

## CASE STUDY

Pharmaceutical Manufacturer

### **Corrective Action Improves Relationships**

#### **Challenge**

This pharmaceutical manufacturer of both sterile and non-sterile products was required to respond to three separate observations from the FDA.

#### **Solution**

Developed and organized over 200 issues into major categories to strategically implement solutions for on-going compliance initiatives.

#### **Benefits**

By responding quickly to the FDA's observations, this company:

- Improved its relationship with regulatory agencies
- Reestablished its reputation with customers for high-quality manufacturing standards

## Challenge

The FDA has been enforcing regulations in the life sciences industry more aggressively. Through internal audits, this contract pharmaceutical manufacturer's operations cited additional problems. Many of the observations faulted:

- How the company was conducting and documenting some of its product filling operations.
- The lack of certain standard operating procedures (SOPs). For example, procedures for bringing tools into the aseptic area were not well documented.
- Cleaning procedures and cleaning validation.

The company was required to address each observation and take corrective action that would meet regulatory standards. Solutions also had to be pragmatic from a business standpoint.

## Solution

This company hired Clarkston Consulting to evaluate and resolve observations. Because the company had previously worked with Clarkston, management knew that Clarkston had experience working in regulated environments and could get to the heart of each observation quickly and develop a solution.

The consultants' methodical approach made it possible for them to manage over 200 issues simultaneously. The steps they followed were:

- Organized more than 200 issues into major categories.
- Appointed a dedicated consultant to oversee evaluation and resolution of all issues in each category.

- Developed solutions that could be accomplished in the timeframe available, and gained consensus from all parties involved.
- Assisted in implementing solutions.

Clarkston issued weekly status reports that outlined completed items, items to be completed that week and the plan for the following week, as well as any outstanding issues; management always knew exactly what progress was being made.

## Benefits

Many of the critical issues facing the client were addressed with prudent and defensible approaches. The company's responsiveness has greatly improved its relationship with regulatory agencies and reestablished its reputation for high quality manufacturing standards with its customers.

Especially noteworthy:

- A number of observations were identical or very similar. Organizing and grouping observations before taking any action allowed Clarkston to formulate solutions that in many cases would cover several issues.
- Clarkston helped the company prepare a 40-page SOP document that covered all issues raised by either the FDA or the third-party auditor regarding the filling operation.

## Company Profile

This client 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).