OpenText Documentum Content Management (CM) for Life Sciences

Stay ahead of regulatory demands, enhance collaboration, and drive innovation

Benefits

- Simplify regulatory content management
- Seamlessly integrate with your existing systems
- Deploy on premises or on cloud
- Kickstart your processes with tailored workflows from life sciences

With more than 25 years of experience in Life Sciences, OpenText™ Documentum™ Content Management (CM) for Life Sciences (OpenText Documentum for Life Sciences) is the comprehensive solution designed to meet the demanding needs of the pharmaceutical, biotechnology, and medical device industries. Built to support good practices (GxP), streamline document workflows, and enhance collaboration, it empowers organizations to manage their critical information with confidence.

Compliance made simple

Meeting global regulatory requirements has never been easier than with OpenText Documentum CM for Life Sciences. The platform is designed to ensure compliance with GxP, 21 CFR Part 11, and other critical industry standards. Built-in audit trails, electronic signatures, and automated workflows provide full traceability and peace of mind, helping your organization stay ahead of regulatory demands.

Designed for life sciences

Tailored specifically for the life sciences industry, OpenText Documentum CM for Life Sciences supports your unique business processes with customizable workflows and metadata based on the extended DIA EDM reference model. Manage content and processes in a unified repository based on roles and permissions, to enhance efficiency and compliance. Our solution adapts to your specific operational needs within clinical, regulatory, quality and manufacturing, allowing you to focus on innovation and quality.

Flexibility and customization

OpenText Documentum CM for Life Sciences allows organizations to tailor workflows, metadata, and user interfaces to meet specific business needs. This is particularly useful for companies with complex and unique processes that require more than out-of-the-box functionality.

Seamless integration for enhanced efficiency

Integrate seamlessly with your existing enterprise systems, including clinical trial management systems (CTMS), laboratory information management systems (LIMS), learning management systems (LMS), electronic publishing systems, quality management systems (QMS) and registration management systems. Reduce manual processes to ensure that critical data flows across various applications and systems. This makes an ideal choice for companies that need to maintain a connected and streamlined IT environment.

“When a regulatory requirement or our internal process changes, we can update the relevant documentation and workflows in the OpenText solutions once, and employees start using the new documents or process automatically.”

Neha Chandel, Project Delivery Manager, Fresenius Kabi

“Thanks to digital workflows powered by OpenText Documentum, we can now process 3.5 times more documents each month, which creates headroom for significant future business growth.“

Yinyong, Quality Director, Milestone Pharma Co. Ltd

Higher product quality in manufacturing processes

OpenText Documentum for Quality and Manufacturing manages documents with Good Manufacturing Practices (GMP) standards to ensure consistent processes and higher product quality. Enforce authoring standards with controlled templates and automatically populate text from document properties, reducing errors and rework. Simplify periodic review and change request processes with a balance of flexibility and control, reducing training requirements and increasing adoption. Trace and control printing of key GMP documents with secure access to printers and print output.

Submission readiness with controlled content

OpenText Documentum for Regulatory streamlines and automates regulatory activities by enforcing document controls for submission-ready, ICH-compliant regulatory filings using taxonomies, lifecycles, and workflows for pharmaceutical and medical devices. Enable contributors to view and edit previous changes, with automatic merging for review, acceptance, or rejection. Improve security and compliance by archiving submissions and health authority correspondence. Use metadata to manage content across the product line and restrict access based on confidentiality.

Inspection-ready trial master files (TMFs)

OpenText Documentum for eTMF allows you to efficiently plan, collect, and maintain essential clinical trial documentation to minimize complexity and risk for sponsors and CROs. Ensure quick, secure access to documentation during and after trials. Automate quality checks to identify and correct issues with inappropriate documents, unclear images, and missing signoffs. Seamlessly link and share submission-ready content across clinical, regulatory, and quality domains throughout the entire product lifecycle, from development to commercialization

Elevate document management

Elevate your document management capabilities and transform your compliant processes with OpenText Documentum CM for Life Sciences. Whether deployed on premises, in a private cloud, or as a managed service, empower your teams, streamline operations, and drive innovation—because when it comes to life sciences, every document matters.

OpenText Documentum CM for Life Sciences deployment options:

Accelerate cloud strategies with OpenText cloud experts

- OpenText Managed Private Cloud
- Pre-qualified environment with an executed Installation Qualification (IQ) and Operational Qualification (OQ) done by OpenText, governed by GxP guidelines to give organizations confidence in meeting good practices.

Run anywhere and scale globally

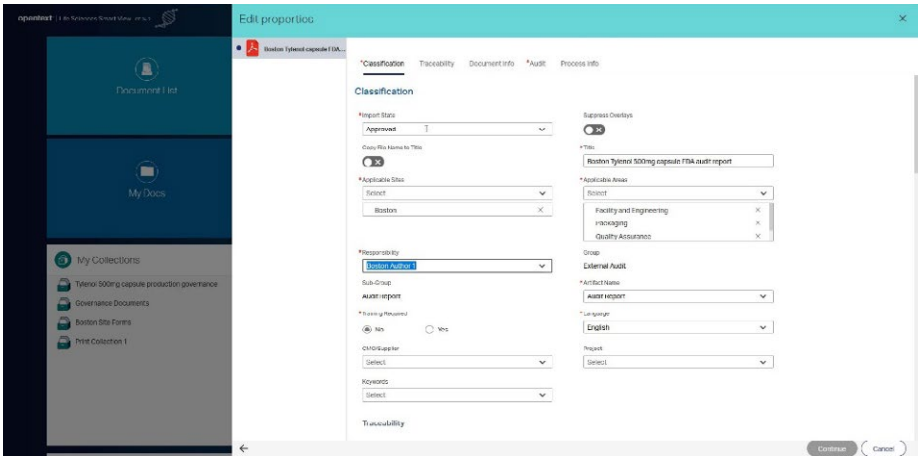
- On-premises software, managed by your organization
- Hyperscaler cloud of your choice (Amazon Web Services, Google Cloud Platform)

Resources

Life sciences blogs ›

Life sciences industry ›

Feature	Benefit
Scalability and performance	Supports the needs of large enterprises, which have large volumes of content and complex workflows. Adapts to increased demand and complexity without compromising performance.
Unified solution layer	Deploy multiple solutions satisfying clinical, regulatory, and manufacturing requirements in the same repository to share and reuse content, leveraging a shared enterprise information architecture with common, industry-standard inventory and data models.
Technology transfer	Share content included in submissions used in manufacturing operations without importing and exporting from one system to another.
Cloud-native technologies	Run anywhere with cloud-native technologies that vastly simplify deployments and upgrades.



OpenText Documentum CM for Life Sciences enhances business processes with flexible workflows and metadata based on the extended DIA EDM reference model.

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