

## CASE STUDY

Global Medical Technology and Services Company

### **Strategy Ensures Compliance and Maintains Market Leadership**

#### **Challenge**

This global leader in medical technology and services needed to ensure that its validation procedures and systems complied with the FDA Quality System Regulation (21CFR Part 820), and FDA electronic records and signatures regulation 21 CFR Part 11.

#### **Solution**

Performed FDA validation assessment of select systems and recommended a strategy for on-going compliance programs to maintain market leadership.

#### **Benefits**

The strategy assessment produced key items for a regulatory action plan, including:

- Developing a validation training program
- Establishing formal Standard Operating Procedures (SOPs) for validation determination, computer systems validation and system development lifecycle
- Developing a 21 CFR Part 11 compliance plan

## Challenge

Recently the FDA has accelerated enforcement of regulations in the life sciences industry. The client, a global leader in medical technology and services, wanted to ensure that its validation procedures complied with the FDA Quality System Regulation (21CFR Part 820), and FDA electronic records and signatures regulation 21 CFR Part 11. These regulations cover quality management and organization, device design, facilities management, equipment, purchasing and handling of components, production and process controls, packaging and labeling control, device evaluation, distribution, installation, complaint handling, servicing and records.

The FDA provides guidelines for systems validation, however, they are not black and white. To a great extent, compliance is based on industry guidelines. The client needed to ensure that the validation assessment team understood and remained current with the industry so that the results wouldn't fall short of guideline requirements and standard practices.

The client decided that a validation assessment was a sound business practice to ensure compliance and quality while minimizing the risk of liability.

## Solution

Clarkston Consulting was hired to assess the computer systems' compliance with FDA guidelines and recommend solutions if needed. Clarkston was selected for this project because of its extensive experience working with life sciences firms worldwide.

The client selected four representative computer systems for the study. Clarkston's assignment was to determine if

these computer systems complied with FDA guidelines for validation, including:

- Customer complaint system
- Data defect tracking system
- Electronic operations methods sheets (used in manufacturing)
- New product introduction system (web-based)

## Benefits

Clarkston made a number of recommendations as a result of the validation assessment, including:

- Assign accountability for validation
- Maintain a master list of IT systems
- Establish formal Standard Operating Procedures (SOPs) for validation determination, computer system validation and system development lifecycle
- Develop a validation training program
- Develop a 21 CFR Part 11 compliance plan
- Replace the customer complaint system with a Part 11 compliant system

Management is in the process of implementing Clarkston's recommendations.

## Company Profile

This medical device company has 27,500 employees in 34 countries and generates \$8 billion in sales annually. Products include: networking and productivity tools, clinical information systems, patient monitoring systems, surgery and vascular imaging, X-ray, tomography, magnetic resonance, ultrasound and bone mineral densitometry, nuclear medicine and a comprehensive portfolio of clinical and business services.

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).