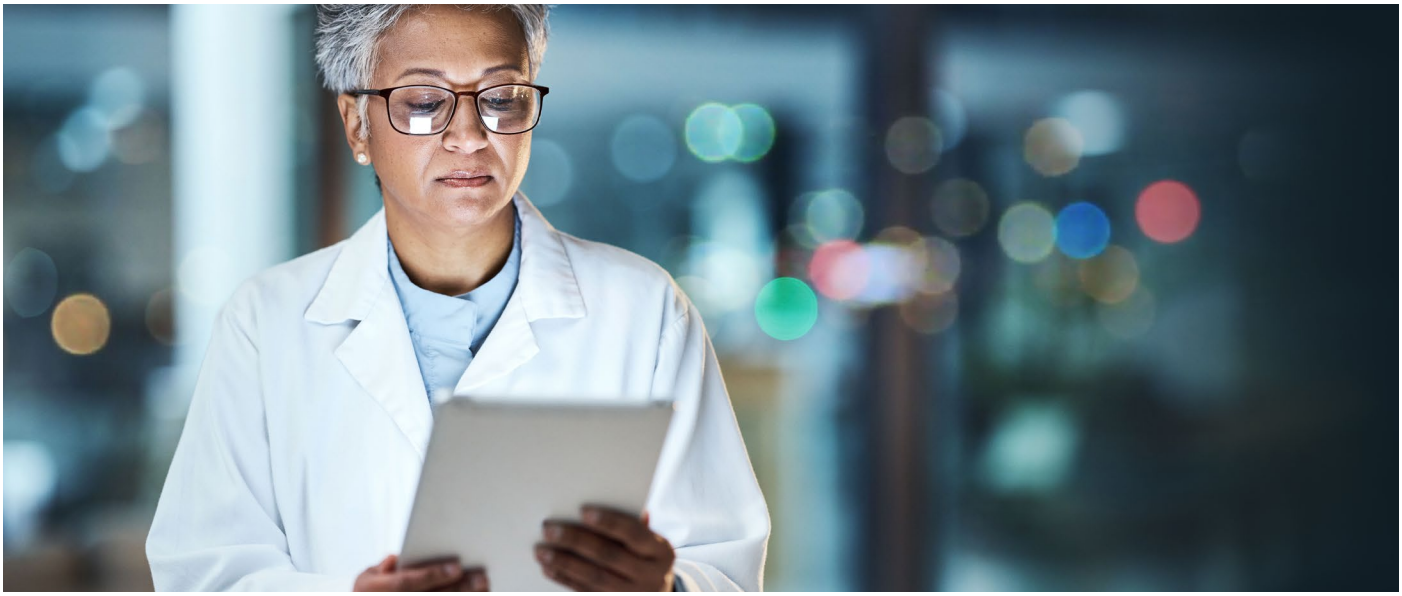
OpenText Documentum Content Management for Regulatory

Simplify the management of regulated content and health agency communications



Benefits

- Unify all regulatory content into one searchable system
- Collaborate easily across global teams and offices
- Track and connect every submission and interaction across the product lifecycle
- Respond quickly to regulators with fast, accurate search

Life sciences companies need to get products to market quickly—but they must follow strict rules that vary by country and region. To stay compliant, they must keep clear records of every document and message sent to health agencies, like drug applications, emails, and meeting notes. These records often end up scattered across laptops, inboxes, and shared drives, making it hard to stay organized and meet regulatory requirements.

OpenText™ Documentum™ Content Management (CM) for Regulatory solves this by bringing everything into one secure system. It helps pharma, biotech, and medical device teams manage regulatory and submission documents in one place. Built on the trusted **OpenText™ Documentum™ Content Management (CM) platform**—used in life sciences for over 25 years—it helps teams work faster by making it easier to plan, create, review, and approve submission documents.

It's part of the **OpenText™ Documentum™ Content Management for Life Sciences** family—a group of connected modules built on a unified service layer that supports audit trails, access control, and lifecycle management. It helps organizations:

- **Store regulated content securely at scale:** Keep large volumes of documents safe, organized, and easy to manage.
- **Create, collaborate, and approve using industry best practices:** Make sure the right people get the right tasks at the right time using built-in workflows.
- **Easily import submissions and emails:** Import emails, paper files, and digital submissions like eCTD and NeeS. Everything stays safe and easy to track.

- **Connect content across the product lifecycle:** Link documents from early development through clinical trials and submissions—all in one system.
- **Search easily across projects, archived submissions, and correspondence:** Quickly find documents, submissions, and emails, with filters.
- **Track every step and meet the rules:** Know who did what and when, with clear records that help you stay on track and meet requirements.

How it works

1. Central control

Stores all your content, including emails, notes, drafts, approved documents, and submissions, in a central secure and compliant location.

2. Submission-ready setup

Uses controlled templates and metadata tagging to ensure documents meet global regulatory standards like GxP, Annex 11, and 21 CFR Part 11.

3. Vector and semantic search

Filters documents and submissions by industry standard metadata so you can easily find what you need.

4. Reporting and audit logs

Automatically captures event history and generates audit-ready reports.

5. Connected content

Links submissions, correspondence, and supporting documents to provide a unified, 360-degree view of regulatory activity.

6. Deploy your way

Offers flexible deployment on premises, in private cloud, or OpenText hosted cloud.

Stay compliant and keep regulatory content secure

Avoid the risks of storing regulatory files on uncontrolled shared drives. OpenText Documentum CM for Regulatory brings all your regulatory content, documents, submissions, and related correspondence into one secure, access-controlled system. Designed to support GxP compliance and aligned with global regulatory standards, it ensures your files are organized, traceable, and audit ready.

With built-in audit trails, indexing, and role-based access controls, your content stays protected and compliant. The system automatically preserves your original folder structure as submitted to agencies, making it easy to navigate and understand.

