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Webinar on

FDA Import Program with COVID-19

Learning Objectives

- *Foreign manufacturers (restrictions and FDA inspections)*
- *Market impact*
- *Product conveyance risks*
- *Entry information and FDA's intensified risk assessment*
- *Risks during transit*
- *Port closures, port availability and ship quarantine*
- *FDA entry review and release practices*

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FDA will be looking at information requirements and implement new import operations to reduce risks to health associated with the COVID-19.

PRESENTED BY:

Casper (Cap) Uldriks brings over 32 years of experience from the FDA. He started with FDA as a field investigator, worked in the Commissioner's Office for Congressional Oversight Investigations and was the associate Center Director for Regulatory Guidance and Government Operations in the Center for Devices and Radiological Health.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Importing FDA regulated product faces new challenges, new risk management procedures, and mitigation of business consequences that will affect corporate profits. Basic issues should be evaluated and updated to help you plan for unprecedented problems and your helplessness to escape the trauma. The COVID-19 creates a global bondage on commerce and drains, if not dries up, the supply of necessary products to protect the health and well fare of your customer base, which actually is the entire U.S. population. In this webinar, you will mentally travel through your import process, how it will or can be derailed and identify issues you need to evaluate during the current interruption of your standard import business.

The Corona Virus – 19 (COVID-19) creates new business risks and problems for importing products that are under FDA's jurisdiction. Business plans and importing logistics require a fresh assessment and implementation of new procedures for managing new risks, delays, unhappy customers and new expenses. Importing products will hurt your net profits if you do not mitigate the risks and related costs of risk management failure. Importers should have revised their import operations by now. Otherwise, your recovery will become needlessly expensive and slower that it should be.

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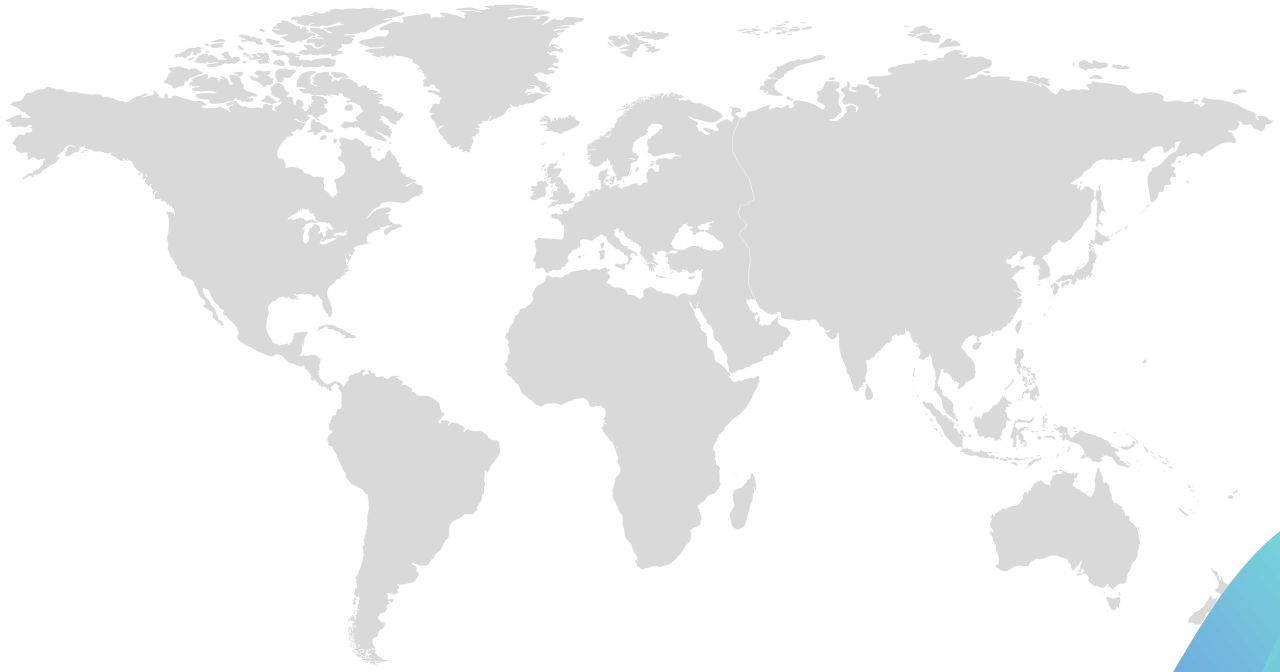
Who Should Attend ?

