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Webinar on

FDA Inspections: Prepare and Survive

Learning Objectives

- *Purpose of an inspection*
- *FDA's inspection compliance program for you*
- *Providing Information and documentation, or not*
- *Discussions with management*
- *FDA Inspectional "observations" – the 483*
- *Administrative and legal consequences*

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You will also take away pointers on what not to say or do during an inspection. FDA investigators can be a little sensitive.

PRESENTED BY:

Casper (Cap) Uldriks brings over 32 years of experience from the FDA. He specializes in the FDA's medical device program as a field investigator, served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health.

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On-Demand Webinar

Duration : 60 Minutes

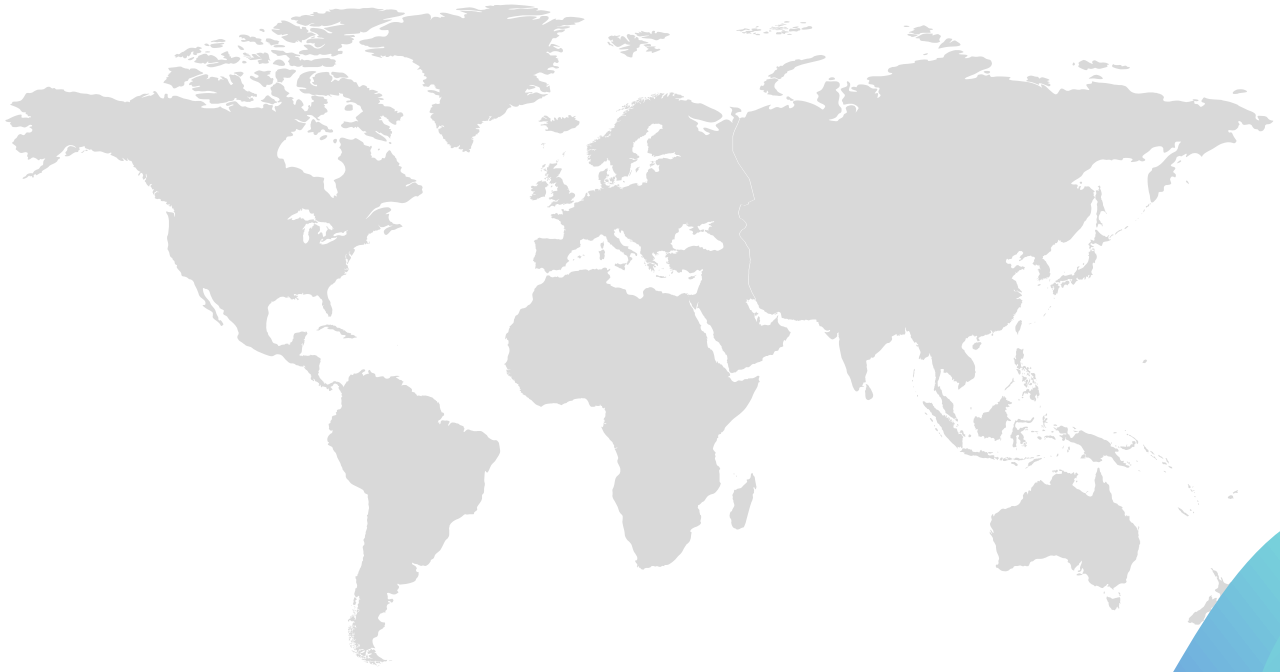
Price: $200

Webinar Description

FDA conducts establishment inspections to determine a firm's conformance to applicable regulatory requirements. Inspections vary based on the type of product you make or plan to make. FDA prioritizes domestic and foreign inspection assignments based on three factors. However, with the current public health crisis with COVID-19, FDA is overwhelmed with work at this time, so it will likely rely on new approaches to conduct inspections. The basic inspectional requirements and procedures remain the same. FDA presumes you know what you are doing, but you have to show them, i.e., trust but verify. There is no secret about what an investigator looks for. If you do not know, you will likely receive a list of observations that provide concrete examples of nonconformance. You can estimate the gravity of your situation using a few simple pointers.

Who Should Attend ?

Regulatory Affairs Directors and Managers
Quality Assurance Directors and Auditors
Manufacturing Directors and Managers
Quality Control Managers
Training Directors
Document Control Managers
Recall Managers
In-house counsel



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Why Should You Attend ?

You can demystify an inspection by using FDA documents and know where the FDA investigator will likely dig for problems based on changing policies. Your FDA "War Room" can relax, really. You can predict what the FDA investigator will do and based on what they find, how they will collect evidence against you. There are some documents that if collected are a very bad sign. At the conclusion of an inspection, you and FDA will discuss the bad things the investigator found. Most firms ask the investigator, "So, how bad was it?" They will not tell you, but you can figure that out yourself using standard criteria already established by the FDA. Consequently, you can lower your regulatory anxiety level and prepare a rational plan for responding to FDA, but even with that, there are some practical "pointers" to make your life easier. You can use a basic technique to quickly evaluate the gravity of a 483. It should take about 5 minutes. You will also take away pointers on what not to say or do during an inspection. FDA investigators can be a little sensitive.

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