

TrackWise enables a large medical device company to streamline compliance



Situation Analysis

A global medical technology company that manufactures and sells medical supplies, devices, laboratory instruments, antibodies, reagents and diagnostic products.

The Challenge - Enhancing Collaboration and Increasing Transparency

For years, this medical device company has been tasked with creating innovative products that improve and enhance the quality of healthcare for patients and minimize the risk of incidents in the administration of routine and critical life-saving procedures. But in doing so, like many medical technology companies, they face day-to-day challenges in ensuring that any unforeseen problems that occur in the manufacturing process are corrected quickly and with precision. As a result, it becomes vital that the company takes the necessary and preventative measures that are needed to make certain that the recurrence of these unforeseen problems are avoided. Add to these duties, the intense scrutiny from FDA and its stringent regulations, the responsibility of reporting mandates, as well as the structuring and managing of quality initiatives across the organization...all become chief concerns for the company.

For this reason, the medical device company devised an Integrated Quality Strategy (IQS) to support an increasingly diverse customer and product base. The company envisioned utilizing information technology assets to manage and provide timely access to quality information, all while aligning critical business processes that delivered differentiated customer value with intangible human, informational and organizational investments.

To achieve the vision outlined in its overarching IQS, they required a software solution that would execute on several key goals: position the company for accelerated growth, reduce Cost of Poor Quality (COPQ) balanced against Cost of Quality (COQ), focus efforts on critical processes, reduce net investment through improved alignment and improve compliance with agency regulations.

The TrackWise Solution

As a first step in the IQS, the medical device company determined to redirect its corrective and preventive action (CAPA) management program to align with the IQS directives, with a refocused emphasis on process, people and technology. It began with an effort to facilitate cross-business and cross-functional development of global CAPA processes, a strategy that required software that would conform to these processes.

Previously, the organization had employed a technology vendor's software solution to manage its CAPA efforts, but found that the solution was having minimal impact at a significant cost – specifically, the company was unable to easily integrate the software with its processes, being forced instead to adapt its processes to the software. The company was also challenged by lacking multi-language and customer help desk support in the previous software implementation.

They decided that a new solution was needed to replace its existing installation and better align with the IQS goals, so the company turned to Sparta Systems' TrackWise quality management and compliance solution. Because of Sparta's in-depth knowledge of both the medical technology market and the business challenges faced by healthcare industry product manufacturers, they decided that TrackWise would be the most effective solution that would competently address all of its CAPA management needs, as well as further compliance and business process requirements. Combined with Sparta's support and expertise, the medical device company was impressed by the TrackWise solution's ease of configuration, breadth of functionality and ability to handle complex workflow processes.

With TrackWise's out-of-box features helping myriad global organizations manage compliance activities, they felt that this would be the optimal solution to its most pressing CAPA management and compliance needs. Together with Sparta Systems, they determined to roll out TrackWise in a multi-phased implementation to simplify and standardize the IQS vision.

Successful Outcome

This medical device company initially implemented TrackWise for CAPA management and the project went live with a pilot program at five locations. The next wave of 20-plus sites went live, with all sites (more than 60) live within a year. Following the successful CAPA management implementation, the company will begin a project that addresses audits for its global manufacturing initiatives, and is considering rolling out the TrackWise solution for change management and document control for another group. The company's implementation and integration of the TrackWise solution required minimal customization combined with maximum results.

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