

## CASE STUDY

Contract Pharmaceutical Manufacturer

### **Quality Systems Implementation Meet Customer Expectations**

#### **Challenge**

The quality group in this global pharmaceutical organization could not accurately monitor, trend or report on quality issues because of the lack of consistency in procedures and data storage.

#### **Solution**

Implemented a centralized system and standardized procedures to track, monitor and trend deviations, out-of-specification test results, change control records and customer complaints.

#### **Benefits**

All issues related to quality control were resolved and regulatory requirements were met, resulting in:

- On-time product delivery
- Quality assurance
- Better positioning as industry leader in contract manufacturing

## Challenge

Headquartered in Europe, this company is a contract manufacturer providing state-of-the art, custom production of health care products for pharmaceutical companies.

The quality control department used customized Access databases and Excel spreadsheets and various procedures for monitoring and recording different aspects of quality control. The quality group could not accurately monitor, trend or report on quality issues because of the lack of consistency in procedures and data storage. For example:

- Deviations and out-of-specification test results were not documented consistently.
- Proper change control procedures were not followed. Some changes were implemented before they were fully approved; other critical changes were never implemented because approvals were not completed.
- Customer complaints were not completely documented and investigated.

The company needed a centralized system and standardized procedures to track, monitor and trend deviations, out-of-specification test results, change control records and customer complaints. The system and processes had to be in compliance with regulations and streamlined so the operation would not be unduly disrupted.

## Solution

This company chose Clarkston Consulting because it had collaborated on other projects with Clarkston and

the management team knew the consultants' experience working in regulated environments enabled them to develop new processes to improve business operations.

Clarkston's role was to:

- Implement Trackwise®, the quality control software package selected by this company
- Help develop new monitoring and trending processes
- Execute the validation of the new software system
- Assist with training hundreds of users on how to use the Trackwise system to generate customized reports on any aspect of quality control

## Benefits

The implementation of an electronic solution, along with standardized procedures, eliminated challenges related to this company's quality control. Customers receive products according to schedule with an assurance that rigorous quality controls are in place. Additionally, the client now has a world-class set of quality processes and systems that ensure that customer demands are met, and position them as a leader in the contract manufacturing arena.

## Company Profile

Headquartered in the Europe, this company is a contract manufacturer providing state-of-the art, custom production of health care products for pharmaceutical companies.

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).