REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

FDA Warning Letter Remediation

Client

Fortune 500 Company

Industry

Medical Device

Business Challenge

To address a FDA warning letter with proper leadership, expertise, and product management.

Project Time-line

Several Months

Background

A Fortune 500 company received a Warning Letter from the FDA, reporting their findings of device adulteration and misbranding, and threatening seizure, injunction, and / or civil money penalties. This action followed a determination by the FDA that the responses of the firm to certain observations noted on an FDA 483 were inadequate.

Challenge

Regulatory Compliance Associates Inc. was contracted to provide leadership, expertise, and project management to address the Warning Letter citations. This critical situation required a heightened sense of urgency to ensure timely completion without sacrificing the thoroughness and integrity of the remediation.

RCA Approach

RCA provided a team of regulatory specialists who led remediation teams in the following areas:

- Process Mapping
- CAPA Leadership
- Formal Problem Solving
- Complaint Handling
- Procedure Audits/Reviews
- Data Trending Methods & Analysis
- Independent Design Reviews
- Medical Device Reporting (MDR)

Remediation included gap analyses, development, implementation and training of new or improved procedures, and comprehensive documentation in preparation for a follow-up audit from the FDA.

Results

Formal problem solving, corrective and preventive action (CAPA), and non conformance data trending methods were implemented, and comprehensive documentation providing objective evidence of effective remediation was prepared. Extensive RCA leadership and coaching over several months were key in transitioning the client culture to ensure that improvements would be sustainable. The subsequent FDA audit following the Warning Letter resulted in zero 483 observations.

> "RCA *leadership and coaching over several months was key.*"

References

1. U.S. Food and Drug Administration, Federal Food, Drug, and Cosmetic Act, Chapter V, Sections 501 and 502.

2. FDA Code of Federal Regulations, Title 21, Parts 803, 806, and 820. April 1, 2010.