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Product overview

OpenText Documentum for Quality and Manufacturing

Control critical, quality documentation and streamline and automate processes while ensuring compliance

- Provides **extensive out-of-the box capabilities with document taxonomy**
- Includes a **modern user interface with mobile support**
- Delivers cloud-native technology to run on-premise and in any cloud
- **Enables robust integration** for connection to enterprise systems

Part of OpenText™ Documentum™ for Life Sciences, OpenText™ Documentum™ for Quality and Manufacturing enables Life Sciences organizations to control quality and manufacturing documents and automate workflows across the extended enterprise. It also ensures compliance with Good Manufacturing Practices (GMP) standards and 21 CFR Part 11 and Annex 11, providing audit trials, e-approvals and e-signatures.

Using cloud-native technologies for on-premise or cloud deployment, the solution is built on OpenText™ Documentum™, the industry's leading and most scalable content management platform, and complies with the Drug Information Association (DIA) GMP Quality Systems reference model for consistent document modeling. This includes specifications, methods, labelling and master batch records, as well as procedures, governance, corporate policies, validation reports and many other document types. The solution expands upon the DIA reference model by supporting medical device documents, including collated Design History Files and Device Master Records.

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OpenText Documentum for Quality and Manufacturing feature chart

Controlled authoring	Enforce authoring standards with controlled content templates and ability to automatically populate text from document properties, reducing errors and rework
Collaborative authoring	Collaborate with internal users and external partners with realtime collaborative authoring and annotation capabilities.
Enforced document change control	Require document change requests on change controlled document types, configure to make them optional for business process flexibility or disable and integrate if using third-party solutions.
Automated review and approval processes	Ensure appropriate steps are taken for each document type with pre-defined lifecycles and workflows. Multiple users can perform simultaneous review and approval from any device.
Configurable views and watermarks	Supports print and export control, as well as preconfigured, dynamic watermarking, with overlays to ensure document security.
Controlled and issued printing	Unique print and reprint number and automated recall or reconciliation help to ensure compliance with print control requirements of FDA and EMA data integrity guidance.
Automated periodic review	Trigger workflows to ensure reviews are started and completed on time.
Streamlined document change management	Track new versions, edits and deletions automatically in an audit trail to maintain accountability.
Tracked "read and understood"	Distribute, track and report all "read and understood" actions to employees.
Automated technical transfer process	Transfer documents seamlessly between regulatory and quality domains in a single step to ensure content consistency and traceability.

Associated OpenText products

- **OpenText™ Documentum™ for Life Sciences**
- **OpenText™ Life Sciences Express**
- **OpenText™ Documentum™ for eTMF**
- **OpenText™ Documentum™ for Research and Development**
- **OpenText™ Documentum™ for Quality and Manufacturing**
- **OpenText™ Documentum™ Submission Store and View**
- **OpenText™ Documentum™**
- **OpenText™ Documentum™ D2**

Documentum for Quality and Manufacturing addresses 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 parallel collaborative authoring and review, giving users consistent, accurate, compliant and quality documentation. This extensive out-of-the-box functionality, built on more than 25 years of experience in the Life Sciences industry, shortens implementation time while providing robust configuration capabilities. And, when a change to documentation is required, such as during a scheduled periodic review, the entire process is automated and tracked.

Uncompromised regulatory compliance

At any time, Life Sciences organizations can be called upon to demonstrate compliance with quality and manufacturing regulations. With Documentum for Quality and Manufacturing, organizations can clearly prove 21 CFR Part 11 compliance with extensive audit trails and access controls, including e-approval and e-signature support, document distribution, version control and lifecycle management.

Automatically distributed effective documentation

As an organization's business network expands, it must harmonize data and procedures across geographically distributed sites, while still enabling localized productivity and efficiency. With Documentum for Quality and Manufacturing, users can automatically distribute documentation to employees and partners, both internally and externally. The solution automatically replaces previous versions with the latest approved documents, ensuring that

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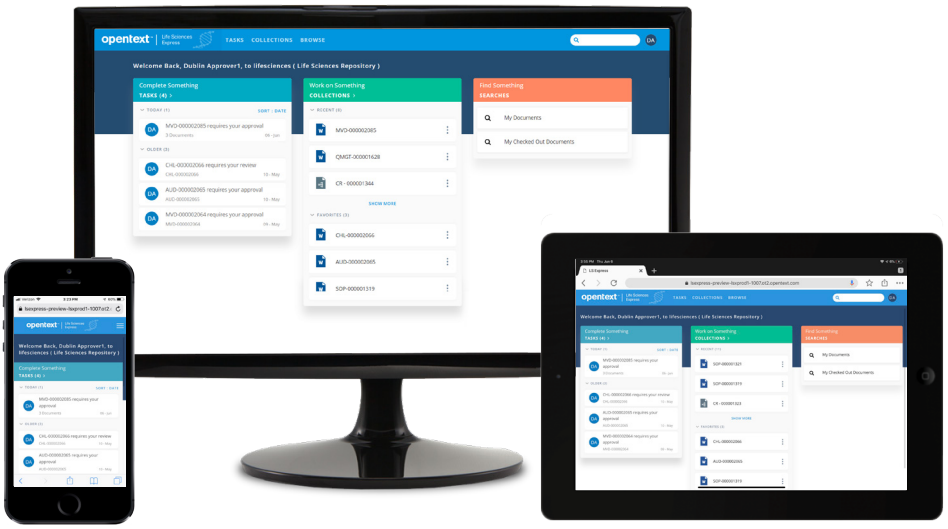
OpenText Documentum for for Quality and Manufacturing »

The way forward: Innovation in life sciences quality management white paper »

the most current version is in use across the extended enterprise. Users can also view controlled documents on mobile devices safely and securely.

Provides mobile accessible and auditable actions

Documentum for Life Sciences provides role-based, personalized views to enable employees to simply and efficiently complete routine tasks. Users can expect an intuitive, personalized experience. Easy-to-use, consumer-like mobile access on phones and tablets ensure that work continues on the go. External users review and approve content in the same compliant way as internal users. And, with watermark support and rights management capabilities, control over distribution and use of content has never been stronger.



Employees and external users review and approve content in the same compliant way using desktop or mobile devices.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) opentext.com.

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