

2018 : 2 Days Conference on UnAnnounced Audits are You Prepared?

Date : Mar 08, 2018 - 08:00 AM - Mar 09, 05:00 PM

Event URL : <http://www.BostonEventsList.com/events/-worldcomplianceseminars-com-seminardetails-32>

Organizer : conference Manager

Venue :

Location : Novotel Ahmedabad,
Ahmedabad, Gujarat, India, ZIP: 380015
Phone: 080-48520271 / 99451 31006

Ticket Price: Price - Seminar One Registration -Â \$ 399 Special Group Discount Register for Four attendees -Â \$ 1400

Description

The Indian Pharma industry has been under scrutiny over the last few years and has faced audits across the year leading to alarming warning letters being received and facing repetitive audits. This has not only impacted reputation of the companies, but it has become imperative for all pharma companies to bring 24/7 quality culture to become all time audit ready.

ABOUT THE WORKSHOP

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.

Areas Covered

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- 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

Who will Benefit

- General Managers, Senior Managers
- Executive Management
- Regulatory Affairs Management
- Regulatory Affairs Specialist
- Compliance Officer, Compliance Specialist
- Clinical Affairs, Auditors
- Quality Assurance Management
- Distributors/Authorized Representatives

Learning Objectives

- Quality Culture and its impact on audit readiness
- Anytime Readiness(ATR) and its implication
- Understanding auditor's expectation during Unannounced Audits
- Training of shop floor executives to face audits with confidence
- Trends in the current inspection practices by FDA and other global regulatory bodies

Event Categories :