Regulatory Affairs Directors
International Logistics Manager
Production Managers
Inventory Control and Warehouse Managers
Quality Assurance Directors
Marketing Manages
Medical consultants



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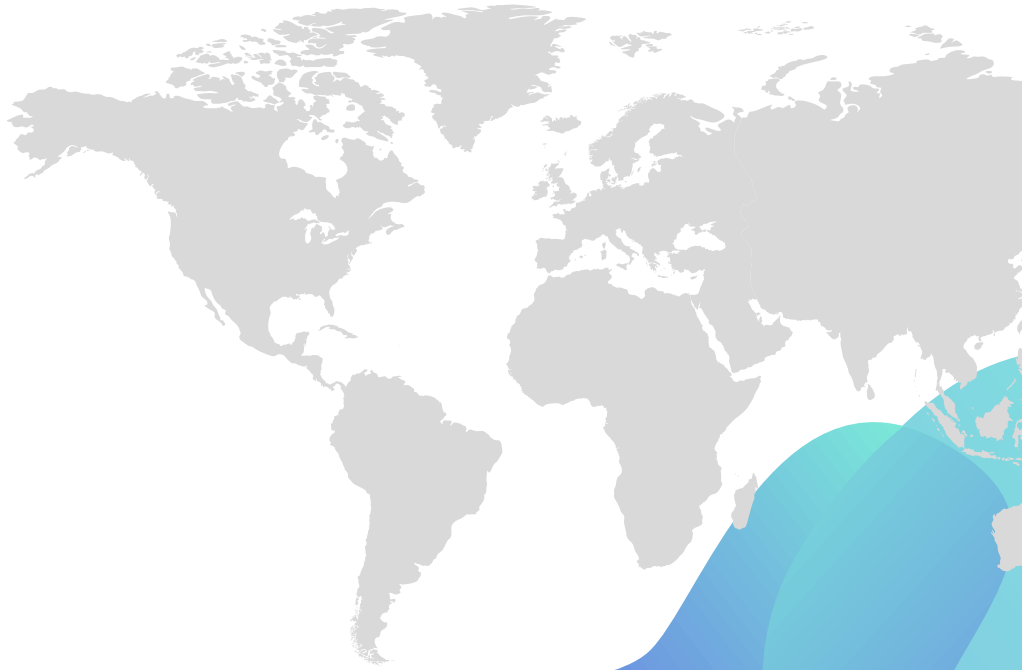
Why Should You Attend ?

Your import business plan requires updating now so you can effectively cope with the impact COVID-19 has on your FDA's Import operations. Your regulatory and business operations must be updated for what will be moving target for safety. You need to consider a raft of issues to make it through this trauma. What are your issues and how can you mitigate their impact? What you do not know and do not mitigate as a risk factor will hurt if not cripple your near-term global import operations and recovery resilience.

If you have not had an emergency plan in place, you should have one now. The risks extend to your foreign manufacturer; port of loading; method and means on conveyance; management of your U.S. port of arrival; and U.S. distribution practices. In each case, it will cost you more money if you have not planned to mitigate untoward barriers. You will have new problems with other federal agencies with overlapping jurisdiction. Your risk mitigation strategy needs to address a more complex maze of import operation.



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Topic Background

FDA regulates how firms promote their products in social media. It creates a regulatory risk for enforcement action when firms step over FDA's somewhat mysterious legal boundaries for advertising and promotion. What you or someone else says about your product, whether true, false or misleading, can become a target for FDA's legal hammer. FDA can levy fines, issue Warning Letters or worse. Such a corporate blunder confuses your customers and may drive them away. Corporate management is accountable and ends up paying an avoidable monetary expense and smear on its corporate face.

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