

2 Day Workshop: FDA Inspections: What Regulators Expect and How to Prepare

Date : Mar 14, 2018 - 08:00 AM - Mar 15, 05:00 PM

Event URL : <http://www.BostonEventsList.com/events/-worldcomplianceseminars-com-seminardetails-19-1516192195>

Organizer : conference Manager

Venue : San Diego CA

Location : Homewood Suites by Hilton San Diego-Del Mar, 11025 Vista Sorrento Parkway
San Diego, California, US, ZIP: 92130
Phone: 858.720.9500

Ticket Price: Price - Seminar One Registration -Â \$ 1395 Special Group Discount Register for Four attendees -Â \$ 3885

Description

This is a practical, hands-on course designed to provide pharmaceutical, biopharmaceutical, biologics and medical device professionals with the information and tools they require to prepare for and manage an FDA inspection efficiently, effectively and successfully. Many regulated companies preparing for FDA inspections are not prepared and the outcome can be negative as we see all the time with enforcement actions. This seminar provides the fundamentals and the ground rules on how to prepare for and survive an FDA inspection no matter if you are a Class I, II, III device or a pharmaceutical or biologics manufacturer.

Areas Covered

- FDA's Inspectional Authority and History
- FDA Inspection Program Overview
- Key factors for a successful FDA inspection
- Quality System Readiness
- Organization Readiness

- Manage Inspection Outcomes
- Information and Documentation
- How a firm should prepare for an FDA inspection?

Who will Benefit

- Executive Management
- Regulatory Affairs Management
- Regulatory Affairs Specialist
- Auditors
- QC/QC
- Compliance Officer
- Compliance Specialist

Learning Objectives

This seminar will provide an overview and in-depth snapshot of the entire process for preparing for and managing and FDA inspection and external regulatory inspections. Employees who will benefit include all levels of management and departmental representatives from key functional areas and those who desire a better understanding or a "refresh" overview of the FDA inspection process from preparing for the inspections, during the inspections and post-inspection responsibilities.

Event Categories :