

CASE STUDY

Training Management: Tracking Requirements in a Laboratory Services Company

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 employee training and continuing education management.

Solution: This company implemented SmartSolve to ensure up-to-date accuracy and ease of access to employee training records. This replaced previous disparate, manual systems used among the various departments and groups with a standardized system for improved visibility and tracking capabilities.

Business Type: Biotechnology & Pharmaceutical Laboratory Services

Users: More than 400 laboratory supervisors and laboratory personnel

Pilgrim Quality's SmartSolve® Solution:

- Training Management

This world-renowned enterprise's founding philosophy is a firm belief 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 and pharmaceuticals 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 among all of its Laboratory Operations departments. Subsequently, it recognized that while mechanical resources could be effectively maintained in top running order, it would benefit internal operations to ensure its staff resources also were operating at maximum efficiency.

The company selected and implemented Pilgrim Quality Solutions' out-of-the-box, closed-loop SmartSolve Training Management to automate, and thereby simplify the checks-and-balances process for employee training, certification, and tracking. While helping ensure staff competency on an ongoing basis, the solution serves as a key component of the company's overall compliance strategy.

Challenge

In addition to the company's own initiative to be more proactive in its training management, across the industry, regulatory demands are becoming increasingly stringent and compliance increasingly critical. As a laboratory facility, this company must comply with Clinical Laboratory Improvement Amendments (CLIA) to ensure the accuracy and reliability of all laboratory testing. In total, CLIA covers approximately 200,000 laboratory entities across the United States. These CLIA regulations set minimum qualifications for all persons performing or supervising tests, along with corresponding responsibilities for each position in the lab. This laboratory must also participate successfully, per CLIA requirements, in approved proficiency testing programs, which provide an external evaluation of the accuracy of the laboratory's test results.

To meet this growing challenge head on, this company sought to enhance tracking and increase enterprise-wide visibility into its employee training and certification status. They needed a solution to give management quick access for locating the most current employee records, and to give employees the ability to proactively track the status of their individual training requirements.

Prior to automation, the company had been using a paper-based system to track and document training, with Microsoft Excel spreadsheets to record individual employee profiles. Similarly, it was engaging primarily manual systems to manage technical laboratory training requirements, regulatory training requirements, and management, continuing education, and trainer requirements.

Solution

SmartSolve Training Management automates the checks-and-balances process for employee training by assigning certification requirements, identifying training needs, and reporting certification status to

support compliance with industry standards and regulations. The software helps this organization comply with a variety of ISO standards and other regulations, such as the FDA's 21 CFR Part 11. Though ISO standards do not dictate the use of commercial software itself, paper-based and homegrown systems can be time consuming and prone to error, and may not effectively facilitate regulatory inspections.

Training Management gives lab personnel access to their individual pending training requirements, ensuring that they do not fall behind and thereby violate imposed standards. Employee training compliance is tracked six months after the date of hire and yearly thereafter, per CLIA and CAP requirements, to confirm that employees are refreshed on their job skills and meet compliance requirements of their positions.

With configurable workflow models built on industry best practices, SmartSolve streamlines the entire training management process — from scheduling, to data capture and tracking, through to reporting. More than 80 standard reports are available in the out-of-the-box solution that can be used to facilitate online reporting.

Training Management also enables enterprise-wide standardized processes and real-time visibility, to quickly and proactively identify where and what action is needed to ensure smooth operations and continuous compliance.

Business Benefits

At the base level, the implementation of Training Management helps ensure that safe, high-quality results will continue to be passed on to consumers, a goal common to this laboratory services operation for continued compliance.

By tracking training records in a validated system, SmartSolve provides the detail and history required

in a regulatory environment. Since implantation, improvements have not only benefitted the laboratory's day-to-day operations, but have also enabled this company to build consistent, efficient processes that increase productivity with proactive employee ownership of training, and help meet industry and regulatory requirements.

Primarily, this organization has improved visibility to overall training processes and certification requirements through the standardized approach of Training Management. Performance data measurements, identification of training requirements, and searchable databases provide organizations with insight into the operation of their training management program.

Through SmartSolve, this organization gains real-time insight into training processes which can then easily reflect the results and effectiveness of that training.

Training performance data is available in out-of-the-box, configurable reports or through custom reports generated by the user. Gap analysis provides insight into completed courses versus required training, and flexible search capabilities allow administrators to quickly find pertinent information. In addition to these operational management benefits, the solution has simplified user experience with this organization's training program with:

- Integrated and streamlined enterprise-wide training
- Easy employee access
- Real-time visibility/tracking of training requirements
- Real-time visibility/tracking of certification status
- Task management support
- Reduced volume of paperwork
- Accurate ROI tracking of training costs on an individual and per class basis

About Pilgrim Quality Solutions

Established in 1993, Pilgrim Software 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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