

CASE STUDY

Global Pharmaceutical Company

Environmental Monitoring Process Decreases New Product Time-to-Market

Challenge

This global, research-driven pharmaceutical and health care products company needed to implement new processes and procedures for environmental monitoring in order to achieve regulatory compliance and deliver products to market faster.

Solution

Designed and implemented a new Environmental Monitoring System (EMS) to meet FDA requirements. Developed procedures for collecting and storing data. Developed and validated the new system. Trained users and supported the new system.

Benefits

The EMS system allows the company to:

- Release products faster than ever before
- Ensure continual FDA compliance

Challenge

Environmental monitoring is an important part of this pharmaceutical company's operations. To get drugs to market, environmental monitoring systems ensure that products produced are safe and effective.

The problem was that the company's environmental monitoring tracking system was a Microsoft Excel-based system—a manual, paper-driven process. Monitors recorded results of the environmental samples they collected on control forms. The data would then be keyed into an Excel spreadsheet for tracking and trending.

Besides not complying with new FDA guidelines, the process impacted the company's bottom line because it was cumbersome. Products ready for release were held an average of three weeks waiting for review and approval of data that proved the products were sterile.

The company needed to implement new processes and procedures for environmental monitoring. These processes needed to be in compliance with regulatory standards and streamlined to expedite environmental monitoring so that products could be released faster.

Solution

Clarkston Consulting has an ongoing business relationship with the company, so management knew that Clarkston had the experience needed working in regulated environments to develop new processes to meet FDA approval—and do it quickly.

Clarkston's consultants:

- Designed the plan to install the environmental monitoring software (EMS) system
- Developed procedures for collecting and storing data
- Assisted in implementing the new system and procedures for data storage
- Developed and executed the validation of the new system
- Provided hands-on training for 40–50 users on the processes and procedures and how to use the software and generate reports
- Stayed on site for a month to provide support

Clarkston had to be creative in designing processes that would fulfill this company's requirements for sample collection within the of the software product. For example, the system didn't have the functionality to handle one environmental test in which monitors take five one-minute air samples in a row. Clarkston developed a process that would dovetail with the software and meet FDA guidelines.

There were a number of other test scenarios that had to be handled in similar fashion. To accomplish this, the consultants first learned all of the company's environmental testing procedures—number of samples taken, sites, limits associated with those sites, etc.—before they could determine how to handle the requirements with the automated system.

Benefits

In less than 14 weeks, Clarkston implemented a system and the procedures needed to meet this company's business needs. This was significantly faster than the company's typical time frame of 12–18 months for system implementation with full validation.

The solution was also good for business because it meant products could be released faster than ever before in the company's history.

Clarkston's continued support after implementation is also noteworthy. Consultants noticed a slowdown in the software; they coordinated an investigation with the software developer and this company's information systems department. As a result, the software vendor made a change and released a new version that improved the speed.

Company Profile

This company is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide.

Clarkston Consulting is a leading management and technology consulting firm that provides strategic business solutions for clients within the life sciences and consumer products industries worldwide. These market leaders turn to Clarkston to help them bridge the gap between strategy and execution to sustain a competitive advantage. Clarkston is a sought-after business partner because of its recognized industry thought-leadership and superior client relationships, as measured by The Conference Board's survey on client satisfaction. For more information, visit www.clarkstonconsulting.com.