

CASE STUDY

Implementing Document Management for Biotechnology GxP Compliance

In Brief

Customer Profile: This biotechnology company designs and develops vaccines to prevent and treat infectious diseases. It currently maintains a broad pipeline of vaccine and antibody candidates focused on infectious diseases in pre-clinical development.

Situation: Operating in a highly regulated industry, quality and compliance has crucial implications for future growth, creating a need to streamline and optimize GxP quality documents and SOPs across the company's multiple divisions.

Solution: To support its quality management initiatives, the company implemented Pilgrim's Document Management solution to integrate document management into its existing value chain — ensuring fast, secure access to critical documents.

Business Type: Biotechnology — Vaccine Development

Users: More than 400 people, from more than 30 countries enterprise-wide.

Pilgrim Quality's SmartSolve® Solution:

- Document Management

Through its own innovation and increasing demand for its products, this biologics company, once a relatively small organization serving a limited number of large accounts, has grown rapidly in the past decade into the industry leader it is today. This enterprise believes it is positioned to become a global leader in the delivery of state-of-the-art vaccine products and technology.

The company has a proven record for advancing a product to the market and one of the strongest pipelines in the vaccine industry. It has committed to further strengthening the pipeline by reinvesting revenue streams into R&D over the next several years.

On the day-to-day operational side, these R&D commitments require a firm commitment to regulatory compliance. The organization is overseen globally by EMEA, FDA, TGA, and Health Canada, so it is vigilant about preparing for and passing regulatory audits. Additionally, with new and increasingly rigid requirements from these bodies, it wanted to quickly implement electronic processes to better ensure regulatory compliance across its global operations.

Challenge

Overall, today's biotechnology industry is maturing, and must continue to evolve as growing pressures bear down. The industry is facing significant challenges from operational factors — including increasingly stringent regulatory forces — as well as from business,

clinical development, and market risks. Business fundamentals, which many biotech companies have had the luxury to ignore, are now emerging as critical elements for sustainability and survival.

Upon self-examination, this company, while appearing successful from the marketplace's viewpoint, recognized its multiple, disparate approaches to critical document management had created an internal vulnerability. Complicated, disjointed, and manual systems leave an organization vulnerable to regulatory scrutiny, and can also lead to failed audits, potential recalls, harmed reputation, loss of customer trust, and loss of profits.

Of particular concern was the risk of potential findings from a regulatory audit concerning its document and record controls. The company's existing document control process used multiple file servers on which employees shifted documents among the company's three global sites. This system had a number of deficiencies: it was not a 21 CFR Part 11-compliant system, an essential requirement to meet U.S. regulations; it lacked an audit trail, search, and notification capabilities; and it had limited security measures. Regulations were being procedurally enforced, but not systematically enforced.

Taking these concerns into account, management defined its quality improvement goals as:

- Improve efficiency in document lifecycle management (time & resources)
- Harmonize document management system (1 process for 3 sites)
- Increase management visibility
- Sustain regulatory compliance
- Take first step toward fully integrated EQMS

Solution

To address these goals, management adopted a single, integrated enterprise-wide document management

solution to automate and standardize QA and compliance processes. They knew this would improve their day-to-day operational issues and information flow throughout the entire organization, and would make the company more streamlined and flexible for future growth.

After assessing multiple providers, from suppliers of entry level products up to market leaders in the quality and compliance systems field, this company selected and began implementing SmartSolve®, Pilgrim Quality Solutions' quality, compliance, and risk solution platform. Based on review criteria, Pilgrim offered the best match for the functionality required by this company, including:

- Proven experience within the Biotechnology industry
- Easy-to-use document management features
- Flexible and powerful reporting options
- Value for Money

Upon implementing Pilgrim's integrated solution, this company's Quality Manager stated: "We anticipate a rapid improvement in the visibility into, and among, our quality and compliance operations at our various sites. These solutions provide the flexibility and scalability to easily integrate critical processes, and also provide a framework for continuous improvement under one quality system platform."

Business Benefits

With the robust flexibility and scalability tools built into SmartSolve, Pilgrim's software will provide a sound framework to continuously support process improvements. It will allow the company to manage process and data oversight, and create a collaborative environment for the businesses to work and improve. The company is now using SmartSolve to:

- Facilitate record management & reporting management of current controlled documents

- Satisfy industry and internal regulatory requirements
- Improve document creation and approval cycle time
- Reduce document release time
- Improve search and access time for documents
- Provide a single up-to-date repository for controlled documents
- Provide an effective system for change management in relation to documents
- Facilitate increased management oversight without increased work load
- Allow automatic routing, escalation, and notification
- Provide an electronic audit trail
- Sustain 21 CFR Part 11 compliance

With Pilgrim's integrated Enterprise Quality Management System (EQMS), this organization is successfully managing, streamlining, and optimizing its GxP quality documents and standard operating procedures. This reduces risk, ensures compliance with current industry regulations, strengthens overall quality and customer satisfaction, and increases efficiency and productivity.

About Pilgrim Quality Solutions

Established in 1993, Pilgrim Quality Solutions is the most experienced enterprise quality management provider in the life sciences industry with more than 750,000 end-users.

Pilgrim is dedicated to research and development and incorporates industry best practices into its products resulting in solutions that are specifically targeted to streamline critical quality processes and provide the bottom-line results that life sciences organizations demand. Built on leading web-based open architecture standards, Pilgrim's cost-effective solutions incorporate industry best practices and limit the need for extensive training, saving customers implementation time and labor costs.

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