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Webinar on

The FDA Inspection: Preparation, Performance and Follow-Up

Learning Objectives

- *Types of Inspections*
- *Preparation*
  - *Dedicated personnel for inspection*
  - *Facility resources to support the inspection*
  - *Internal audits*
- *SOP for inspections*
- *Behavior during an inspection: What to say and do, and what NOT to say and do*
- *Inspection process*
- *How and when to craft a written response*

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This webinar will provide valuable assistance to all regulated companies, since FDA inspects across the Medical Device, Diagnostic, Pharmaceutical, and Biologics fields.

PRESENTED BY:

Jeff Kasoff, RAC, CMQ/OE, LBB, is the Principal at Lean to Quality, LLC. He has more than 30 years in Quality and Regulatory management. Jeff has also been the primary liaison with FDA inspectors and notified body auditors. Jeff has the following certifications: Manager of Quality and Organizational Excellence certification from ASQ, Regulatory Affairs Certification from RAPS, and Lean Black Belt from IIE.

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On-Demand Webinar

Duration : 60 Minutes

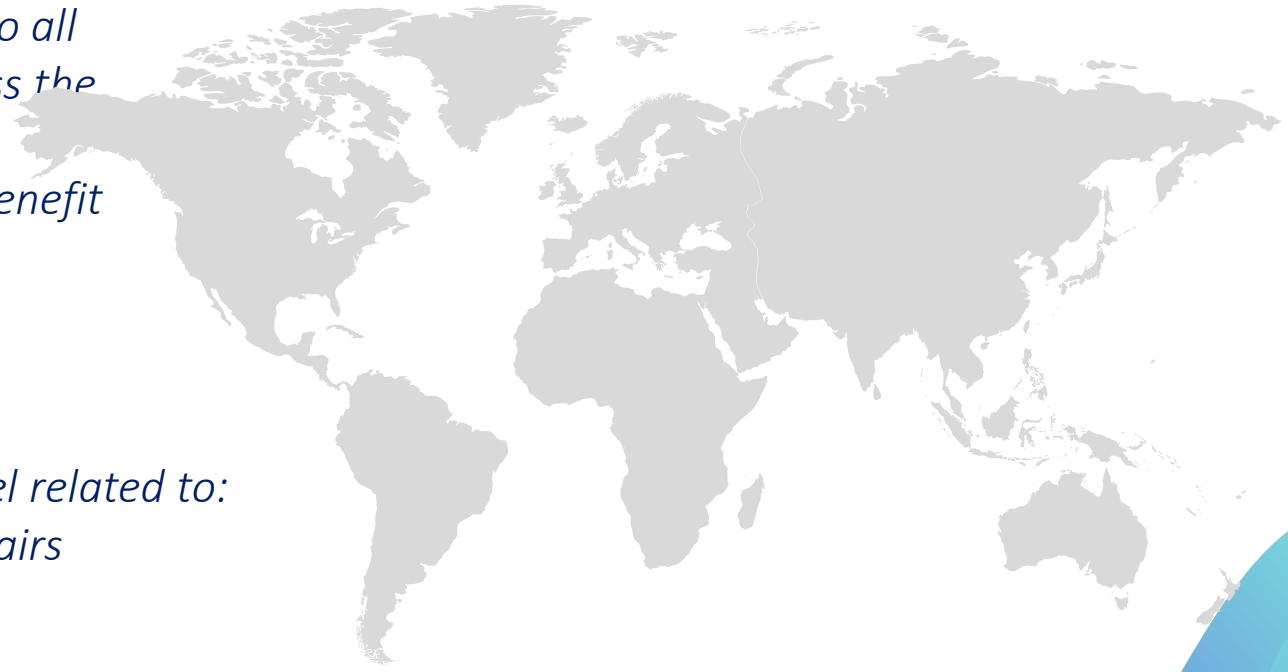
Price: $200

Webinar Description

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.

Who Should Attend ?

This webinar will provide valuable assistance to all regulated companies, since FDA inspects across the Medical Device, Diagnostic, Pharmaceutical, and Biologics fields. The employees who will benefit



Quality Auditors
Compliance Officers
Executive Management
Managers/Directors/Supervisors and Personnel related to:

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

Complaint Handling
Personnel new to the regulated industry
Training personnel
Document Control Personnel

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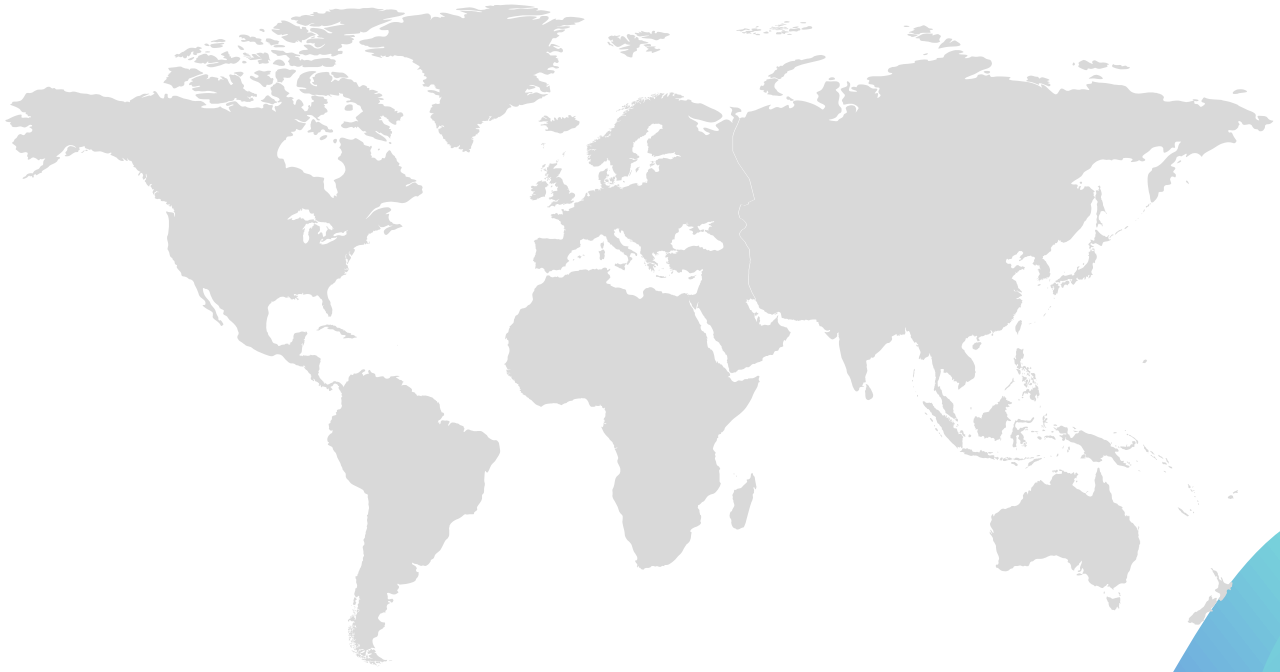
Why Should You Attend ?

Without adequate preparation and cross-functional communication, it is difficult to manage a good FDA inspection. Your goal is to illustrate your firm is in substantial compliance with all regulations, but also to respond to the inspector's questions or concerns in a timely manner. This webinar will identify systems and processes, and recommended tactics, to make the inspection as painless as possible.



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