Leading Biopharmaceuitcals Company Ensures Better Quality with Stratas

Sparta Systems

Improving Quality Management is a Core Value

An innovative developer of neurological disorder therapies, this California-based biopharmaceutical company feels a direct connection with their patients and caregivers. They take to heart their company's core values and strive to make a difference in their customers' lives. Upon the recent introduction of a new drug, the company wanted to ensure better quality by efficiently and effectively tracking and acting on quality-related data.

To better support its objectives, the company wanted to move away from traditional paper-based methods to an all-digital method of tracking and managing quality. It wanted to leverage an electronic system with quality event forms that could drive standardization and improve accuracy. This would also eliminate the reliance on spreadsheets, and support compliance.

Also critical was the ability to search quality data in real-time, and use analytics to identify quality trends and outliers. The company also wanted to ensure visibility across functional areas of the company, including: quality, pharmaceutical development, regulatory affairs, and operations.

Finding a Robust Cloud-Based QMS

While evaluating solutions, the most important considerations were end user experience, and the implementation and configuration experience. The solution also needed to support the organization's primary IT strategy of utilizing scalable cloud-based technologies whenever possible.

They selected Stratas Quality Management from Sparta Systems as their cloud-based quality management solution. The company's Quality & Compliance team was familiar with Sparta's flagship solution, TrackWise QMS, and knew that Stratas leveraged its maturity and best practices, while still supporting their IT strategy. Additionally, the ability for Stratas to be delivered within a narrow implementation timeframe was imperative.

Implementation Helped Drive Company-Wide Improvements

Leveraging the QuickStart methodology, Stratas was implemented in 35 days with custom workflows for complaints, incidents, and corrective and preventive actions (CAPAs). Cross-functional teams, a core team and an extended team, were involved in the implementation incorporating feedback from subject matter experts, and those most closely aligned with business processes. Getting end users involved early generated excitement about the project,

Company Overview:

Industry: Pharmaceuticals

Headquarters: California

Employees: Approximately 300

Solution: Stratas

and provided the implementation team with real-life use cases. This helped ensure processes were aligned across the organization, while providing an opportunity for process improvement.

With Stratas, this leading biopharmaceutical company improved operational efficiencies by eliminating manual and paper-based methods. The company can see real-time trending on issues now that everything is immediately captured electronically. This allows it to address customer issues and concerns in a timely manner. With improved systems and processes, they can catch and tackle issues earlier to ensure better quality for its customers.

"Stratas Quality Management has helped us in our objective to be compliant with industry regulations. But just as important, it's supporting our objective to ensure a high level of quality for our customers. We're pleased to have the support of Sparta Systems to help us achieve excellence."