Porton Pharma Eliminates Paper and Gains Efficiencies with TrackWise®

COMPANY OVERVIEW

NAME:
PORTON PHARMA

INDUSTRY:
CDMO

DISTRIBUTION:
Global

EMPLOYEES:
2,600+

SOLUTION:
TrackWise

Porton Pharma Solutions, Ltd. is a Chinese top-tier contract development and manufacturing organization (CDMO) that provides end-to-end CDMO services for both chemical drugs from APIs to formulation and biological drugs for global pharmaceutical companies and biotechs.

Porton Pharma is committed to being the most open, innovative and reliable pharmaceutical service platform in the world and enabling the public's early access to good medicines. The company strives for excellence and has been recognized through awards by industry forums and global pharmaceutical companies for process innovation, supply chain performance and compliance with global quality and EHS standards. By efficiently advancing development and enabling commercialization of multiple high-impact medicines, Porton Pharma has earned the trust of some of the world's leading and most innovative pharmaceutical companies and many biotechnology companies across the US, EU and Asia.

This level of innovation demands the digital tools necessary to drive success. Porton Pharma found the vehicle for enabling its digital transformation in the TrackWise quality management system (QMS).

THE OPPORTUNITY: Eliminating the Risks of a Paper-Based System

Porton Pharma previously used a paper-based system to manage quality. Manual, paper-based systems often pose risks like human error and less efficient communication. The risks inherent in a manual system, and a need to align with Industry 4.0 led the company to look for an alternative that would nurture efficiency and streamline the process of meeting compliance.

"The challenges and high risk posed by a paper-based system and the desire to align with Industry 4.0 pushed us to introduce an eQMS within the organization," said Porton Pharma's TrackWise Project Manager, Si Yang.

Through Sparta Systems' partner, Tri-I Biotech, the company was introduced to the TrackWise enterprise QMS. A combination of TrackWise's reputation as the gold standard for QMS, as well as the availability of Tri-I Biotech's implementation team in China resulted in the company choosing TrackWise as its end-to-end quality solution.

THE SOLUTION: An Integrated, Digital Quality System

Eight months after selection, Porton Pharma went live with the first phase of its implementation, deviations and CAPA. Future phases of eQMS implementation will be based on user requirements.

The TrackWise project team not only paid great detail to the eQMS, but also collaborated with key users who were involved in the project and took part in the requirement and performance qualification tests.

THE RESULTS: Taking a Proactive Approach to Quality Management

With the implementation of TrackWise, Porton Pharma now has the tools needed to take a proactive approach to quality management. What's more, the company will be able to trace quality events and analysis and benefit from notifications to keep tasks top of mind and ensure timely completion.

Since implementing TrackWise, Porton Pharma has experienced reduced event and investigation report turnover time due to the online review and approval process. This has also improved work efficiency throughout the organization.

TrackWise will also streamline the process of meeting GMP compliance and in ensuring data integrity. By improving the accessibility and availability of data, TrackWise will help Porton Pharma align and keep pace with the smart factory of the future.

"The reputation of TrackWise as the gold standard for QMS and the presence of an implementation team in China, made TrackWise the clear eQMS choice," said Yang.

LOOKING AHEAD

Porton Pharma has plans to implement processes for change control and lab events next, along with integration with its ERP system and LIMS.

TrackWise will serve as Porton Pharma's key information-based system in the quality system and provide the company with a highly efficient tool for statistics and analysis. It will provide these capabilities while enabling efficiency and helping to meet compliance—a critical capability for organizations like Porton Pharma.

> "We are looking forward to improving our confidence in GMP compliance and data integrity with the capabilities of the TrackWise QMS, and in taking a proactive approach to quality," said Yang.

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