opentext™

OpenText™ Documentum™ for Life Sciences

Unified processes, seamless information sharing across the extended enterprise

The life sciences industry is in a state of flux. Against the backdrop of patent losses and pressure to accelerate time-to-market for new medicines, today's business realities and governmental reform are driving new models of healthcare. These new models demand lower costs and emphasize positive, measurable outcomes and patient well-being.

Life sciences organizations are tasked with thinking outside the box to find ways to identify, prioritize, and develop promising therapies more quickly; to leverage their existing (and rapidly growing) data to derive meaningful insight; and to maximize efficiency across the full drug lifecycle. Bringing safe, high-quality drugs to market faster at a lower cost requires unifying processes that extend across domains, divisions, and external partners. It requires the ability to link and seamlessly share documentation—the critical element inherent throughout the drug lifecycle. In short, it requires a business transformation that parallels the radical changes in the industry.

Efficiency improvements via purpose-built solutions

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 industry guidance and best practices to meet these challenges. Documentum for Life Sciences breaks down information silos to transform how organizations access, manage, and share regulated content. Available on-premises or in the cloud, the solution is designed to offer you choice and flexibility with the ultimate goal of unifying and streamlining processes while reducing complexity.

Documentum for Life Sciences, built on the industry's leading content management platform, harnesses an information architecture based on the Drug Information Association (DIA) Electronic Document Management (EDM) and Trial Master File (TMF) Reference Models. The fully integrated set of configurable solutions includes the following:

SUMMARY

- *OpenText provides a set of comprehensive purpose-built solutions, leveraging industry guidance and best practices to link and seamlessly share documentation, which is critical throughout the drug lifecycle.*
- *Available on-premises or in the cloud, OpenText™ Documentum™ for Life Sciences breaks down information silos to transform how organizations access, manage, and share regulated content*

- **OpenText™ Documentum™ for eTMF:** Effectively plan, collect, track, and maintain essential GCP-compliant clinical trial documentation
- **OpenText™ Documentum™ for Research and Development:** Manage the creation, review, and approval of regulatory submission content
- **OpenText™ Documentum™ Submission Store and View:** Simplify the search and retrieval of archived submissions and associated correspondence, while improving security and compliance
- **OpenText™ Documentum™ for Quality and Manufacturing:** Control quality and manufacturing documents, automate workflows, and ensure GMP compliance

Seamless content sharing and a single authoritative source

Why introduce unnecessary complexity, inaccuracies, and risk to business processes by exporting and importing content 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, an intuitive user experience, and efficient and compliant business processes.

Mobile: Auditable actions just a swipe away

Documentum for Life Sciences provides role-based, personalized views to enable workers to simply and efficiently complete their routine tasks. Users can expect an intuitive, personalized experience; power users need not apply. And they can enjoy easy-to-use, consumer-like mobile applications on their phones and tablets to ensure that work continues even when they are on the go.

Whether you are a clinical investigator needing to capture required documentation at a site, a regulatory operations worker needing to approve a document, or a quality manager needing to distribute SOPs as part of a “To Be Read and Understood” process, the solutions’ mobile capabilities enable access and continuous workflows from your desk, phone or tablet. And with watermark support and rights management capabilities, control over distribution and use of the content has never been stronger.

Solutions delivered your way—in the cloud or on-premises

Today’s life sciences organizations need to maximize their resources and budgets in a way that enables innovation, seamless business processes and quick responses to changing business needs, while ensuring that their security, privacy, and control requirements are met. Whether you are deploying in the cloud or on-premises, there is no one-size-fits-all. With a comprehensive portfolio of services that offer flexibility, agility and security, we deliver solutions your way to meet your specific needs—private, public, hybrid cloud, or traditional on-premises.

Specialized validation, migration, and consulting expertise

Especially because of the mergers and acquisitions so prevalent in the industry today, many organizations find themselves trying to maintain multiple content management systems that are often highly customized and function as silos. As you move to today’s configurable, user-friendly solutions and leave operational complexity behind, OpenText Services has the tools and industry expertise you need to ensure low-risk migrations, expert validation, and comprehensive training.

The OpenText Documentum Validation Package is a set of Life Sciences solution documentation templates, created to support the validation efforts of a computerized system, based on GAMP compliance. It is designed to help you jump start your validation activities and reduce overall validation effort. For cloud deployments, OpenText provides a qualified cloud environment that is compliant with regulatory requirements and is supported by the OpenText Documentum Validation Package. A validation package is also available for on-premises deployments.

Unique tools for migration of data enable you to consolidate multiple systems, migrating both structured and unstructured information into a single, unified, accessible repository. With self-service and fully-delivered options, 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 you 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.

A strategic partner to ensure your success

As life sciences companies transform, they require a partner that can address pressing needs and support a long-term vision. As digital officers and enterprise architects look at new business models built around effective, personalized, and predictive medicines and healthcare, they need a partner that can deliver the complete content solution. The Life Sciences organization at OpenText leverages the entire OpenText portfolio of offerings, including records management, analytics, archiving, and more. Our solutions are designed to provide flexibility and scalability as your organizational needs evolve.

Increased value with partner solutions

The drug lifecycle is long, complex, and often involves numerous systems that must work together to share complete, accurate, and compliant documentation. Our partner-built solutions transform critical life sciences business processes These solutions extend the value of Documentum and our life sciences solutions to reduce risk, drive faster time-to-value, and deliver a high level of confidence.

Get started today

With Documentum for Life Sciences, you are embracing the future with unprecedented efficiency, agility, document control, and compliance, which is key to getting products to market ahead of the competition. To learn more, visit us at www.opentext.com.

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