

EMC Documentum Compliance Manager

Automating controlled content processes to meet quality and compliance goals

THE BIG PICTURE

- **Promotes compliance** with Good Manufacturing Practices, OSHA regulations, ISO 9000 quality guidelines, and 21 CFR Part 11 electronic recordkeeping
- **Automates the management of controlled content** such as financial reports, material safety data sheets, standard operating procedures, product documentation, marketing materials, and engineering drawings
- **Supports local languages** (including English, French, German, Japanese, and Spanish) to facilitate a global deployment
- **Incorporates the best practices** of many successful global implementations of EMC Documentum compliance solutions for managing controlled content

When controlled content is out of control

Controlled content often exists as a combination of paper documents, collected in binders and distributed manually, and electronic files routed for editing and approval using e-mail. Paper documents are a burden to store, even more difficult to share widely, and they can quickly become outdated. Electronic content reduces the storage and distribution problem, but as e-mails circulate their attachments may be revised, resulting in different versions in use across the organization. Poor controls over content can result in a host of problems:

- Employees may work with incorrect or out-of-date information, causing inefficiencies and compliance risk.
- Document processes may not comply with regulations and standards, again causing inefficiencies and potentially legal consequences.
- Review and approval cycles often take too much time and resources.
- An organization may be unable to prove to auditors that a document was properly approved or that it has remained unaltered since approval.
- Distributing new or revised documents costs more than it should.
- In industries such as manufacturing, cycle times can be prolonged, citations issued, and operations shut down.

EMC® Documentum® Compliance Manager offers a better way. Instead of cumbersome and disjointed manual or e-mail-driven processes, Documentum Compliance Manager offers an automated, integrated online environment for creating, reviewing, revising, approving, distributing, and auditing controlled content.

The advantages of EMC Documentum Compliance Manager

Compliance Manager helps customers achieve compliance with external regulations such as FDA 21 CFR Part 11 and internal policies while maintaining high product and service quality standards. Compliance Manager replaces unreliable and inefficient processes with streamlined processes for review, approval, and distribution, dramatically reducing the time and effort employees spend managing controlled content.

Compliance Manager can audit all controlled content activities, enabling relevant parties—users, managers, and external agencies—to know when and why changes were made. And by helping organizations meet quality objectives and comply with internal and external regulations and standards, Compliance Manager can help you reduce operating costs; minimize waste, errors, and production delays; and deliver products to market faster and with greater confidence. With Compliance Manager, you can:

- Easily respond to external regulatory agencies and internal auditors
- Quickly determine who has interacted with content, as well as when and why, and detect attempts to alter or remove documents

- Enforce signatures and proper approvals
- Ensure content authenticity and immutability
- Ensure document retention for required periods

Key features designed for real-world needs

Compliance Manager meets and exceeds customer requirements for the management of controlled content.

- **Secure, globally accessible repository:** Manage documents from one secure location for review, approval, and reuse.
- **Intuitive web interface:** Get up to speed with little or no training; easily access available content.
- **Automated change management:** Ensure access to approved versions to minimize cost and delays.
- **Document signoff with enforced justifications:** Meet regulatory requirements such as 21 CFR Part 11 with electronic signatures on approved versions.
- **Proactive notification and tracking:** Satisfy user acknowledgement requirements of auditors and regulators and ensure approved content is in use.
- **Full document and user audit trail:** Store signoffs in the audit trail to ensure validity and prove to regulators or auditors who has seen and approved a document.
- **Print control with banner and watermark:** Audit printing, restrict printing to authorized users, and manage hardcopy distribution.
- **Configurable document lifecycle:** Adapt Compliance Manager to new or existing customer business rules for document review, approval, and distribution.
- **Rapid search capability:** Quickly locate the most current content relevant to a given business situation.

Leverage the EMC Documentum content server and repository

Documentum Compliance Manager is built on the EMC Documentum platform and content repository, which includes Documentum-based lifecycles and workflows, EMC Documentum Trusted Content Services for audit trails and digital signatures, and the Documentum client development environment (Web Development Kit). As a pure extension of EMC Documentum Webtop, Compliance Manager takes advantage of advanced user interface and platform services such as model dialogues for navigation, extended search capabilities, and configurable presets for convenient user interface configuration.

Compliance Manager is integrated with EMC Documentum Collaborative Services, EMC Documentum Retention Policy Services, and EMC Documentum Branch Office Caching Services. Thus, users can collaborate while authoring content, manage review and approval cycles, and control retention and disposition. Once a document is approved, it can be distributed to remote sites for high-performance access.

Compliance Manager is highly configurable, minimizing the need for customization. As a result, it is easy to upgrade, implement, and validate. Java-based Compliance Manager is designed to blend seamlessly with any J2EE-based web development and deployment strategy. The business rules that enforce compliance are exposed as a set of services and components through the EMC Documentum Business Objects Framework. This makes it easy for integrators, partners, and customers to create applications that work with Compliance Manager by simply implementing and validating user interface controls; no changes to the underlying business logic are required. And because there already exists a large network of experienced service providers for Compliance Manager, you can quickly find the right implementation partner.



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Take the next step

To learn more about managing controlled content with EMC Documentum Compliance Manager, visit www.EMC.com or call **800.607.9546** (outside the U.S.: +1.925.600.5802).