TrackWise® by Sparta Systems

MedImmune Harnesses the Power of TrackWise for Enterprise-Wide EH&S System

Company

A wholly owned biologics unit of the global biopharmaceutical leader AstraZeneca PLC, MedImmune employs approximately 3,300 employees in eight locations in the United States, the United Kingdom and the Netherlands. With 20 years of innovation in the biologics industry, MedImmune is headquartered in Gaithersburg, Maryland.

Business Challenge

Businesses in the biopharmaceutical industry must observe stringent procedures for tracking and reporting in respect to environment, health and safety (EH&S), both to reduce risks to the organization and meet legal requirements. MedImmune's old paper-based EH&S system had serious drawbacks, with inefficient incident reporting and no standardized means of tracking corrective and preventive actions (CAPAs). The company sought a modern, web-based, holistic EH&S solution that would incorporate a common philosophy and approach, standardize definitions and processes at a corporate level (while providing flexibility for site-level variations) and result in continuous improvements in EH&S management throughout the organization.

Solution

MedImmune analyzed the company's EH&S management information system (MIS) needs for the present and also assessed expected growth for the decade ahead. The company's initial plan called for a subsequent evaluation of commercial off-the-shelf software systems in light of these requirements. However, the team decided to first investigate a parallel ongoing IT initiative to maximize existing investments in enterprise-wide software systems, including SAP and TrackWise®, Sparta Systems' enterprise quality management system (EQMS).

The team determined that nearly all of MedImmune's EH&S requirements could be satisfied within these existing systems. TrackWise is a flexible, configurable workflow management tool with multiple applications across the enterprise, which MedImmune had previously deployed to manage and track various quality management processes. MedImmune realized that the mechanisms for processes such as investigating and diagnosing root causes and implementing corrective and preventive actions (CAPAs) were identical, and therefore determined that EH&S requirements could be achieved through TrackWise. According to Ron Clot, associate EH&S director at MedImmune, one of the most compelling factors driving the decision to use TrackWise for EH&S was that the core functionality is entirely configurable, which allows the vendor to avoid custom-coding software to requirements – a very costly and time-consuming approach.

> ***"With configuration using TrackWise, I can go through a menu and tick off what I want done," Clot says. "I can make changes locally, and can change the workflows in an incredibly short time as the systems evolve. We implemented our initial seven EH&S workflows within six months."***

Leveraging best-of-breed technology to deliver centralized and consolidated tracking, workflow management and regulatory reporting for all critical business processes, TrackWise also facilitates comprehensive audit management, including for audits relative to Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

"Our ability to take advantage of the audit trail TrackWise leaves behind was another key decision driver for us," Clot says. "Many commercial off-the-shelf systems out there do not meet our standards."

Results

After going live with the EH&S system in 2007, MedImmune is today approaching 5,000 records in TrackWise. Clot attributes much of this rapid adoption to the ease of navigation in the TrackWise workflows and simple web interfaces for end user usage for incident reporting and Adobe PDF forms for risk assessment.

> ***"A typical workflow in TrackWise is straightforward enough that, shown it once, someone can use it from that point on," he says. "That is critical; our EH&S systems just would not work if we did not have end-user acceptance. Any time there is to be an interface with our customer base, TrackWise is the preferred platform."***

As the EH&S initiative revealed the comprehensive capabilities present in TrackWise, additional departments that had a need for a powerful workflow management tool – such as clinical programming – became interested and began using the system within 18 months of its rollout. This has given the project truly enterprise-wide dimensions, delivering even more of the benefits characteristic of a closed-loop system.

MedImmune enjoys a notably low incident rate in comparison with other pharmaceutical organizations, and it has become measurably lower over time. Clot attributes much of this to the EH&S management system now in place.

"Our mantra of identify, evaluate, control and document is satisfied with TrackWise," he reports. "We're identifying things proactively. They don't slip through the cracks, and that's reflected in the low incident rate, resulting in cost savings in terms of worker's comp claims, lost productivity and the like."

By centralizing MedImmune's EH&S compliance process areas into a single solution while providing global visibility, ensuring risk mitigation and tracking the organization's environmental footprint, TrackWise:

- Ensures compliance with industry and governmental regulation and ISO standards
- Identifies incidents and risk factors and prompts corrective/preventive actions before they develop into serious problems
- Streamlines EH&S processes to facilitate thorough and timely completion
- Reduces time, effort and costs associated with manual, paper-based processes

Founded in 1994, Sparta Systems, Inc. is the industry leader for Enterprise Quality Management Solutions. Its product, TrackWise®, is used by companies around the world to ensure compliance, improve control, reduce risk and lower costs by consolidating issues and actions, automating workflow, and facilitating trending and reporting. Additional information about Sparta Systems and TrackWise can be found at www.spartasystems.com

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