*Webinar on*

# Set Of 4 Webinars To Help You Prepare For A FDA Inspection

# Webinar Description

The webinar format is 1-1.5 hours of audio-visual presentation, including a brief Q&A session.

This webinar bundle includes below 4 recorded webinars/ Best Seller

Fatal FDA Inspection Mistakes

How to Prepare for and Host an FDA Inspection and Respond to 483's

Best Practices for Investigating Deviations

Proper Management of Regulatory Agency Inspections

# Fatal FDA Inspection Mistakes

Presented by Casper Uldriks

When FDA shows up at your door to announce an inspection, what do you think is going to happen? More importantly, what are you going to do?

An ex-FDA investigator will conduct this webinar to share an “insider’s” perspective about inspections. What’s important, what’s not, and what is a fatal mistake on the part of a firm. Firms need an established FDA inspection protocol that describes what happens during an inspection, what the roles are for employees and how to interact with the FDA.

# How to Prepare for and Host an FDA Inspection and Respond to 483's

Presented by Edwin Waldbusser

In this webinar you will learn about the types of FDA inspections, preparations such as assigning dedicated personnel to specific tasks for the inspection, facility requirements to support the inspection ( front room, back room), the value of mock audits, how personnel should conduct themselves, the inspection process and how to respond to 483s and warning letters. How to respond and when is critically important. Also covered will be the FDA's rights during the inspection and documentation you are not required to show them.

# Best Practices for Investigating Deviations

Presented by Danielle DeLucy

This webinar will help attendees understand the fundamental steps of a deviation investigation with a focus on using facts and objective evidence to arrive at root cause and CAPA. This webinar will focus on how to avoid the pitfalls that may occur during FDA inspections and help eliminate 483 observations. Learn how to identify and avoid potential pitfalls during deviation investigations.

# Proper Management of Regulatory Agency Inspections

Presented by Danielle DeLucy

The purpose of the Regulatory inspection is an activity that should demonstrate that your company is operating according to the proper CFR requirements and maintaining a state of compliance. The key to a successful audit is being able to communicate how your quality systems assure this state of control. Many times, the arrival of a Regulatory Investigator is a daunting experience for some. In this webinar, you will learn how to properly alert key members that an investigator has arrived, the proper protocol for setting up the Inspection room and any associated “war” rooms that will support the inspection, and how to manage requests from the investigators in a timely and accurate manner. This preparation minimizes stress and disorder during the inspections.

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