A Partner Solution for the Public Sector

Improving Regulated Content and Submissions Management for Life Sciences

IBM Information Management software

IBM Life Sciences
IBM Solution for Compliance in a Regulated Environment (SCORE)

Partner Solution

- ***Target Industry***
  Healthcare Providers
  Life Sciences
- ***Business Application***
  Quality and Regulatory Compliance
- ***Product***
  IBM Content Manager

Business Challenge

The life sciences industry is characterized by lengthy and highly regulated development cycles where extensive information must be managed, analyzed, catalogued and exchanged with outside agencies – often over many years. Bringing high quality, safe and effective products to market faster and at the lowest cost possible is the primary goal.

Life sciences companies seek to reduce cycle times, gain greater control over documents, data and medical images, and improve internal and external collaboration while maintaining a high level of quality and regulatory compliance from development and manufacturing, through marketing, sales, and distribution.

Regulatory submissions are critical to Life Sciences companies gaining approval to sell their products. Current processes are often labor intensive, hard to ensure high quality, and done in a rush at the end of the development cycle. The move to electronic Common Technical Document (eCTD) submissions provides an opportunity to revamp the process and start preparation sooner, avoiding the last-minute time crunch.

Two focus areas for Good Manufacturing Process (GMP) compliance include: Standard Operating Procedures management and Corrective Action Preventive Action processes to ensure quality.

Solution

The IBM Solution for Compliance in a Regulated Environment (SCORE) offers flexible regulated document management and submission management. This allows companies to effectively manage regulated content across the enterprise, from clinical trials, regulatory submissions and manufacturing through distribution, sales and marketing. It meets stringent requirements such as 21CFR11 and GMPs from the FDA and Annex 11 of the EU/EC GMP directives.

Users collaboratively create, review, approve and release or publish documents and submissions. The solution supports automatically or manually adding documents to a submission as they are completed. Hyperlinks between documents can be done during authoring rather than waiting until all documents are finalized and exported to a publishing system, thus avoiding the complications of handoffs and a publishing rush at the end of the process. IBM SCORE manages traditional documents and data as well as biomedical images collected during clinical trials.

IBM SCORE can be easily tailored to meet an organization's needs through a full range of configuration options. SCORE's flexible, role-based portal interface allows casual users to easily access information via a simple user interface, yet provides robust capabilities for "power users."

IBM also offers services required for a successful needs assessment, justification, design specifications, installation, configuration, validation and training. Additionally, IBM offers hosting services for this solution.

Value Proposition

IBM has extensive experience implementing regulated content management and submissions management systems for life sciences companies, including six of the top 10 pharmaceutical companies.

IBM SCORE offers the following benefits:

Information access/visibility

- Provides real-time access to medical images and imaging metadata.
- Reduces incidence of missing data.
- Facilitates sharing of information and images among organizations.

Productivity

- Improves productivity in collecting, analyzing, managing, and publishing information.
- Enables organizations to repurpose information submitted to an agency in one country for submissions in other countries.

Cycle time

- Speeds product time-to-market by streamlining workflow processes.
- Reduces cycle time between closing out a clinical program and readiness for regulatory submission.
- Speeds regulatory submissions and responses to regulatory requests and queries.

Costs

- Reduces costs for compliance and maintaining "audit-ready" manufacturing processes and regulated documentation.
- Reduces clinical trial costs.

Company Description

IBM Life Sciences brings real-life business and information technology solutions to customers across pharmaceutical, biotech, medical devices, and supporting organizations like Contract Research Organizations and Academic Medical Research Centers. IBM is a proven leader in regulated content management, high performance computing infrastructures, and the services and expertise needed to leverage IT investments. The company has more than 2,000 professionals dedicated to providing solutions, services, expertise and support to Life Sciences companies.

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For more information about SCORE, visit **ibm.com**/industries/healthcare/doc/content/solution/1156599105.html

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