

Global Agrochemical Company Maintains Compliance with TrackWise



Business Challenge

A prominent agrochemical company with a global leadership position in crop protection and high-value seed production was looking for a way to automate their active ingredient and product registration process to ensure global regulatory compliance. The current solution was an older technology and not scalable to accommodate advances in web-based applications or support additional product lines and other business processes.

In order to track the product registrations for national, regional and local regulatory bodies, the company needed a scalable system to meet the growing and future needs of the business.

A central repository to track registrations and compliance activities across the enterprise would streamline the process and keep multiple teams updated on the status of the product. And with the process taking up to nine years to complete, the system would need to be flexible enough to support employee turnover and business process changes.

Solution

The company implemented Sparta Systems' TrackWise® Enterprise Quality Management Software (EQMS) in 2010 and was supported by the Global Regulatory department.

In the early stages of implementation, the new product introduction process was updated to provide a consistent process for the collection and review of documentation to support stewardship activities. The team was able to use the solution to track the lifecycle of Good Laboratory Practice (GLP) studies, the facility and audit records for the Quality Assurance (QA) units, as well as the audit and observations done by field inspections. Additionally, training requirements for regulatory employees could be tracked and managed in the training management application to support compliance requirements.

Results

After implementation of the TrackWise solution, the organization was able to centralize and consolidate their quality data for regulatory compliance and business process improvement. By combining automated quality processes and incorporating best practices for product registration tracking, the company improved its compliance and audit preparation for better traceability. Finally, management could see the benefits of streamlining the regulatory and QA processes and create better visibility across the enterprise.

The company proactively implemented Corrective and Preventative Action (CAPA) in areas of the business where problems became transparent. The EQMS software allowed regulatory and QA personnel to track and manage their quality processes to provide additional

Company Overview:

Industry:
Agrochemical

Distribution: *Global*

Revenue: *Over \$3 billion*

Employees: *More than 5,000*

Solution: *TrackWise*

compliance information to regulatory bodies, customers, external auditors and other authorities.

Conclusion

This leader in the agrochemical industry has realized the benefits of TrackWise as a fully integrated quality management system. With initial help from Sparta Systems' professional services team, the company 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 across the enterprise. The TrackWise platform has resulted in a centralized system to manage product registrations at the country or regional level and extract application information to perform required assessments.

TrackWise also enables the company to effectively manage the new product introduction process to ensure timely completion of key activities through the entire product life cycle. Managing audits and tracking finding associated with stewardship audits and field inspections allows the company to capture non-compliant responses and develop corrective actions to support compliance efforts.

Product Registration Investment (Per jurisdiction per product)

Testing Data: 70 specific tests

Registration Cost: \$10 million

Review Process: 6-9 years

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