REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

FDA Warning Letter Response and Remediation

Client

Pharmaceutical and Medical Device Company

Industry

Pharmaceutical, Medical Device

Business Challenge

Developing a phased program plan that addresses FDA warning letters.

Project Time-line

6 months

Background

A mid-sized company received a 10-item FDA 483. The company responded but subsequently received a Warning Letter. This company was not sure how to best approach the FDA after their first pointed responses resulted in a Warning Letter.

Challenge

The FDA clearly set expectations for the manufacturing of drug and device products at this location. The management team had responded to the observations once, and was unsure how to respond the second time.

RCA Approach

Regulatory Compliance Associates® Inc. (RCA) developed a phased program plan to address the Warning Letter and the larger quality systems challenges. The first phase provided the FDA with Warning Letter responses with aggressive completion timing and objective evidence detailing the completed commitments. The second phase of the program assessed and corrected the overall quality system. A comprehensive plan with aggressive but realistic milestones was developed along with supporting tasks and task dependencies. Definition of roles and responsibilities and milestone ownership was determined early on in planning the project. RCA provided a certified Project Management Professional (PMP) to lead the program, as well as engineers with expertise in quality systems and manufacturing engineering to execute the program in concert with client resources

Result

The Warning Letter timing, responses, and objective evidence were received favorably by the FDA. The Warning Letter was closed out with the FDA within six months. Best-in-class project management methods employed in Phase II of the program helped to ensure success in achieving quality systems compliance milestones on time and within budget.

"The Warning Letter was closed out within six months."

References

1. FDA Code of Federal Regulations, Title 21, Part 820, "Quality System Regulation," April 1, 2010.

2. FDA Code of Federal Regulations, Title 21, Parts 210 and 211, April 1, 2010.

3. Project Management Institute, Inc., "A Guide to the Project Management Body of Knowledge (PMBOK Guide)—Fourth Edition," ANSI/PMI 99-001-2008.