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Case Study

Flexibility is Key to Providing Game-Changing RIM Solution for a Contract Manufacturing Organization

Bachem Americas, Inc., a subsidiary of Bachem Holdings which is a leading global CMO, faced a real challenge: supporting a wide variety of customers with high quality Active Pharmaceutical Ingredients (APIs) for research, clinical development and commercialization of both generic products and New Chemical Entities. The Bachem Americas Inc. regulatory team manages the submission and maintenance of Drug Master Files (DMFs) and other registrations in many markets around the world. Accurate information and rapid responses are essential to avoid delays in their customers' marketing authorizations and maintenance.

Maintaining regulatory information was becoming increasingly difficult with their system of spreadsheets and "folders" containing product information. A complicating factor was that their staff is deployed on projects based on availability, not assigned permanently to a substance or client. As a result, understanding product histories that might stretch back to the 1980s was challenging and time-consuming.

The RA team started searching for a Regulatory Information Management (RIM). Many vendors did not offer a RIM solution addressing the use cases of an API manufacturer, and did not offer any options for developing a solution. Bachem Americas Inc. needed to identify a partner with a flexible solution that could meet their specific needs.

About Bachem

Bachem is a leading, innovation-driven company specializing in the development and manufacture of peptides and oligonucleotides. The company, which has 50 years of experience and expertise, provides products for research, clinical development, and commercial application to pharmaceutical and biotechnology companies worldwide and offers a comprehensive range of services. Bachem operates internationally with headquarters in Switzerland and locations in Europe, the US and Asia. The company is listed on the SIX Swiss Exchange. For further information, see www.bachem.com.

BACHEM

The Project: The Team Comes Together to Develop the Best Solution

Bachem Americas, Inc. was impressed with Ennov's solution and partnership approach, including the ability to evaluate a sandbox environment without a financial commitment. Like many other solutions, Ennov's RIM is primarily focused on addressing the needs of drug and device sponsors. However, the flexibility and configurability of the solution allowed the Bachem team to envision a future state that met their needs.

The Bachem Americas and Ennov team members came together to work through Bachem's use cases and develop the best solution. The team took a "clean slate" approach in redefining their processes for efficiency and effectiveness. Some key requirements included:

- Supporting NCEs used by a single customer
- Supporting APIs used in generic products by multiple customers, supplied in different markets and having different requirements
- Tracking upcoming submissions, which included proactive communication with their customers about requirements and potential issues
- Tracking customers' (external) and internal requests, which are handled as RIM tasks
- Transfer of all administrative tasks to Ennov RIM
- Providing rapid response to customer requests related to inquiries from Health Authorities
- Supporting DMFs, technical packages for INDs, site registrations, and more.

Although many team members were new to software implementation, the project was completed on-budget and on-time. Validation and user acceptance testing was completed without issues.

Bachem Americas decided on a manual migration process that would allow them to address data cleansing and standardization needs while bringing product information into the new RIM. The Regulatory team is making good use of the system. For example, they were recently asked to identify which of their products use a specific container/closure. Previously, this would have taken a whole day of looking through folders, but the answer was identified in five minutes with their new RIM views – a huge efficiency benefit.

Looking Forward

Bachem Americas continues to identify opportunities for improving their efficiency and customer service using Ennov RIM. They look forward to rolling out Ennov's new dashboard functionality (Ennov Analytics) later in the year, which will provide even better insight into status, workload and risk.

With product information and history, client requests, and impact assessment capabilities at their fingertips, Bachem is becoming proactive, not reactive, and has become a better service provider to their customers.

Conclusion

Even though Ennov RIM was not preconfigured specifically for the needs of an API contract manufacturer, the team was able to efficiently configure the system to Bachem's use cases, realizing the project's vision.

Although the project was conducted virtually in the time of COVID, with the exception of a single requirements meeting, progress was smooth and consistent. Bachem's upper management demonstrated their commitment and provided oversight. Thanks to a close collaboration between the Bachem Project Leader and the Ennov Project Manager the RIM was launched on time and with a high degree of user satisfaction.

Some key benefits experienced by Bachem include:

- **Improved Customer Service.** The team has instant access to product history including submissions in multiple markets, which used to be stored in many locations. Now, this history is easily accessible, increasing efficiency and a faster response to customers.
- **More Time on Value Added Activities.** Because significantly less time is spent collecting data from multiple sources, team members can spend more time on valueadded activities.
- **Standardization.** Ennov RIM has helped Bachem implement standard workflows and standard vocabularies, improving the quality of processes and expediting the generation of reports.
- **Elimination of Spreadsheets.** Bachem formerly had about 20 spreadsheet trackers that had to be maintained, updated and collated manually. These spreadsheet processes have been retired and instead, Ennov RIM provides spreadsheet reports on demand.

"Last year, our team needed to pull historical data on submissions in the US. It took our entire team one full week to identify and assemble the necessary information. With Ennov RIM, we will now be able to do this in 10 minutes or less. Ennov RIM truly is a one-stop shop for our needs."

Jamie Brugnano
Sr. Manager, Regulatory
Affairs Bachem