

POWERING REGULATORY TRANSFORMATION

Improving Efficiency Across the Extended Enterprise

ESSENTIALS

- Streamline the regulatory submissions process and reduce operational complexity
- Improve efficiency and productivity, as well as data quality, accuracy and compliance
- Facilitate information access, sharing, visibility and communications across the extended enterprise
- Eliminate information silos with a single platform for regulated content management across domains
- Utilize collaborative authoring to streamline review, editing and approval of regulatory documentation
- Implement best practices for using a Global Regulatory Index (GRI) to provide approved content to affiliates
- Gain a complete view of regulatory activity by storing published submissions and related agency communications in the secure Documentum repository

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 existing 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 A STRATEGIC, 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. What is needed as part of this is 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.

A Single Platform for Regulated Content Management Across Domains

Fortunately, the evolution of ECM systems has given rise 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.

EMC® Documentum® Research and Development, part of the EMC Documentum for Life Sciences solution suite, 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. EMC solutions enable reliable and seamless collaboration between people separated by geographical and organizational boundaries.

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.

EMC® Documentum® Submission Store and View, also part of the solution suite, 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 ECM solution that powers an integrated RIM solution is fundamental to making operational complexity a thing of the past.

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EMC DOCUMENTUM FOR LIFE SCIENCES

For over 25 years, EMC Documentum has helped life sciences organizations meet compliance requirements, increase productivity and securely collaborate across the extended enterprise. For additional information about EMC Documentum for Life Sciences solutions, please visit www.emc.com/documentumforlifesciences.

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