

OpenText™ Documentum™ for Life Sciences

Powering regulatory transformation

Life sciences companies are under pressure to reduce the costs of regulatory operations and speed up health agency approvals to accelerate time to market. And to compete in a global marketplace, they need to incorporate global regulatory intelligence into business processes and do a better job of maximizing assets to expand reach into emerging markets. Process efficiency is paramount.

Yet even after making significant strides in establishing cross-divisional regulatory information management (RIM) programs, many companies are still not meeting their efficiency goals. Processes span a myriad of disjointed systems. Operational complexity reigns and accessibility and usability are problematic, particularly for affiliates and infrequent users.

Clearly, effecting convergence of critical processes, reducing complexity, and improving the user experience are all essential to improving efficiency, as well as data quality, accuracy, compliance, and visibility.

The need for an enterprise-wide RIM strategy

With these complex dynamics in play, life sciences companies must adopt a big-picture RIM strategy that drives smarter, faster, and lower-cost decision-making. A key objective is rethinking and recasting the core set of regulatory systems with an intelligent, interconnected RIM framework. To achieve this, companies need an enterprise content management (ECM) solution for life sciences that facilitates and supports information access, sharing, visibility, and communications seamlessly across the extended enterprise—for both internal and external participants.

BENEFITS

- Streamlines the regulatory submissions process and reduces operational complexity
- Improves efficiency and productivity, as well as data quality, accuracy, and compliance
- Facilitates information access, sharing, visibility, and communications across the extended enterprise
- Eliminates information silos with a single platform for regulated content management across domains
- Offers collaborative authoring to streamline review, editing, and approval of regulatory documentation
- Delivers a mechanism to implement best practices for using a Global Regulatory Index (GRI) to provide approved content to affiliates
- Provides a complete view of regulatory activity by storing published submissions and related agency communications in the secure OpenText™ Documentum™ repository

A single platform for regulated content management across domains

Fortunately, the evolution of ECM systems led to solutions that offer a different approach, with an enterprise information architecture serving as a single authoritative source across all functional areas: non-clinical, clinical, regulatory, and quality. Instead of operating in silos, an enterprise-wide ECM solution enables documents in one domain to be used by key stakeholders in another.

This approach minimizes discrepancies and uncontrolled copies, ensuring that information is accurate, timely, and accessible. Organizations can respond faster to product changes, compliance concerns, or health authority requests.

A streamlined process for creation, review, and management of submission documentation

With outsourcing prevalent, streamlining processes for managing submission documentation across the extended enterprise is critical.

OpenText™ Documentum™ for Research and Development, part of Documentum for Life Sciences, enables organizations to create, review, and approve regulatory submission documentation more efficiently.

Industry-standard dictionaries, taxonomies, and object models with a template-based authoring process boost author productivity and collaboration. Collaborative authoring tools for simultaneous editing can streamline review and approval processes. The result is not only streamlined workflows, but accuracy and completeness of submission-ready documentation. And with the ability to seamlessly integrate with publishing tools, documents can be placed directly into the submission outline.

Seamless information sharing between headquarters and local affiliates

While sponsors are responsible for the accuracy of submission content—and ultimately, product quality and safety—visibility into regulatory activities continues to be a challenge for many. Organizations must have confidence in the quality of product registration information maintained in global systems, while ensuring that

affiliates have information access, flexibility and adaptability, along with bidirectional communications. With OpenText solutions, people separated by geographical and organizational boundaries can collaborate seamlessly.

Archiving for a complete view of regulatory activity

Once products are approved and commercialized, life sciences organizations must still keep current, complete records of all documents associated with regulatory submissions for each product in each market—as well as related agency communications including emails, meeting minutes, and phone records. Sponsors need easy access to regulatory correspondence linked with the submission, and the ability to quickly search and retrieve archived submissions and associated documents to respond to queries.

OpenText™ Documentum™ Submission Store and View simplifies the search and retrieval of archived submissions and their associated correspondence, while improving security and compliance. The solution links regulatory correspondence and communications to submission files, enabling a full view of regulatory activity within a scalable, secure Documentum repository.

Eliminating operational complexity

Streamlining processes, achieving enterprise-wide efficiencies, boosting productivity, and supporting regional affiliates are all essential elements for life sciences organizations today, whether global multinational or midsize company. Choosing an OpenText solution that powers an integrated RIM solution is fundamental to making operational complexity a thing of the past.

Documentum for Life Sciences

For more than 25 years, OpenText has helped life sciences organizations meet compliance requirements, increase productivity, and securely collaborate across the extended enterprise. For additional information about Documentum for Life Sciences, please visit www.opentext.com.

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