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Product overview

OpenText Documentum for Life Sciences

Unified processes and seamless information sharing across the extended enterprise

- Offers **a single, authoritative source** for regulated content
- **Controls documents, automates workflows and ensures GxP compliance** through the entire drug lifecycle
- **Leverages agency guidance and industry leading practices**
- Offers **cloud-native software to run anywhere.**

With more than 25 years of experience in Life Sciences, OpenText™ Documentum™ has developed and continuously improved upon a set of comprehensive, purpose-built solutions, leveraging agency guidance and industry leading practices to meet its challenges. OpenText™ Documentum™ for Life Sciences breaks down information silos to transform how organizations access, manage and share regulated content. The solution is designed to offer choice and flexibility to reduce complexity while unifying and streamlining processes.

OpenText Documentum for Life Sciences feature chart

Unified solution layer	Deploy multiple solutions in the same repository to share and reuse content, leveraging a shared enterprise information architecture with common, industry standard inventory and data models
Cloud-native technologies	Run Documentum for Life Sciences anywhere with cloud-native technologies that vastly simplify deployments and upgrades.
Industry-standard business processes	Leverage comprehensive, predefined document taxonomies, lifecycles and workflows based on industry leading practices for pharmaceutical and medical device products

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Associated OpenText products

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

OpenText Documentum for Life Sciences feature chart

Role-based options	Choose the interface that best suits users, including a fully configurable, personalized option and a simplified, mobile ready option for external partners and infrequent users
Technology transfer	Share content included in submissions that is used in manufacturing operations without importing and exporting from one system to another

Documentum for Life Sciences provides a single, authoritative source for regulated content across the extended Life Sciences organization. Clinical documents that must be included in regulatory submissions can be linked to both clinical and regulatory stakeholders. Similarly, relationships can be created between quality and regulatory documentation to enable stakeholders to conduct quick impact assessments when a change is required. This capability, when combined with mobile and cloud options, provides ubiquitous access, intuitive user experience and efficient and compliant business processes.

Provides mobile accessible and auditable actions

Documentum for Life Sciences provides role-based, personalized views to enable workers to simply and efficiently complete routine tasks. Users can expect an intuitive, personalized experience. Easy-to-use, consumer-like mobile applications on phones and tablets ensure that work continues on the go.

Whether a clinical investigator capturing required documentation at a site, a regulatory operations worker approving a document or a quality manager distributing SOPs as part of a "To Be Read and Understood" process, the solution's mobile capabilities enable access and continuous workflows from a desk, phone or tablet. And, with watermark support and rights management capabilities, control over distribution and use of content has never been stronger.

Solutions delivered with cloud-native technologies

Today's Life Sciences organizations need to maximize resources and budgets to enable innovation, seamless business processes and quick responses to changing business needs, while ensuring that security, privacy and control requirements are met. With a comprehensive portfolio of services that offer flexibility, agility and security, OpenText delivers solutions using cloud-native technologies that meet any organization's specific needs.

By leveraging state-of-the-art technology from Docker and Kubernetes, Documentum for Life Sciences can be efficiently deployed on-premises and in any cloud providing streamlined deployment, management, and upgrades. These new technologies have come together to make it easier than ever to upgrade Documentum to the latest version and take advantage of new features, capabilities and updates.

Specialized validation, migration and consulting expertise

Because mergers and acquisitions are so prevalent in the industry today, many organizations find themselves trying to maintain multiple content management systems that are often highly customized and siloed. As organization's move to today's configurable, user-friendly solutions and leave operational complexity behind, OpenText has the tools and industry expertise needed to ensure low-risk migrations, expert validation and comprehensive training.

The OpenText Validation Package is a set of documents and templates created for the Documentum for Life Sciences solution. It supports the validation efforts of a computerized system based on GAMP compliance and is designed to help organizations jumpstart validation activities and reduce overall validation effort. For cloud deployments, OpenText

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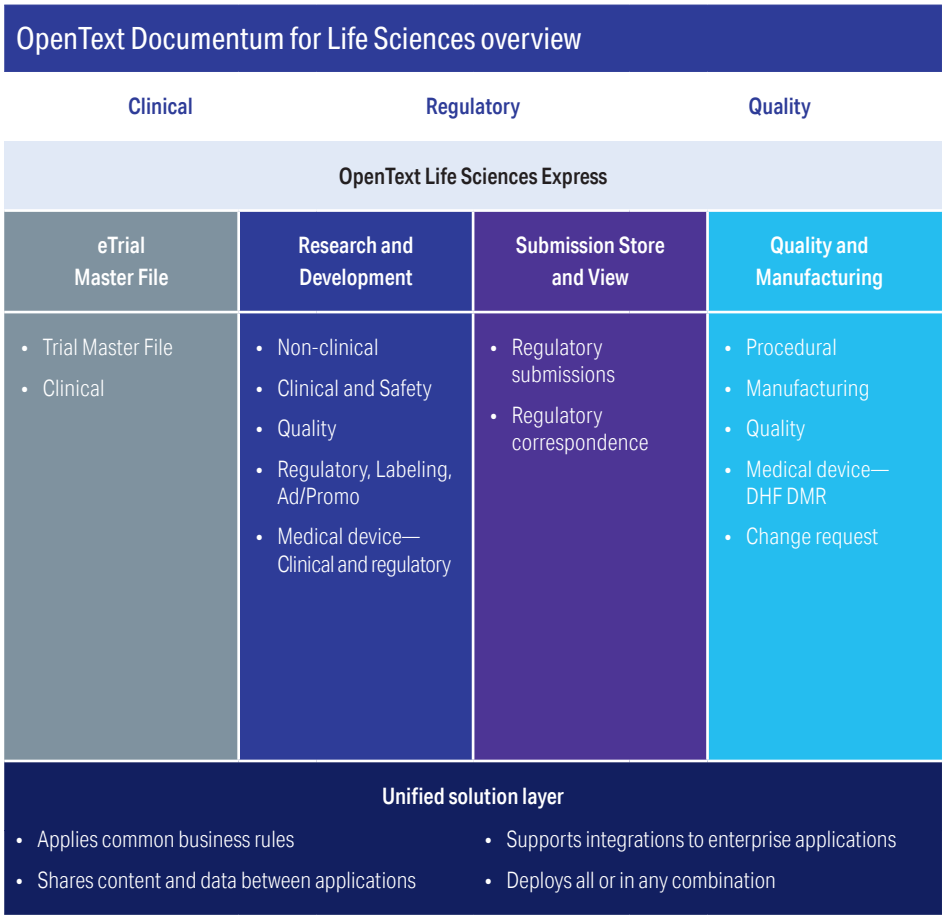
Breaking down information silos white paper »

provides a qualified cloud environment that is compliant with regulatory requirements and supported by the OpenText Validation Package. A package is also available for on-premises deployments.

Unique tools for migration of data enable users to consolidate multiple systems, migrating both structured and unstructured information into a single, unified, accessible repository. These tools are designed to expedite large-volume data transfer with minimal downtime and maximum data integrity, whether migrating in the cloud or on-premises. And organizations can free up budget on maintenance and storage by decommissioning legacy applications while still retaining historic content, such as testing and patient data, in a live archive.



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) visit: opentext.com.

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