BUSINESS CHALLENGE

The life sciences industry has undergone radical changes in business model. The industry is moving toward a more virtual, lean organization that relies more heavily on partners and service providers to bring new products to market. In particular, as competition has increased and product pipelines have dwindled, there is a greater need to enable innovation while managing costs such as one-off, labor-intensive methods of collaborating on documents. Current processes and applications for managing R&D and regulatory submissions documents are no longer effective in today’s model and are costly to maintain. The business needs a way to quickly collaborate with internal and external parties and reduce cycle times for document authoring, review, and approval.

Another market factor impacting life sciences companies is the drive to decrease the total cost of ownership of regulatory applications and the data center systems that support them. Aging infrastructures and home-grown, often brittle solutions hamper the ability to adopt newer, more efficient technologies and leverage lower cost hosted solutions that may include managed IT services. Maintenance contracts on legacy applications and infrastructure are costly and restrict the organizations ability to reduce spending. Lack of optimization in both infrastructure and business processes makes it difficult to take full advantage of business process outsourcing and optimization opportunities.

SERVICE DESCRIPTION

EMC Consulting can deliver a Collaborative Authoring Solution Framework that starts with a Microsoft® SharePoint®—EMC Documentum® collaborative authoring solution. Based on leading industry requirements and processes, this framework can be leveraged to jumpstart your implementation efforts. We start with strategy and planning to mobilize the initiative, clarify objectives, and develop your roadmap for improving collaboration. Our solution includes services such as:

• **Process Excellence**: Update business processes to facilitate easier collaboration and be in line with industry-leading practices.

• **Requirements and Design**: Define solution requirements based on leading industry practices and develop a solution architecture and design for the collaborative authoring solution.

• **Solution Implementation**: This service includes program management, configuration/development of EMC’s starter framework or other solutions based on the business needs, validation, deployment, change management, and training services to implement a collaborative authoring solution.

• **Ongoing Support**: Services for application support, hosting, and business process outsourcing are available.
Once your solution framework is in place, you can engage in simultaneous collaboration with the flexibility and scalability to meet changing business demands at appropriate costs—without the time-consuming effort of breaking documents into smaller XML components. Reviewers can provide comments and tracked changes while authors make their updates, thus cutting down cycle times. External and remote users can use our solution via the web to perform their tasks without the need to even have Microsoft Office installed on their desktops.

Our solution enables you to meet global regulations, guidelines, and industry standards including eCTD and other submissions guidances, GxP, SAFE, FDA 21CFR Part 11, DITA, and the DIA EDM Reference Model. This solution will enable your organization to increase collaboration and innovation while reducing time to market and maintaining compliance in today’s complex life sciences environment.

Our process-oriented solutions leverage best-in-class EMC technologies, where appropriate, based on client requirements, including technology such as the Documentum xCelerated Composition Platform (xCP) to ensure integrated dashboards and workflow capabilities. Through our ongoing Gold Level Partnership and joint solution development with Microsoft, we use several common Microsoft tools to automate the process. We use Microsoft SharePoint to provide a familiar, straight-forward user interface coupled with Documentum web parts to expose required document lifecycle, workflow, and compliance capabilities. This enables robust web functionality, a flexible framework, and the ability to scale to meet future needs. Security is layered throughout our solution stack from document-level security provided by xCP to role/rule-based security.

EMC Consulting will drive the implementation of the solution, leveraging our partnerships with Documentum and our EMC Global Services Implementation Practice. EMC Global Services also provides ongoing support of the deployed technical solution and access to world-class training through our Education Services group.

**SERVICE VALUE**

EMC Consulting has recognized expertise in integrating compliance, business processes, and technology into innovative and practical IT solutions. Our Collaborative Authoring Framework supports multiple authors at the same time which enables better management of the authoring cycle. This tool shortens review and approval cycles by allowing work streams to occur simultaneously on the same document. EMC Consulting combines our knowledge of Regulatory Affairs business processes, business/technology roadmap development, implementation, validation, and program management to deliver a cost-effective, collaborative solution.

**EMC CONSULTING**

As part of EMC Corporation, the world’s leading developer and provider of information infrastructure technology and solutions, EMC Consulting provides strategic guidance and technology expertise to help organizations exploit information to its maximum potential. With worldwide expertise across organizations’ businesses, applications, and infrastructures, as well as deep industry understanding, EMC Consulting guides and delivers revolutionary thinking to help clients realize their ambitions in an information economy. EMC Consulting drives execution for its clients, including more than half of the Global Fortune 500 companies, to transform information into actionable strategies and tangible business results.