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Webinar on

The FDA Inspection: From SOP To 483

Learning Objectives

- *Types of Inspections*
- *Preparation Dedicated personnel for inspection*
- *Facility resources to support the inspection*
- *Behavior during inspection-what to say, what not to say*
- *Inspection process, 483 response process*
- *Internal audits, Mock audits*
- *SOP for inspections*

Areas Covered

- *Where do I let the inspector go?*
- *Do I give them a tour?*
- *What should I let them see?*
- *Who should I let them talk to?*
- *Are they ever going to leave*
- *Does the FDA call in advance or just show up at my door?*

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This webinar provides the rationale, strategies and flows on how to plan for an inspection, the inspection process and approach, and which company roles should be assigned for these types of inspections, among other related topics.

PRESENTED BY:

Jeff Kasoff, RAC, CMQ/OE has more than 30 years in Quality and Regulatory management. Over that time, Jeff has implemented and overseen quality system operations and assured compliance, at all sizes of company, from startup to more than $100 million in revenue. This multi-faceted experience makes Jeff uniquely qualified to address compliance issues across the entire range of company sizes.

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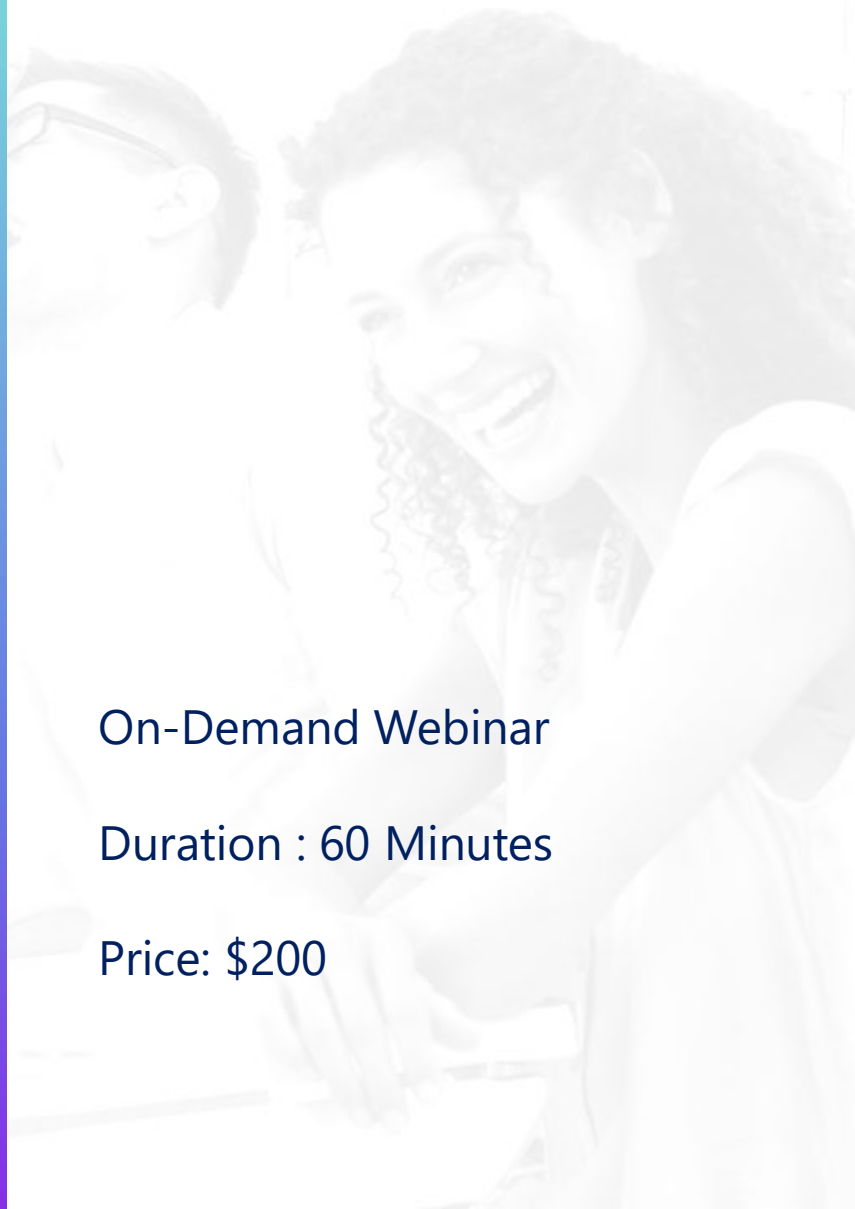


