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

**Date :** Mar 14, 2018 - 09:00 AM

**Event URL :** http://www.BostonEventsList.com/events/-worldcomplianceseminars-com-seminardetails-19

**Organizer :** conference Manager

**Venue :**

**Location :** WCS Consulting Inc.3190 Stirling Rd, Unit K4, Hollywood, FL 33021,
Hollywood, Florida, United States, ZIP: 33021
Phone: 347 282-5400

**Ticket Price: Seminar One Registration - $1,295.00 Special Group Discount Register for Four attendees - $ 3885**

Course “FDA Inspections: What Regulators Expect and How to Prepare “has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

**An Interative Workshop Presented BY WCS & David R. Dills**

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. This presentation will review and emphasize the do's and don'ts and cardinal rules as to interviewing, how to respond, reviewing documentation, etiquette, use of certain words, body language, responding to questions/requests, etc., and certainly replying to 483's and Warning Letters.

The course will go through what typically goes on during an FDA Inspection and will then cover

how to prepare for, host and follow up to a regulatory inspection. It will emphasize and focus on the critical and vital elements that you should do or not do during the inspection. Typically, FDA inspections can be highly structured and there are procedures that are to be followed as you prepare for state of readiness. It is important for anyone who might be involved in the inspection to be aware of these procedures, including all employees and personnel to ensure there are no surprises.

The course will also provide information for inspections conducted by international agencies as well as non- FDA agencies, including self-inspections for manufacturing and the famous FDA Mock Inspection or Mock Audit. It will explain how to prepare for an inspection, how to handle a scheduled or non-scheduled inspection, what to expect during an inspection and what follow up to expect after an inspection.

## 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?

- Ways to train employees in view of the inspection

- How to ensure that required documentation is in place

- How to interact with the investigator-DO's and DON'T's

- What companies should do when the inspection ends

- How to reply to 483's and warning letters

## Who will Benefit

- Executive Management

- Regulatory Affairs Management

- Regulatory Affairs Specialist

- Auditors

- QC/QC

- Compliance Officer

- Compliance Specialist

- Clinical Affairs

- Quality Assurance Management

- Marketing & Sales

- Laboratory

- Distributors/Authorized Representatives

- Legal Counsel

- Engineering/Technical Services

- Operations/Manufacturing

- Consultants

## 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 :**