ISP Achieves Integrated Quality Management with TrackWise

Business Overview

In ternational Specialty Products Inc. is recognized globally for developing, manufacturing, and supplying innovative specialty ingredients that enhance product performance. The extensive products that it manufactures are used in a wide array of industries, including pharmaceutical, hair care, skin care, coatings and adhesives, specialty biocides, beverage, food ingredients, agrochemical and oral care. With 160 years of experience, ISP serves over 6,000 customers in more than 90 countries.

ISP Technologies Inc. (ISP) is a manufacturing affiliate of International Specialty Products Inc. with several facilities in the United States and Europe. ISP Technologies places a strong focus on increasing its manufacturing capabilities through achieving quality-driven operational efficiencies.

Before TrackWise

Prior to its implementation of TrackWise, ISP Technologies used a paper-based system to manage batch record reviews, out of specifications (OOS), corrective/preventive actions (CAPAs), variance/nonconformance and other quality processes. The company was ISO certified and in compliance cGMP requirements, but its manual processes were becoming increasingly resource intensive and were not enabling ISP to fill its vision of running lean operations. As a specialty chemical manufacturer, the ISP quality team was faced with industry pressures to decrease production time and achieve cost and resource savings without scarifying the quality of the final product.

Jeanné Mensingh, ISP's quality systems manager, envisioned a web-based electronic quality management system (QMS) that would automate manual processes, remove non-value added activities and provide a centralized repository for all quality information. Based on her past experience in implementing other systems, Mensingh knew that a key prerequisite was finding a system that was highly flexible and would not require any custom code changes to meet ISP's specific needs. A highly configurable software platform would enable ISP to rapidly deploy the QMS with lower implementation and maintenance costs. Mensingh also desired a system that could provide powerful reporting and trending to allow the organization to consolidate information from its manufacturing sites.

Solution and Implementation TrackWise Implementation & Deployment

ISP made the decision to implement TrackWise based on the product's ability to meet its functional requirements and its capacity to provide an expandable platform that could accommodate the addition of future quality and regulatory process areas. The organization took an aggressive yet thorough approach to its TrackWise implementation, with the goal of

Company Overview:

Name: *International Specialty Products Inc. (ISP Technologies)*

Industry: *Chemical*

Location: *90 countries*

Employees: *2,700*

Solution: *TrackWise*

being in production in four months. Jeanné Mensingh led the project with valuable input from Sparta Systems' professional services and ISP's subject matter experts from various disciplines throughout the organization.

Implementing the system across five sites and moving from a paper to an electronic system gave the ISP implementation team the opportunity to think outside the box when developing and reviewing its system. "The workflow development phase was critical to the success of the implementation," explained Mensingh. "We realized that it would be a mistake to force our paper system workflows into TrackWise. TrackWise is a very powerful tool; leveraging its automated workflow functionality can bring tremendous efficiency to an organization by condensing the steps required in many workflows."

ISP underwent a comprehensive workflow review and redevelopment process. Despite the large component of process re-engineering, the initial design and configuration process for its Texas City, Texas pilot location took less than 30 days, based in large part on TrackWise's user-friendly configuration tool. ISP decided to use the next three months to optimize its configuration based on user feedback and then to validate the system.

While ISP initially deployed TrackWise for Out of Specifications (OOS) in its manufacturing areas, the positive feedback from the users of the system proved to be a driving factor for the expansion of TrackWise to manage other applications. Additionally, as the system gained visibility, ISP expanded the user base to other manufacturing plants and user groups across the organization. TrackWise was rolled out to three additional plants in the United States, a plant in Europe, and ISP's corporate headquarters.

ISP Leverages TrackWise Features and Functions

ISP used the TrackWise StateMachine™ to implement sophisticated workflow management, and to ensure that a structured process followed any OOS occurrence. For instance, when an OOS in ISP's LIMS occurs, a lab analyst creates an OOS record in TrackWise with all pertinent information.

