

*Webinar on*

# **FDA's and U.S. Custom's Import Entry Program**

# Learning Objectives

*Importing FDA regulated product requires the submission of specific information prior to entry. Understanding what information is required and how to identify it becomes critical. Importation requires money under U.S. Customs and Border Protection's (CBP) authority and requires compliance with FDA law, which is a partner government agency. You and your import broker must properly link the money and the law. Implementation of the Automated Commercial Environment (ACE) program is designed to make import entry easier, but you must now what you are doing, or supposed to do.*

This webinar covers detailed information required for a successful import operation and how to correct the weakest link(s) in the commercial chain. The course will include tips on how to understand FDA's approach and FDA's import program curiosities.

**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. Cap is the President of Encore Insight, LLC, a consulting service for FDA matters.*

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

# Webinar Description

The webinar address the critical elements of information required to present a product for entry into the U.S. We will cover what information for FDA is mandatory. You must use the new software program, Automated Commercial Environment (ACE), you need to decide on who will do that, establish operational procedures and what to do if your entry is detained. The course will explain how you can make your import operations easy, or a disaster, which ends up costing you a lot of money and frustrating your customers.

FDA and the Customs and Border Protection Service (CBP) have become increasingly sophisticated and equally demanding in the submission of import information and adherence to government procedures. Firms that fail to understand and properly execute an import and export program find their shipments delayed, detained or refused. FDA and CBP officially implemented the Automated Commercial Environment (ACE) entry filing system. You either meet ACE requirements or face entry refusals and monetary penalties of up to \$10,000 per offense. Other factors can derail the expectation of a seamless import entry process. The webinar covers detailed information required for a successful import operation and how to correct the weakest link(s) in the commercial chain. The course will include tips on how to understand FDA's approach and FDA's import program curiosities.



# Who Should Attend ?

*Domestic Importers, Foreign Exporter*

*Initial Importers, U.S. Agents*

*International trade Executives*

*Import Brokers, Regulatory Affairs Managers*

*Import / Export Consultants*

*In-house Counsel, Contract Specialists, Logistics Managers*

*Third party establishment inspection entities, Sales Managers*



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