*Reduce the risk of non-compliance and speed time-to-market with a portal solution that helps streamline business process management*

# IBM Solution for Compliance in a Regulated Environment

## Highlights

- ***Enables faster time-to-market through improved regulatory submission (e.g., NDA, ANDA, BLA, eCTD) assembly, review and approval process***
- ***Supports faster, more effective sales and marketing efforts through integration of content and data with customer relationship management systems***
- ***Reduces IT costs with a more flexible, easier to configure system and with validation test scripts designed to enable rapid implementation with fewer resources***
- ***Offers out-of-the-box compliant document and data management functionality, including document types specific to R&D and manufacturing configurations to help facilitate compliance with GxP and 21 CFR Part 11 requirements***
- ***Portal-based user interface provides users with immediate access to multiple information sources and delivers the appropriate content and tasks for their roles within the organization***
- ***Increases information quality by reducing manual hand-off points through the use of a business integration layer with connectors into many enterprise applications, including Siebel and SAP***

Developing, manufacturing, marketing and selling targeted treatments is becoming increasingly complex and is driving significant changes in the pharmaceutical industry. New federal regulations are evolving to a more scientifically based approach—requiring new methods for drug development and regulatory compliance. In this deeply competitive, highly regulated environment, management of information is critical to increasing the speed of product development and manufacturing cycles, reducing compliance risk, ensuring accurate and expedited submissions and boosting productivity across the organization—from development to manufacturing to sales and marketing.

Many organizations already rely on document management systems to control regulated information, and on other systems to manage related data. But with the FDA and EMEA bringing renewed focus to business processes and scientific principles—in addition to their focus on discrete documents—document management alone cannot help ensure consistent, accurate content across an organization. Compliance now requires a solution that unites document and data management

with business process management and application integration. Such a solution allows easier connections and flow of information of both data and documents through regulated processes across the entire value chain.

**The next generation of compliance solutions**

IBM Solution for Compliance in a Regulated Environment (SCORE) is a new, flexible and easy-to-configure solution that addresses a client's regulatory compliance needs. IBM SCORE delivers key life cycle and workflow management, security and auditing functionality to help facilitate compliance with regulations, such as GxP and 21 CFR Part 11. In addition, IBM SCORE functionality includes business process management technology designed to enable the integration of information across applications and operational processes. The solution utilizes portal technology that allows access to multiple applications and data sources. IBM SCORE also facilitates rolling submissions, product labeling, accessing electronic batch records and report-level publishing — critical capabilities to help biopharmaceutical companies shorten their submission and regulatory review cycles.

This unique solution is built on proven technology used within the industry, and leverages the deep industry expertise and experience IBM has in developing and implementing solutions specifically for the biopharmaceutical industry. Going beyond traditional document management, IBM SCORE's robust architecture and functionality allow companies to manage processes and information through all stages of the product life cycle, from development through manufacturing to sales and marketing. The solution can help you:

- *Reduce the risk of non-compliance with critical industry regulations such as GxP and 21 CFR Part 11*
- *Shorten the development cycle of the submission process through controlled assembly, approval, tracking and publishing submissions–enforcing consistent use of best practices and facilitating regulatory agency review earlier in the process*
- *Improve manufacturing processes, including automatic notification of changes, electronic distribution of SOP and batch records, integration with enterprise systems and ability to track, review and approve batch records*
- *Decrease time to peak sales by electronically streamlining the review and approval of marketing material and other sales-related information*
- *Promote fast deployment and integration with the use of pre-defined and pre-characterized research and manufacturing configurations, allowing for up to 50% faster implementation times and validation test scripts that cut the cost and length of testing and validation*
- *Reduce development time through configurable applications that support client-specific requirements and implementation accelerators that support validation, implementation, training and migration*
- *Improve control with a robust audit trail and security, annotation and electronic signature features that allow users to identify and correct mistakes earlier, enhancing the quality of the content managed throughout the system*

IBM SCORE offers life sciences companies advanced functionality based on highly reliable, robust middleware. IBM SCORE has been specifically designed to take advantage

of the latest technologies while enabling companies to protect their current investments. IBM SCORE components include:

- *IBM WebSphere® Portal, which provides a user interface that enables scientists, manufacturers, investigators, managers and marketers to access regulated and non-regulated information from disparate sources, and execute business processes across critical applications with users inside and outside the organization*
- *IBM WebSphere Business Integration, which delivers business process management, workflow and application integration; and collaboration to optimize clinical trials management and supply chain synchronization while reducing the complexity and cost of marketing and promotion management*
- *IBM WebSphere Application Server, a high-performance, extremely scalable transaction engine for high-throughput and complex applications—an ideal environment to handle the high volumes of secure transactions necessary in the highly regulated environment of life sciences*
- *IBM DB2® Content Manager, which provides uniform access to multiple content types (images, documents, emails, audio, video and Web content) and scales to numerous business applications and repositories*
- *IBM DB2 Universal Database™, a relational database management system that delivers the reliability and scalability needed to mine, analyze and store vast amounts of data*

The SCORE solution components described above can be implemented on a number of document and data repositories that include IBM DB2 Content Manager, Documentum, IBM DB2 Universal Database and Oracle as well as other existing data repository systems.

The IBM Global Services team provides hands-on experience to speed implementation, migration and validation for all SCORE components. IBM Global Services also offers requirements analysis, solution business case justification and return on investment analysis. Solution design and implementation, integration with business processes and ongoing global support and enhancements are part of the standard IBM project approach. The IBM services team has implemented dozens of systems for life sciences customers in the Americas, Europe and Asia-Pacific.

**A single source for advanced solutions**

With proven technologies, knowledge of regulated life sciences processes and systems, strong investments in healthcare and life sciences as well as global support and services, IBM offers a unique solution that helps enable our clients to achieve their business goals and objectives. IBM SCORE is based on our ongoing commitment to helping life sciences companies facilitate regulatory compliance and provide effective, economical therapies. IBM SCORE helps biopharmaceutical companies develop, manufacture and deliver targeted treatments by integrating document, data and process management with application integration. Designed to help life sciences companies meet changing market dynamics, facilitate compliance with new regulatory requirements and enhance productivity, IBM SCORE delivers the functionality to help support regulated environments now and in the future.

## About IBM

The goal of IBM Healthcare and Life Sciences is to rapidly bring real-life business and information technology solutions to customers in the fields of pharmaceutical research and development, compliance, biotechnology, genomics, information-based medicine, biomedical imaging, healthcare delivery and other specialties. IBM is a proven leader in data integration, supercomputing, high performance storage, and on demand information technology services.

Long-term projects at IBM Research Centers and the IBM Deep Computing Institute foster collaboration with life science and healthcare companies —bringing domain expertise and innovative technologies to the development of our solutions. Together with our Business Partners, IBM can provide customized, effective solutions that include hardware, software, services and the brightest ideas in the business.

## About IBM Business Consulting Services

With consultants and professional staff in more than 160 countries globally, IBM Business Consulting Services is the world's largest consulting services organization. IBM Business Consulting Services provides clients with business process and industry expertise, a deep understanding of technology solutions that address specific industry issues and the ability to design, build and run those solutions in a way that delivers bottom-line business value.

## For more information

To learn more about IBM Healthcare and Life Science Solutions, visit **ibm.com**/industries/lifesciences or contact an IBM Healthcare and Life Sciences specialist at LS@us.ibm.com.



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