

CASE STUDY

Global Consumer Products Manufacturer

Strategy and Compliance Program Management Office Ensure Compliance

Challenge

This Fortune 100 consumer products company needed to ensure that all of its facilities complied with new FDA regulations, particularly 21 CFR Part 11.

Solution

Conducted a computer system validation assessment of all affected systems and departments. Integrated all validation assessment activities into current business and IT initiatives and created a compliance validation plan. Built a Compliance Program Management Office to direct internal regulatory processes and help executives understand which regulations apply to the home and personal care industry.

Benefits

The company is now fully educated and prepared to meet FDA requirements and implement a firm-wide compliance strategy that includes:

- Enterprise documents for interpretation of 21 CFR Part 11
- Cost/risk matrix for corporate systems validation
- Corporate training plan

Challenge

Following an FDA inspection of one plant, this global consumer products company recognized that some of its documentation was not sufficient to meet FDA requirements. The company developed a plan to correct the situation, but was concerned that there may be other risks not yet identified.

The FDA requires companies that make personal care products to maintain specific records on safety, efficacy and purity. Computer systems that produce these records, and any linking systems, must be validated following FDA guidelines. Recently the FDA has accelerated enforcement of regulations in the consumer products industry. If computer systems do not comply, the FDA could take adverse action, resulting in costly production delays, expensive recalls or legal action that could damage the company's credibility.

The guidelines for systems validation, however, are not black and white. To a great extent, compliance is based on standard industry practices. It's important that the validation assessment team knows and monitors the industry so that results don't fall short of standard practices.

The company needed assistance to determine if all facilities and all aspects of its operations were in compliance with FDA regulations and 21 CFR Part 11. In addition, if any deficiencies were discovered, the company would need help to develop solutions.

Solution

The company had worked with Clarkston Consulting on other projects and knew that the consultants had the expertise and experience to conduct a computer systems validation assessment of *all* affected systems, whereas other vendors could only provide partial coverage of the systems to be studied.

The goal of the project was to evaluate the current validation and compliance status of the factory floor, factory lab and inventory systems, in conjunction with the SAP® ERP systems in the plants and associated co-packing facilities.

Specifically, Clarkston's mission was to:

- Help management understand how to interpret FDA regulations as they apply in the home and personal care environment
- Integrate all regulatory efforts with current business and IT initiatives
- Conduct a comprehensive study of all affected systems to identify any gaps in compliance with FDA 21 CFR Part 11
- Complete a process analysis of the current validation state for each system and associated policies and procedures
- Develop plans to correct deficiencies at each site
- Create new quality procedures for computer systems validation, change control, deviation management and documentation management
- Develop policies and procedures that would be compliant with the law, while meeting business requirements
- Create a Validation Master Plan, including a 21 CFR Part 11 Plan, for North America and individual plans for every plant
- Build a Compliance Program Office that allows for the management of all regulatory activities and promotes a standard approach to validation and remediation, as well as installs a governance model for current and future business and IT projects

All of the following systems were evaluated to determine the need and extent of validation:

- Factory floor systems
- Factory lab systems
- All computer systems for over-the-counter products
- Support systems:
 - ERP
 - Specification system
 - Documentation management

Benefits

Clarkston helped the client understand how FDA regulations apply to its business and what needs to be done to be in "full compliance." As a result, the client can demonstrate to the FDA that it took immediate action and developed plans to systematically address regulatory requirements.

The client now has the first level of documentation for an enterprise-wide interpretation of 21 CFR Part 11. The next step is to validate and correct those systems and processes that will improve their level of compliance. The company also has a risk matrix that will allow it to analyze and prioritize systems, processes and procedures if additional work is ever needed to reach higher compliance levels.

In addition to fulfilling all requirements of the project, Clarkston developed a top-to-bottom training plan as part of the next phase of the project. Plans are to educate the executive, director and line management on the policies and procedures on computer systems validation, change control, deviation management and documentation man-

agement. A train-the-trainer approach was developed for line personnel.

The client is confident that its organization is well positioned to begin the FDA validation process. Clarkston continues to work with the client to implement the remediation and training plans.

Company Profile

This company is one of the world's largest consumer products companies with annual sales of more than 40 billion. It produces and markets a wide range of food and home and personal care products. The company operates in 88 countries around the globe.

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.