BUSINESS CHALLENGE

Life sciences companies are challenged to manage and track the status of their regulatory submissions components from the initial submission to post-approval. They must also manage and track their progress on responding to correspondence and queries from health authorities. They need to ensure timely closure of any commitments they made to regulators before their products can be approved. These business-critical processes are often paper intensive and cumbersome, requiring multiple manual interventions. Companies often struggle to streamline and automate these processes. With the regulatory landscape becoming more stringent, it is critical that organizations understand their regulatory obligations and address them based on established timelines. The lack of automation, lack of a view of status, and the inability to dynamically adjust their processes limits their ability to respond to health authority correspondence in a timely and accurate fashion, and the manual processes involved limit productivity.

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 IT’s ability to adopt newer, more efficient technologies. Maintenance contracts on legacy applications and infrastructure are costly and restrict the organization’s 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.

One way of overcoming these challenges is through the implementation of a regulatory submissions planning and tracking system built based on a comprehensive understanding of the organization’s regulatory needs. However, many organizations feel trapped in their existing environments because they do not have the expert resources or the time to develop a thorough regulatory tracking strategy that considers the various elements of the process, including submission project planning and management, agency correspondence, and commitment management. The regulatory risks cannot be mitigated if a more automated business process is not put in place.

SERVICE DESCRIPTION

EMC Consulting has the experience and expertise to be your trusted guide as you simplify your regulatory submissions planning and tracking processes. We can assess your current processes for managing submissions, correspondence, and commitments against industry-leading practices, while considering today’s regulatory landscape. We evaluate your existing application environment to build a strategic vision for a future state that ensures compliance and takes cost out of your business processes, as well as the IT application environment that supports it. Using our process analysis experience, we deliver solutions that enable your organization to achieve process excellence and make it easier to leverage low-cost service providers. Our industry experts will jumpstart requirements definition and deliver a solution.

THE BIG PICTURE

- EMC Consulting has recognized expertise in integrating compliance, business processes, and technology into innovative and practical IT solutions for regulatory submissions planning
- EMC Regulatory Submissions Planning and Tracking services, enabled by best-in-class EMC and Microsoft technologies, enable simplified document governance and system maintenance
- EMC delivers optimized processes and tools that reduce the TCO of your regulatory applications
that meets those requirements and enables you to optimize productivity while maintaining compliance with global regulations and industry standards such as GxP, SAFE, FDA 21CFR Part 11, DITA, and DIA EDM Reference Model.

The EMC Consulting Regulatory Submissions Planning and Tracking Solution Framework is a starting point for a Microsoft® SharePoint®—EMC Documentum® and MS Office Project Server solution based on leading industry requirements that can be leveraged to jumpstart your implementation efforts. It includes services such as:

- **Strategy and Planning**: Mobilize initiative, clarify objectives, and develop a roadmap to streamline submissions planning and tracking, correspondence, and commitment-management processes and systems.
- **Process Excellence**: Update business processes to facilitate easier planning and tracking and be in line with industry-leading practices.
- **Requirements and Design**: Define solution requirements based on leading industry practices and develop solution architecture and design for a submissions planning and tracking solution.
- **Solution Implementation**: Program management, configuration, and development of EMC's starter solution framework or other client preferred solution as designed, validation as needed, deployment, change management, and training services to implement a submissions planning and tracking solution.
- **Ongoing Support**: Services are available for application support, hosting, and business process outsourcing.

Our process-oriented solutions leverage best-in-class EMC technologies, where appropriate, based on your business needs, including technology such as the Documentum xCelerated Composition Platform (xCP) to ensure integrated project and workflow management and provide a holistic dashboard view into the work being performed by your organization.

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 Project Server as a part of our integrated workflow engine, and we also utilize user-interface tools based on the common Microsoft SharePoint tool set. 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 provided by RSA®.

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 for regulatory submissions planning. We combine this technical expertise with in-depth knowledge of the regulated industry to provide unmatched capabilities that quickly enable businesses to realize their TCO ambitions. EMC Regulatory Submissions Planning and Tracking services, enabled by best-in-class EMC and Microsoft technologies, allow simplified document governance and system maintenance. EMC Consulting leverages standard, non-proprietary development and deployment frameworks for this technology to simplify implementation and ongoing maintenance. We deliver optimized processes and tools that reduce the TCO of your regulatory applications while delivering enterprise-class performance and unmatched security.

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.

TAKE THE NEXT STEP

To learn more about EMC Regulatory Submissions Planning and Tracking Service and EMC Consulting, contact your local EMC representative or visit the website at www.EMC.com/consulting.