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Webinar on

Managing an FDA Foreign Inspection

Learning Objectives

The webinar covers tasks that should be performed and completed well before an FDA inspection. There are basic mechanics of the inspection you should follow. They are not the same as domestic inspections. You will understand why the inspection seems rushed and how you should respond to the FDA during and after the inspection. That is critical. Yours follow up action or inaction can make or break your U.S. market. Some basic Do's and Don'ts will be included.

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PRESENTED BY:

Casper (Cap) Uldriks, through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. He specialized in the FDA's food and medical device programs as a field investigator, served as a senior manager in the Office of Compliance and as an Associate Center Director for regulatory guidance and government operations. He developed enforcement actions and participated in the implementation of new statutory requirements, such as FDA's import/export program.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Agreeing to an FDA foreign inspection requires careful preparation on a firm's part. If you do not manage your inspection wisely, you will set yourself up for disaster. We will cover fundamental issues, such as pre-inspection tasks, preparing your documents and having an interpreter before, during and after the inspection. We will also address how you should respond to inspectional problems noted by the FDA and prepare for another inspection. If you do not, your business in the U.S. will suffer and be very costly.

FDA's foreign inspection program becomes more demanding each year. Foreign firms must prepare for an FDA inspection, just as they do for any third party audit. Otherwise, your import business may be halted or at least suffer severely. Following some basic points for a foreign inspection can prevent a regulatory disaster. For FDA, foreign inspections are expensive. FDA does not want to come back if you say, "Sorry, we are not ready." Foreign manufacturers must understand their obligations before, during and after the inspection. What may appear to be little oversight can put you into big trouble. The sad part, it is avoidable.

Who Should Attend ?

Foreign Manufacturers, Foreign Exporters

Initial importers, U.S. Agents

International trade executives, Import Brokers

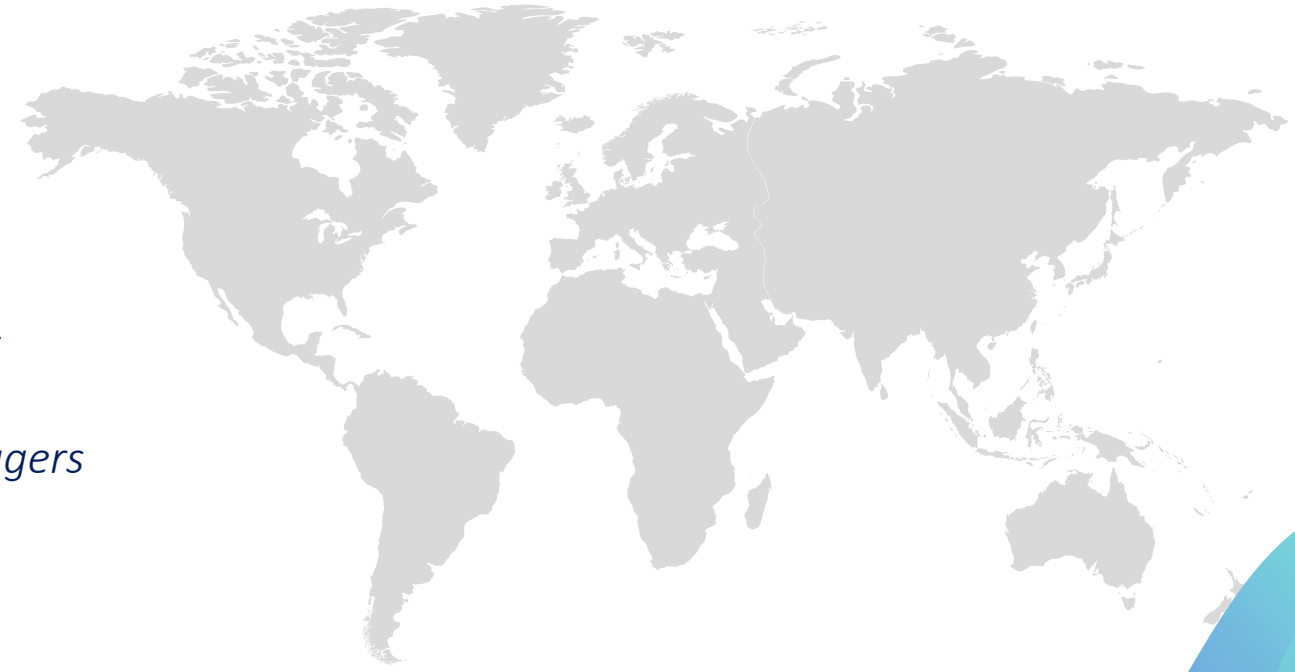
Regulatory affairs managers, Marketing managers

Import / Export consultants, In-house counsel

Contract specialists, Logistics managers

Third party establishment inspection entities

Sales managers



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