opentext™

OpenText™ Documentum™ for Quality and Manufacturing

Control critical quality documentation, streamline and automate processes, and enable compliance

How Efficient are Your Document Management Processes?

Getting to market quickly is critical to the success of your business. In short, that requires running lean, efficient, and uninterrupted manufacturing production at the lowest possible cost. But how efficiently you manage document creation, review, approval, and change management can affect time to market, especially when you are dependent upon a global, virtual extended enterprise.

By automating this process using Documentum for Quality and Manufacturing, you can eliminate time-consuming manual review and approval processes and gain centralized document control for both pharmaceutical and medical device products—all while adhering to compliance regulations and mitigating the risk of fines and production delays.

Automate Processes to Gain Control Over Quality and Manufacturing Documentation

Part of OpenText™ Documentum™ for Life Sciences, and available on-premise or in the cloud, the solution enables life sciences organizations to control quality and manufacturing documents, automate workflows across the extended enterprise, and ensure compliance with Good Manufacturing Practices (GMP) standards.

Built on Documentum, the industry's leading and most scalable content management platform, the solution fully harnesses and extends the information architecture based on the Drug Information Association (DIA) Electronic Document Management (EDM) reference model for consistent document modeling. Documents related to Quality and/or Chemistry, Manufacturing and Controls (CMC) as well as procedures, governance, corporate policies, and validation reports are supported.

Documentum for Quality and Manufacturing takes advantage of this robust platform, specifically addressing the challenges of managing documents governing manufacturing, quality, compliance, and other standard operating procedures. It provides prebuilt templates and lifecycles, automated workflows, and support for collaborative authoring and review, giving you consistent, accurate, and compliant quality documentation. And when a change to documentation is required—for example, during a scheduled periodic review—the entire process is automated and tracked.

SUMMARY

- *Streamline the creation, review, approval, and change management of documents across the extended enterprise*
- *Use an industry-standard, out-of-the-box document taxonomy to quickly create, search, retrieve, and navigate documents for pharmaceutical and medical device products*
- *Leverage flexible lifecycle support for multiple control levels within a single repository*
- *Streamline the periodic review and change request processes and strike a balance between flexibility and control*
- *Automate the distribution of new, effective documentation internally, externally, and to mobile devices*
- *Support the Technical Transfer process by ensuring document traceability and visibility*
- *Understand controlled document compliance with detailed, graphical reporting*
- *Leverage a proven, trusted, scalable platform that is available on-premise or in the cloud*

Key capabilities include:

- Configurable, role-based views
- Collaborative authoring and review process
- Configurable document views, print controls and watermarks
- Automated periodic review process
- Streamlined document change management
- Automated Technical Transfer process to ensure traceability
- To be read and understood tracking
- Graphical reporting of controlled document compliance
- 21 CFR Part 11 compliance with audit trials, e-approval, and e-signatures

Ensure Compliance as Regulatory Scrutiny Increases

Regulation of manufacturers in the life sciences industry is evolving and escalating worldwide. With Documentum for Quality and Manufacturing, you can establish streamlined, auditable processes that support global compliance with Good Manufacturing Practices (GMP) standards across all manufacturing locations. The result is an accountable, single authoritative source for managing controlled documentation that is easy to access and maintain, even as business needs change.

Uncompromised Regulatory Compliance

At any time, you may be called upon to demonstrate compliance with quality and manufacturing regulations. With Documentum for Quality and Manufacturing, you can clearly prove 21 CFR Part 11 compliance thanks to extensive audit trails, access controls (including e-approval and e-signature support), and document distribution, version control, and lifecycle management. The solution also supports print and export control services and preconfigured, dynamic watermarking, and overlays to ensure document security.

Automatically Distribute Effective Documentation to Mobile Devices

As your business network expands, you need to harmonize data and procedures across geographically distributed sites—and still enable localized productivity and efficiency. With Documentum for Quality and Manufacturing you can automatically distribute documentation to employees and partners (internally and externally) when it reaches its effective state. The solution automatically replaces previous versions with the latest approved documents, ensuring that the most current version is in use across the extended enterprise. You can also automatically push controlled documents to mobile devices safely and securely.

Available On-Premise or in the Cloud

OpenText gives you choice and flexibility when deploying Documentum for Quality and Manufacturing to meet your unique combination of access, security, and privacy needs. The solution is available on-premise or in the cloud so you can decide how to best align with your security, budget, and IT administration requirements.

With OpenText Documentum as a Service, you can leverage a managed service to reduce demands on your internal IT staff while reducing total cost of ownership by 30 to 60 percent. If accessibility for your contract manufacturing partners is paramount, a public cloud solution provides the ubiquitous access needed in a single tenant application. And as always, you can choose a traditional on-premise deployment that gives you full control. Regardless of your choice, OpenText offers enterprise-grade, best-in-class security, back-up, and recovery options so you can deploy Documentum for Quality and Manufacturing with confidence.

Get Started Today

With Documentum for Quality and Manufacturing, you get innovative functionality designed to address the challenges of managing quality and manufacturing documentation—and the benefits of a trusted and highly scalable foundation: Documentum, the life sciences industry standard for enterprise content management. The result is unprecedented efficiency, agility, document control, and compliance that is key to getting products to market ahead of the competition. To learn more, visit us at **www.opentext.com**.

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