

CASE STUDY

Change Control, Nonconformance/Deviation and CAPA Management in a Laboratory Environment

In Brief

Customer Profile: This company is a world leader in developing and marketing molecular diagnostic products for the treatment of a variety of cancers. It performs diagnostic tests for doctors and genetic counselors.

Situation: The company's rapid expansion led them to seek a more efficient operational process for recording, managing, and trending operational nonconformances and deviations in its lab environment.

Solution: The company implemented SmartSolve to ensure nonconformances and deviations are handled efficiently and effectively. This replaced previous disparate, manual homegrown electronic systems with a standardized system for improved visibility and tracking capabilities.

Business Type: Biotechnology & Pharmaceutical Laboratory Services

Users: 324 Quality, Business and Laboratory personnel, including Management

Pilgrim Quality's SmartSolve® Solutions: Nonconformance Management, CAPA Management, Change Management and Complaint Management.

This world-renowned enterprise's founding philosophy is that the future of medicine lies in a shift from a treatment paradigm to a prevention model. It has developed and commercialized new molecular diagnostics that prevent or mitigate the toll of some of the deadliest diseases. From research, to clinical trials, to production, every undertaking is executed proactively in keeping with their "prevention" philosophy.

In an effort to remain ahead of increasingly stringent regulatory requirements, the company began adopting 21 CFR Part 11-compliant automated software solutions, including an employee training management platform and an equipment management solution among all of its Laboratory Operations departments. As a result of effectively maintaining mechanical and human resources in top running order, they recognized the benefit internal operations would realize by ensuring key "events" management processes were also operating at maximum efficiency.

Challenge

In addition to the company's own initiative to be more proactive on the quality and compliance front, it had become apparent that across the industry, regulatory demands have become increasingly stringent and compliance increasingly critical.

As a laboratory facility, this company must sustain a certifiable level of compliance with the FDA's 21

CFR Part 58, or Good Laboratory practices (GLP); Clinical Laboratory Improvement Amendments (CLIA); Occupational Safety and Health Administration (OSHA); Health Insurance Portability and Accountability Act of 1996 (HIPAA), and additional regulations intended to ensure the highest quality delivery of services.

With this in mind, the company recognized potential deficiencies within a critical component of QA/RA operations. Its manual, paper-based, and even its homegrown “informal” processes for managing CAPAs were taxing staff resources. The existing event deviation system was slow, cumbersome, and not intuitive. With multiple disconnected tracking sheets in circulation, and a lack of data visibility among key Quality and Regulatory team members, employees were adversely impacted by the resulting email overload.

Additionally, information on events and deviations did not always reach the correct individuals through email channels. Meanwhile, other unnecessary or lower-priority notifications were reaching the executive team, clouding the critical CAPA items on which they should have been focused.

In turn, tracking and trending action plans and assigned tasks for both deviations and change controls were difficult, and escalations and follow-up for corrective actions were inadequate. On a broader level, their disparate, manual system was resulting in inconsistent auditing of GLP processes, higher IT administrative and overhead costs, less IT productivity, and ineffective resource utilization.

Solution

The company selected and implemented Pilgrim Quality Solutions’ out-of-the- box, closed-loop SmartSolve CAPA Management and Nonconformance Management. The solution allows users in any department to capture an event; determine if it is a

problem and assess any associated risks; investigate to the appropriate level; capture and track all corrective and preventive actions; and review for CAPA effectiveness.

By facilitating an effective CAPA process, Pilgrim’s solution helps them resolve issues quickly and prevent recurrence — ensuring an organization’s future well-being and compliance with industry and regulatory requirements. The system also allows the identification and tracking of proactive events through an effective change management workflow including an effectiveness check after implementation.

This company leveraged SmartSolve, the automated quality management platform, to manage its change control, CAPA, and deviation activities with standardized processes and instant real-time visibility. Now they can quickly and proactively identify what action is needed to ensure smooth operations and continuous compliance.

The solution has given this company an easy means to link incidents and changes online. Under the paper-based system, changes were disconnected from the incident management system, and there was no way to easily trend when an incident led to a change, or when the progress of the change conducted actually resolved the incident. With SmartSolve, individuals have their own list of tasks for changes, CAPAs, investigations, etc. Increased visibility makes it easier to see which issues are open, what work has been done, and what items still require completion.

The software also enables the company to link, via attachments, all data created as the result of an investigation with the incident. This replaces offline investigations and tracking, consolidating summaries and results and providing all related data at the user’s fingertips.

Improved communication and automated task assignments within the out-of-the-box SmartSolve workflows reduce lag time between the origin of notifications and resolution activities, providing the ability to see all open changes and their associated tasks. While practical, it also shores up regulatory compliance within the CAPA management process. Its pre-built tools enable electronic signatures and automate regulatory recordkeeping, helping conduct safety, risk, and compliance monitoring through the flexible workflows for product complaint resolution, change management, nonconformances/deviations, CAPAs, and audits.

Business Benefits

At the base level, the implementation of Nonconformance Management and CAPA Management is helping ensure that safe, high-quality lab results will continue to be passed on to consumers, a goal common to this laboratory services operation. From a strategic management perspective, SmartSolve allows management to view compliance in a comprehensive and integrated manner, while driving efficiencies upward and costs down.

Major soft costs savings have included:

- Improved accuracy and efficiency of event recording and reporting
- Automatic routing and escalation
- Reduced event time-to-resolution
- Detailed trending and reporting
- Improved access to records and information
- Increased management oversight of compliance risk without an increased workload

Since it has been managing its change control, CAPA, and nonconformance/deviation processes with SmartSolve, resulting improvements have not only benefitted the laboratory's day-to-day operations,

but have also been enabling the company to build consistent, efficient processes to increase productivity, reduce job quality issues, and meet industry and regulatory requirements. And, visibility has dramatically increased into action items and tasks that must be completed in a timely manner.

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.

Visit www.pilgrimquality.com for more information.

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