

Compliance Assurance Engagement Leads to Passed FDA Inspection and Improved Workflow

Client

Medical Device Company

Industry

Medical Device

Business Challenge

Creating a remediation strategy and improving workforce efficiency.

Background

The medical device company received an FDA warning letter and sought Regulatory Compliance Associate® Inc.'s guidance to create a response and remediation strategy. While researching the company's situation, RCA noticed staff were inexperienced with FDA inspections and could benefit from Inspection Readiness Training.

Solution

RCA prepared a response to the FDA and began Inspection Readiness Training throughout the organization. Besides conducting mock inspections, RCA led the company through a process that included development of a planned FDA tour, behavioral training for the staff, document review processes, roles and responsibilities and setting up both an Inspection Room and Control Room. This inspection process formalized internal procedures and helped prepare staff in answering audit questions, accessing documents and providing information to common FDA requests.

Result

The company passed their next FDA inspection with only one minor observation which was easily remediated. The company continued to practice their learnings and will be ready for an inspection, with little or no notice from a regulatory agency.

“We now know we are in good shape and are getting better by practicing what we learned. RCA provided great value to us.”

