



PharmaMar Streamlines and Expedites Business Processes around Chemistry, Manufacturing & Control Operations with TrackWise

Company

Founded in 1986, PharmaMar is the world's leading marine biopharmaceutical company. Based in Madrid, Spain, PharmaMar is dedicated to advancing cancer treatments through the discovery, development, production and marketing of marine-sourced drugs. With a marine organism library of 100,000 specimens and counting, the company studies the coping, defense, attack, adaptation and communication strategies of marine life and how they can be used to benefit human health. More than 12,000 patients with different types of cancers have benefited from PharmaMar's treatments worldwide.

Business Challenge

As a biopharmaceutical company tasked with delivering safe, effective cancer treatments for thousands of patients worldwide, PharmaMar must adhere to strict compliance guidelines like the Good Manufacturing Practices regulation, as well as many additional directives for the protection of employees and the environment. The company also maintains rigorous internal standards for quality management and continually looks for ways to improve quality across the entire organization.

Traditionally, PharmaMar used a paper-based system to track and report on the quality management and regulatory reporting of its CMC (Chemistry, Manufacturing & Control) operations. Everything from deviations, investigations and CAPAs (Corrective and Preventive Actions) were paper files that were transferred from one department to the other and filed away. Reports would get lost within the organization or be filed improperly, and collecting and reporting on information from various parties took considerable time and effort. Given the increasingly stringent global regulatory environment for life sciences companies, PharmaMar knew it had to find a more efficient, standardized way to track processes related to CMC quality management and collect data for easy reporting to regulatory authorities. In addition to a paperless system, it also needed a solution that would seamlessly scale to meet the evolving needs of its rapidly growing global operations.

Solution and Implementation

Rather than undergo a long, multi-vendor evaluation, PharmaMar knew right away that it wanted to implement Sparta Systems' TrackWise® quality management software. José Luis Ortega, quality unit director at PharmaMar was familiar with TrackWise software and knew of the strong cost-to-benefit ratio. The remainder of Ortega's team took little convincing as well, since many of them had heard about Sparta Systems' sterling reputation and proven track record of implementations at life sciences institutions across the globe.

Sparta Systems worked closely with PharmaMar during the implementation process. While initially concerned with employee reaction to transitioning to an electronic system and the level of training that would be required, PharmaMar found the transition to be easy. The dedicated Sparta Systems' Professional Services staff worked closely with the team to ensure a high level of comfort and usability. Given the time-savings and reporting benefits, as well as having easier access to timely information, PharmaMar employees welcomed TrackWise with open arms.

Results

A configurable, flexible workflow solution, TrackWise provided PharmaMar with a centralized platform to manage and report on all of its CMC quality processes, track the status of activities in real time and identify and analyze issues and trends as they arose. Among the many benefits PharmaMar experienced with TrackWise, the game-changers included:

- **Faster Information Gathering and Improved Process Management:** The most radical change was PharmaMar's improved and streamlined processes around its CMC operations. With information readily available and easily collected and reported, PharmaMar has achieved 100 percent of the deadlines it established for CMC cases since it implemented TrackWise.
- **Higher Quality of Information:** Due to the permanence of information entered into TrackWise, PharmaMar found that its employees took more time and effort to enter quality information into the system. The level of information sharing improved and became much clearer and more precise, helping PharmaMar gain a better look into its processes, identify trends or issues earlier and ensure its reporting was accurate and credible.
- **Better Understanding of Specification Results:** Before TrackWise, PharmaMar did not possess the capabilities to uncover the root causes of specification results. Today, PharmaMar can identify a broad set of root causes, treat the issues and ensure that steps are taken so that they won't happen again.

PharmaMar is rolling out a second TrackWise implementation for its Change Control & Audits operations in 2011.

"TrackWise enabled us to implement new workflows associated with quality processes, track and manage activities and commitments, analyze trends and improve quality across the entire organization," said Ortega. "We are convinced that the cost-to-benefit ratio of the TrackWise implementation is extremely positive for companies like PharmaMar, and we look forward to reaping the benefits that will continue to come from using the system."

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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