On-Demand Webinar

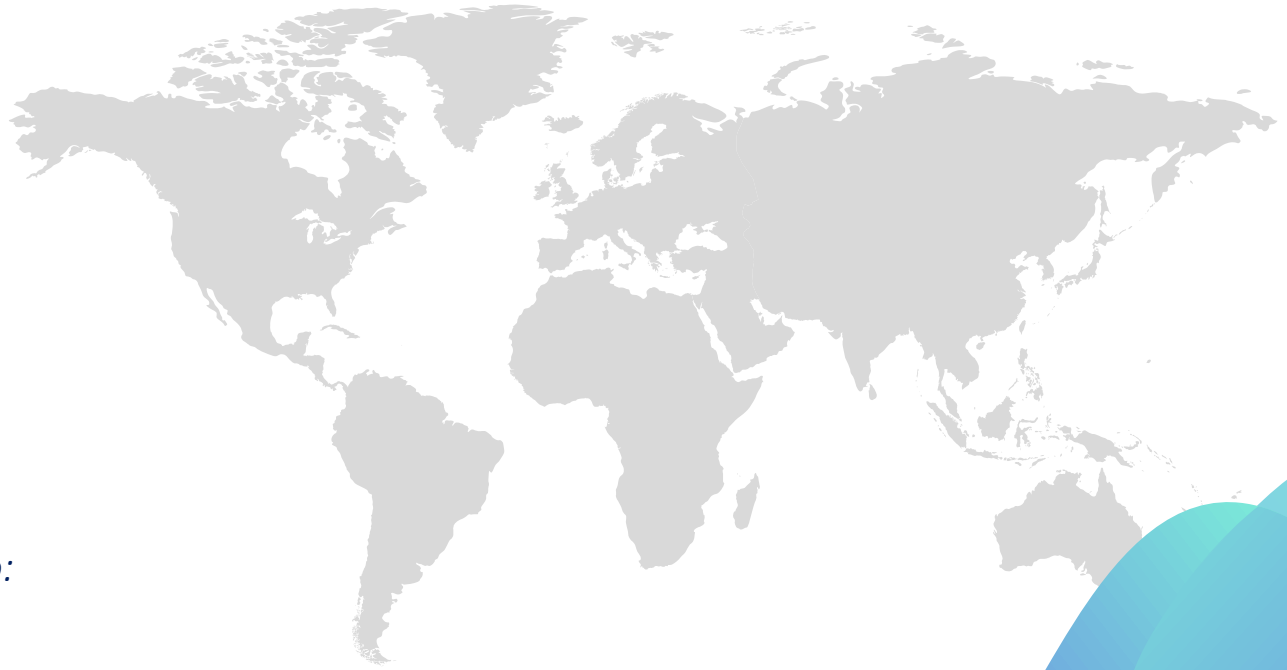
Duration : 60 Minutes

Price: $200

Webinar Description

This is a detailed course designed to provide medical device/pharmaceutical professionals with the information they require to prepare for and manage FDA inspections. This course provides the rationale, strategies and flows on how to plan for an inspection, the inspection process and approach, and which company roles should be assigned for these types of inspections, among other related topics.

Who Should Attend ?



Quality Auditors, Compliance Officers

Executive Management, Complaint Handling

Personnel new to the regulated industry

Training personnel, Document Control Personnel

Managers/Directors/Supervisors and Personnel related to:

- *Regulatory Compliance and Regulatory Affairs*
- *Quality Management System*
- *Quality Assurance*
- *Quality Control*
- *Product Development*
- *Engineering*
- *Manufacturing*
- *Risk Management*

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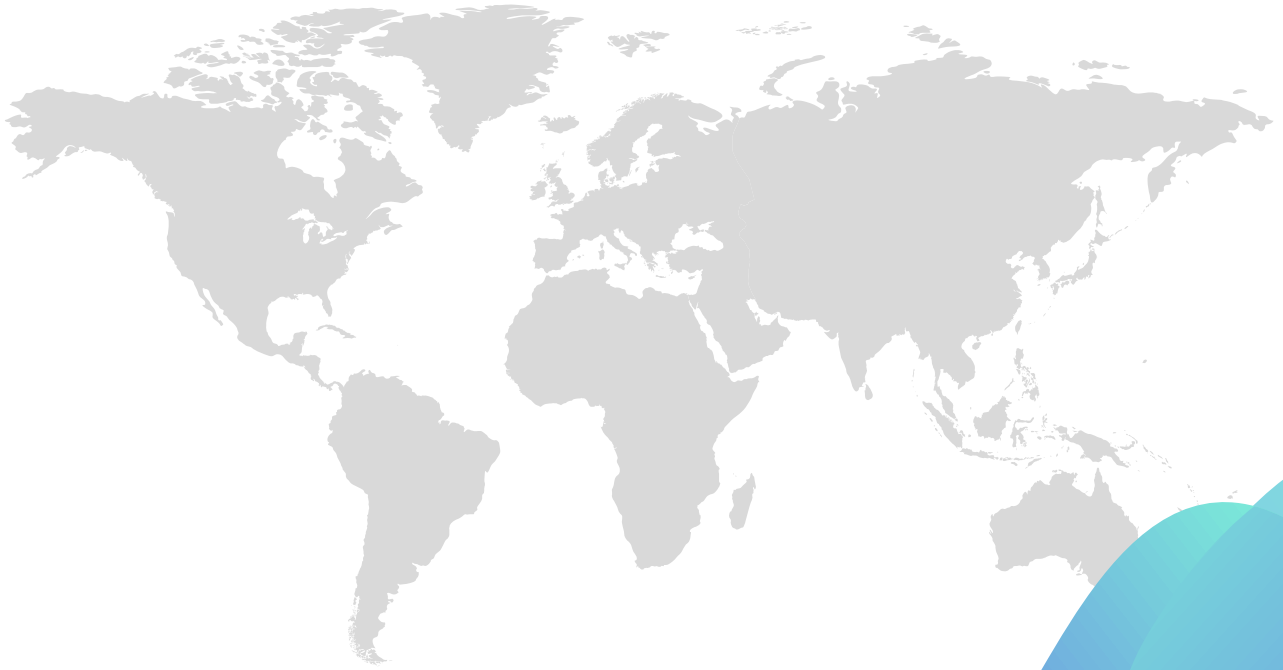
Why Should Attend ?

The FDA inspection is the most nerve-wracking event in the life of a regulatory professional - you're in charge of compliance, usually in the background, and NOW you're in the spotlight, and if your performance isn't good, it's not the show that may close, it's YOUR COMPANY! However, adequate planning, training, composure, and understanding should result in many encore presentations!

This session will discuss how to prepare for the inspection, what to do during the inspection and the close-out interview, and how to respond to the inspection. Also contained in this session will be the limits of FDA's scope during an inspection, including what documents you are not required to show them, and the permissibility of photographs and affidavits.



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