Netherlands Vaccine Institute Achieves Seamless EU Compliance with TrackWise® Software

Company

The Netherlands Vaccine Institute (NVI) was established in January 2003 as the result of a merger between SVM, the government-run vaccine production unit, and the Vaccine Division of the National Institute for Public Health and the Environment (RIVM). NVI's mission is to guarantee (by procurement or production) the supply of vaccines necessary to protect the Dutch population against infectious diseases. To achieve its goals, the Institute works to develop strategic collaborations with various partners, including international pharmaceutical companies. Such collaborations include the exchange of knowledge and products and cooperation in research and product development.

Business Challenge

A highly regulated agency charged with guaranteeing the supply of vaccines against infectious diseases for the Dutch population, NVI maintains a vast quantity of records that must be reported regularly in compliance with EU Good Manufacturing Practices (GMP). In 2008, the Institute realized that its previous system for managing these records – a combination of Microsoft Excel, Microsoft Access and old-fashioned, paper-based methods – had become insufficient for managing documentation and readying reports for submission to the EU. It decided to seek out a centralized electronic system for document management that would not only ensure efficient and effective compliance with reporting standards, but also seamlessly integrate with its current systems.

Solution and Implementation

After an extensive evaluation of multiple solutions, NVI ultimately chose Sparta Systems' TrackWise® Enterprise Quality Management System (EQMS) to meet its demanding document management needs. According to Sandra Zwambag, NVI's document controller, the Institute selected TrackWise for the following reasons:

- It was compliant with European Standards: The versatile reporting capabilities and built-in, multi-language functionality in TrackWise allowed NVI to easily generate reports for submissions to the EU that were in full compliance with GMP standards.
- It easily integrated with other systems: With its robust web services capabilities, TrackWise was able to seamlessly integrate with the other electronic document management systems used by NVI with minimal configuration required.
- It was easy to use: The simplicity of the TrackWise user interface meant that all NVI's employees, regardless of level or technical proficiency, would be able to manage, track and generate the reports they needed without costly investments in training.

The Institute's choice was clear. Once it selected TrackWise, NVI worked with Sparta Systems to guide the agency through the implementation process, which was executed on time and with minimal complications.

"Our on-site TrackWise specialist was very helpful in overseeing our implementation and training us on the new system," said Zwambag. "We were able to handle most of the configuration ourselves, while Sparta offered its own set of best practices and guided us through every step of the process."

Results

Once TrackWise was implemented, NVI was able to create a centralized repository for all its critical documents, immediately migrating more than 20,000 documents into its new system, and eventually doubling that number to 40,000 over the next two years. The Institute was so satisfied with its new solution that it extended its use of TrackWise to manage a full range of quality management functions. This included the addition of 13 workflows within it its quality assurance department, including:

- **Deviations:** TrackWise now ensures successful documentation and reporting of any deviations that occur in the procurement and production of vaccines.
- **Corrective and Preventive Actions (CAPA):** If a deviation occurs, NVI can effectively issue actions to rectify it and take the necessary steps to ensure it does not happen again.
- **Change Control:** Changes to quality and compliance processes made by NVI employees are now efficiently implemented, accepted and enforced as standard operating procedures across the organization.
- **Internal and External Audits:** NVI now possesses the ability to compile and manage records for easy compliance with both regulatory audits and those imposed by its own management.

The Institute is now seeing significant gains from the enhanced efficiency of its compliance processes. The most tangible benefit NVI has seen from the TrackWise solution is its employees' sense of empowerment in being able to easily use it.

"Our users love the dashboards and reporting capabilities of TrackWise, and the power they have to make changes to the system on their own," said Zwambag. "As an application owner, I love that we don't have to ask for a lot of support from Sparta in configuring the system. The flexibility and overall usability of the system means we can do just about everything ourselves.

Founded in 1994, Sparta Systems, Inc. is the industry leader for Enterprise Quality Management Solutions. Its product, TrackWise®, is used by companies around the world to ensure compliance, improve control, reduce risk and lower costs by consolidating issues and actions, automating workflow, and facilitating trending and reporting. Additional information about Sparta Systems and TrackWise can be found at www.spartasystems.com

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