

## CASE STUDY

Pharmaceutical Company

### **Implementing a Compliant Environmental Monitoring System**

#### **Challenge**

This company's environmental monitoring department did not have well documented procedures for collecting environmental samples, and did not comply with FDA requirements.

#### **Solution**

Developed and implemented new environmental monitoring processes, procedures, and systems that are FDA-compliant.

#### **Benefits**

Significant benefits of the new solution implemented by Clarkston included:

- Increasing the number of lots released per week from an average of 5 to 15
- Customers receive product according to schedule with product sterility assurance
- Environmental monitoring information is now included as part of lot records, as required by the FDA

## Challenge

This life sciences company's environmental monitoring department did not have established, documented procedures for collecting environmental samples in the sterile manufacturing and filling areas, or an efficient method for consolidating and organizing the data in a format that could be evaluated and trended to prove product sterility.

The environmental monitors used a paper-based process that was prone to errors and omissions. Employees printed copies of an Excel spreadsheet on which they hand-recorded sample data. One sampling session for one product lot could consist of thousands of samples. Because filing procedures were not consistent, documents could be easily misplaced.

## Solution

Clarkston Consulting was chosen to develop both the short- and long-term solutions. Because the two companies had collaborated on other projects, this company knew that the consultants' experience working in regulated environments enabled them to develop new processes to improve business operations.

Clarkston's mission was to help this company develop and implement new processes and procedures for environmental monitoring. These processes had to comply with regulatory standards and support the timely evaluation of data for product release.

To accomplish this, Clarkston:

- Developed procedures to collect, organize and store all existing documents that contained raw environmental sample data
- Converted all paper-based environmental sample data into an Access database for electronic evaluation and storage
- Created trending reports for 2001 and 2002
- Trained users on the processes and procedures for the storage of raw data, conversion of data into the Access database, evaluation of the environmental data and development of trending reports

Once the immediate concerns were addressed, Clarkston developed a long-term solution for a paperless system of data storage. To accomplish this, Clarkston:

- Implemented an environmental monitoring software package
- Developed procedures for data storage and trending of the environmental data on a quarterly basis
- Executed the validation of the new software system
- Trained the entire environmental monitoring department on how to use the system and report on the environmental data

## Benefits

In less than five months, Clarkston implemented processes and procedures to eliminate concerns. The short-term fix allowed the company to quickly get back into production, and the long-term solution means that the company can continue to stay in compliance without slowing product release.

Significant benefits of the long-term solution implemented by Clarkston were:

- This company was able to increase the number of lots released per week from an average of 5 to 15
- Customers receive product according to schedule with an assurance of product sterility
- The environmental monitoring information is now included as part of lot records, as required by the FDA
- The company has greatly improved its relationship with regulatory agencies, and reestablished its reputation for high quality manufacturing standards with its customers.

## Company Profile

This company is a contract pharmaceutical manufacturer of both sterile and non-sterile products and a leading producer of pharmaceutical products, performance materials and industrial chemicals.

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](http://www.clarkstonconsulting.com).