

TrackWise Configuration, Validation & Support

For the U.S. group of a leading Japanese pharmaceutical company

Challenge

The client had begun implementing the complaint handling process in TrackWise, but nine months later, the project was still incomplete.

Solution

HighPoint provided a dedicated TrackWise team to implement new complaint handling processes, revise existing audit processes, and provide maintenance and support.

Results

- Complaint handling initiative and upgrades to audit management processes completed with an estimated time savings of four months
- Allowed the client to maintain the existing system and address outstanding user requests and concerns without diverting internal resources
- Fully validated system with constant updates and improvements, which increased user satisfaction and productivity

Company Overview

The client is a pharmaceutical and medical device company that commercializes products in North America for its parent, a multi-billion dollar Japanese group of companies. The firm focuses on neuroscience, cardiovascular, and oncology treatments to improve patients' health and quality of life.

Business Challenge

The company had originally implemented TrackWise to manage clinical auditing, so only the audit management process was configured. Realizing that the system could be used to greater potential, the firm began to define user requirements for the complaint handling process. With this initiative still incomplete after nine months, the client realized that a dedicated TrackWise team was needed to oversee the implementation of new processes, revisions to existing processes, and maintenance and support activities.

Solution

HighPoint Solutions was first brought in to complete the complaint handling project. The team, consisting of a system administrator, a validation lead, and the program manager, completed the requirements definition within a month and subsequently undertook the configuration and validation activities.

While the project was underway, they realized that the audit management process needed to be updated. The team also anticipated the need to configure additional processes in the future as the company increased its use of TrackWise. To address this, the project manager suggested expanding the scope to include a long-term managed services approach.

Because of HighPoint's expertise with the software and their familiarity with the company's existing validation processes, the client agreed that this was the most efficient option.

Building on the current project, the system administrator was given responsibility for configuring the TrackWise system as well as addressing user questions and requests. The validation lead oversaw the creation, review, and approval of all validation documents. The program manager supervised the entire project and led weekly status meetings to update the client and end-users on the project's status, budget, timelines, and concerns.

As the project progressed, the administrator maintained a change request log to track the client's desired enhancements. This log was reviewed and prioritized based on business need and configuration complexity to determine which requests to implement in the next release. Once the release scope was defined, the validation lead assembled the initial user requirements and the system administrator began the configuration development process. The prototype was then demonstrated to users to conduct a hands-on review of the system, with feedback used to refine the prototype. The system administrator subsequently developed the requested reports before locking the system configuration.

Once the user requirements were satisfied in the revised prototype and the system configuration was accepted, the validation lead sent the requirements out for review. Once these were approved, the validation plan, functional requirements specification, traceability matrix, and validation summary report were updated with the revised scope and requirements. New protocols and reports were developed to test them.

- **User Acceptance Test Plan:** Executed by the users, this formally confirmed acceptance of the system configuration. If users determined one or more of their requirements had not been met, the configuration could be updated.

- **Operational Qualification Protocol:** This verified that all of the functional requirements defined in the functional requirements specification were implemented.

- **Installation and Performance Qualification Protocol:** This verified that the system configuration was properly migrated into the production environment and was working as expected.

The validation lead ran each test and created a report to summarize the results and verify that deviations had been resolved. Approval of the validation summary report marked the final step in preparing for release.

Results

The dedicated HighPoint team completed the complaint handling initiative as well as upgrades to the audit management process with an estimated time savings of two months on each project. The managed services approach allowed the client to maintain their existing system and address outstanding user requests and concerns without diverting additional internal resources.

By delivering configuration, validation, and support for TrackWise, HighPoint gave the firm a fully validated system with constant updates and improvements, which increased user satisfaction and productivity.