Event Date	Details
user1	Object Created	Feb 3, 2007 9:25:42 AM EST	Details
user2	Property Change	Feb 3, 2007 9:27:03 AM EST	Details
admin	ACL Changed	Feb 3, 2007 9:31:47 AM EST	Details
user3	New Version Added	Feb 3, 2007 9:34:34 AM EST	Details
user3	Property Change	Feb 3, 2007 9:34:34 AM EST	Details
user3	Document Printed	Feb 3, 2007 9:34:54 AM EST	Details

**For more information on DocuShare, contact a Sales Representative at 1.609.897.9180, or visit us at <http://www.sitrof.com>.**

## Configurable document Lifecycles

Easily configure new or existing business rules for document management, review and approval.



## Speedy and Easy Searching

Easily locate content relevant for a business situation.

## Change Requests

Apply change management processes to minimize cost and delays when modifying existing documents.

## Automatic PDF rendering, watermarking, and controlled printing

DocuShare security, enhanced with the Compliance Module, prevents unauthorized alteration or removal of controlled documents.

## Full validation package

Includes the following validation documentation which will greatly reduce the effort involved with validating the solution:

- o Validation Master Plan
- o Requirements and Design Document
- o Installation Guide with IQ/OQ scripts

## Enhanced auditing and reporting functionality

Enhanced audit trail captures actions against a document and associates the user's personal information where the action was initiated.

Built for use with

**Xerox DocuShare®**

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