TrackWise assures that the subsequent confirmation and investigation processes are managed according to ISP's OOS procedure. If an analyst records that there is an "unknown lab error," TrackWise changes the record's status to "Re-test and Re-prep" so the analyst can follow the related workflow. If the OOS is confirmed "out of specification," the analyst records this and TrackWise then routes the OOS record through a Failure Investigation workflow which triggers an OOS action item for the analysis and the determination of cause. CAPA records are initiated in the event the root cause analysis determines that a problem exists.

ISP's ability to automate notifications and implement escalations has enabled it to consistently address investigations before their due dates, which has resulted in an overall reduction of investigation cycle time.

ISP also utilizes the TrackWise Coordinator® 24/7 Business Rules Engine for enforcement of SOPs and CAPA effectiveness checks. The Coordinator institutes alerts to lab supervisors when certain types of OOS' occur. The Coordinator also identifies investigations that are approaching their due dates and issues notifications to established distribution lists based on the criticality, type and age of the investigation. ISP's ability to automate notifications and implement escalations has enabled it to consistently address investigations before their due dates, which has resulted in an overall reduction of investigation cycle time.

The TrackWise Coordinator also facilitates follow-up on CAPA effectiveness checks. Due dates for checks are automatically set to six months after a CAPA has been closed. The users who were originally involved in the CAPA process receive an email notification

signaling an open effectiveness check that reminds them to complete the check prior to the due date. TrackWise also plays a critical role in ISP's supervisory review process as required for FDA cGMPs. Product designs are routed to designated supervisors for first-pass quality review and reporting, and analytical data is routed to designated supervisors for review and closure. Batch record reviews now take, on average, four fewer business days to process. TrackWise users, including senior management, use the TrackWise Dashboard to review open action items based on their assigned role. Reports are used to obtain critical information in seconds. In short, efficient quality operations result from the immediate availability of data.

Today, TrackWise manages ten process areas at ISP: CAPA, variances/deviations, out of specifications (OOS), failure investigations, batch record reviews, analytical result reviews, internal and external audits and first pass quality reporting on all products. "We even use TrackWise for tracking configuration changes to TrackWise," said Mensingh. In the past, ISP had employed Sparta's professional services organization to assist with implementation. Through a combination of live training, provided by Sparta Systems, and hands-on experience with the initial implementation, ISP's internal technical group has evolved into a highly self-sufficient support organization. "The user-friendly TrackWise Administrator™ tools enable our TrackWise system administrator to implement new TrackWise applications and make configuration changes when needed," said Mensingh.

Future Direction

Based on its success with TrackWise to date, ISP is planning the implementation of a global complaint handling system. The complaint handling system will likely utilize TrackWise's mulit-language capabilities to broaden the scope of deployment to the worldwide user community. In addition, ISP plans to leverage the TrackWise Integration Manager™ to implement an integrated, LIMS-driven variance investigation process. The process will be managed in TrackWise with full access to all related lab information in LIMS. "We realize that while we have made great strides with TrackWise, we can do even more. Even considering all the benefits we have recognized so far, ISP is just now tapping into the true potential of TrackWise," said Mensingh.

Conclusion

ISP has realized the benefits of TrackWise as a fully electronic and fully integrated quality management system. With initial help from Sparta's professional services team, ISP used a flexible, systematic approach for reviewing its existing paper processes and implementing TrackWise features to automate and streamline operations, while at the same time achieving complete control. The TrackWise platform has resulted in a harmonized system that allows ISP to exchange information and monitor key metrics faster, with increased accuracy.

TrackWise efficiently accelerates problem resolution by combining, recalling, and enabling evaluation of quality processes over time. The closed-loop methodology provides clarity and consistency for reviewers, and ensures that cGMPs and company procedures are followed. Additionally, TrackWise has further improved ISP's processes by reducing cycle times, increasing procedural visibility and proactively enforcing quality controls. ISP has achieved its vision of running lean quality operations, and proactively implementing continuous improvement processes.

"TrackWise has made our vision of a fully integrated quality management system a reality."
---Jeanné Mensingh,, Quality System Manager, ISP Technologies