Teams can plan, author, manage, and archive submissions with full confidence, supported by clear records, linked messages, and complete visibility across all regulatory activities.

Help authors work faster

Give authors the tools to work faster and smarter with controlled, up-to-date templates tailored to your organization and the ability to select from a curated inventory of reusable document types, automatically linked to submission requirements. They can collaborate in real time with built-in editing tools, while a lead author manages changes and approvals, keeping content compliant and moving forward.

Work better across teams

Whether your teams work in clinical, regulatory, or quality, everyone can access the same trusted content based on their role. This helps reduce confusion and makes teamwork easier, especially across global teams.

Improve submission accuracy

To support accurate submissions, the system uses built-in dictionaries and taxonomies that follow the DIA EDM reference model. Metadata tagging supports ICH and eCTD standards, helping teams create consistent, compliant content. Preconfigured document inventories and templates help teams efficiently create content aligned with ICH CTD formatting and structure, minimizing rework and enabling customization when needed.

Plan and execute submissions easily

Easily plan and manage submissions with document inventories across seven regulatory domains, with documents automatically placed in the right eCTD sections. Teams can approve plans faster, reuse them when needed, and pull in draft or approved documents automatically. Reports make it easy to monitor progress, help teams stay on track, and support smooth hand-offs to publishing tools like **LORENZ docuBridge**.

Navigate submissions with ease

View archived eCTD, NeeS, and paper submissions directly in a familiar folder structure or through the eCTD table of contents. It supports all global eCTD formats, including US, EU, and Japan, and is ready for future updates like eCTD v4 without needing a system upgrade. If a change affects multiple submissions, the system supports Grouped Variations/Submissions and automatically checks related products and manufacturers to suggest which applications should be included in the regulatory activity package, helping you stay organized and compliant across regions.

Track the full regulatory lifecycle

See how submissions, correspondence, and meeting notes connect across time and products. By linking related content in one place, the system helps teams understand what was submitted, when, and why, making it easier to track progress, identify open items, and respond with confidence.

Respond quickly to regulators

Faceted search filters, such as product, country, document type, or date, help users find specific documents and correspondence easily—speeding up responses to inquiries and audits. The system helps you check and suggest which applications to include when managing Grouped Variations so nothing gets missed.

Stay compliant and secure

Keeping regulatory files on uncontrolled shared drives can lead to security risks and missed details. With OpenText Documentum CM for Regulatory, all your documents and submissions are stored in a secure, compliant repository with audit trails, indexing, and full access controls built in.

It automatically keeps your original folder structure just as it was submitted to the agency, so everything stays organized and easy to understand. You get clear, complete records of submissions and queries, making it easier to work with regulatory agencies and prove compliance every step of the way.

Choose a deployment method that meets your long-term IT strategy

Whether hosted on premises, deployed in a private cloud, or delivered as an OpenText hosted cloud service, OpenText Documentum CM for Regulatory offers flexibility that aligns with your organization's IT and cloud strategy. Its architecture is designed to scale with the needs of global operations and evolving workloads, while maintaining data sovereignty and control where required. This architecture helps ensure high availability, performance, and security, giving IT teams the ability to meet the needs of both local facilities and corporate cloud initiatives without costly custom development or rigid infrastructure limitations.

Summary

Rather than piecing together fragmented documents from spreadsheets, shared drives, or disconnected systems, **OpenText Documentum CM for Regulatory** brings everything together in a single, traceable system. With a clear view of your regulatory journey, you can confidently meet local and global compliance requirements while reducing delays and manual effort. Built on the scalable and secure OpenText Documentum CM platform, it helps make every step— from planning to approval—easier, faster, and compliant. With enhanced search power and strong compliance controls, you can quickly answer regulatory questions, lower risk, and trust that everything is stored in one place.

Whether you're tracking submissions or responding to regulators, this flexible platform keeps you moving forward.

Feature	Description
Compliant document creation	Easily assemble submission content for pharmaceutical and medical device products using controlled templates with predefined inheritance rules and metadata based on industry-leading practices.
Collaborative authoring, editing, and review	Allow multiple contributors to co-author documents with real-time, simultaneous authoring and editing of document content using the standard "track changes" functionality of Microsoft® Word®.
Search and retrieval	Quickly find submission-related documentation using faceted navigation to automatically reduce the document list, reflecting only relevant results. This boosts productivity and increases content and metadata reuse.

Feature	Description
Compliance with real-time visibility	Leverage access control, detailed audit trails, e-approvals, and e-signatures to easily meet compliance. Answer questions about progress and readiness with “where used” reports and gain insight on the day-to-day performance of applications around the globe.
Link content throughout drug lifecycle	Support full product lifecycle with a common data model. No manual intervention is required to share documents from the early development phase through to clinical trials and submissions to product.
Controlled compliance	Store regulatory submissions and associated communications in a compliant and secure repository. Set access controls, password strength, and log-in attempts to strengthen your compliance.
Easy import	Add legacy and current submissions in eCTD, NeeS, or paper format. Automatically assign submission properties, document types, and security levels to ensure accuracy. It maintains all eCTD navigation, inter-document hyperlinks embedded in PDF files, and encryption.
Quick response to health authorities	Search for archived submissions based on metadata properties, such as product, country, submission type, manufacturer, or date. Automatically query and suggest applications to include during instances of Grouped Variations/ Submissions.
Integration with Microsoft® Outlook®	Drag and drop emails and their attachments directly into the repository for automatic import.
Streamlined viewing	Unlock standard eCTD views—single, current, and cumulative—of the full regulatory submission lifecycle, including navigation of hyperlinks.
Cloud-ready deployment	Run the solution on premises and in AWS or GCP.

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