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2-Day In-Person Seminar by Ex-FDA Official:

Preparing for FDA's New Import/Export Trauma in 2020

By: **Casper E. Uldriks**, Former Associate Center Director of FDA's CDRH

Location 1: Chicago, IL | December 12-13, 2019 **Location 2:** Orlando, FL | March 19-20, 2020

"This education activity has been submitted to the Compliance Certification Board (CCB)® and is currently pending their review for approval of CCB CEUs."

SPEAKER

Casper E. Uldriks, Former Associate Center Director of FDA's CDRH

Casper (Cap) Uldriks, through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. He specialized 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. He developed enforcement actions and participated in the implementation of new statutory requirements. His comments are candid, straightforward and of practical value.

He understands how FDA thinks, how it operates and where it is headed. Based on his exceptionally broad experience and knowledge, he can synthesize FDA's domestic and international operational programs, institutional policy and thicket of legal variables into a coherent picture.

LEARNING OBJECTIVES

- FDA's new cost-saving import programs
- Understand how U.S. Customs and FDA legal requirements intersect
- Know how to manage foreign suppliers
- Understand FDA's internal procedures
- Learn how to mitigate and resolve import detentions
- Learn how to avoid common problems
- Develop practical ways to improve your import and export business
- You will be able to answer the following questions with this course without saying, "I don't know?"
- What are the FDA's import legal requirements and policy?
- How do you deal with the FDA and the U.S. Customs and Border Patrol procedures?
- What happens when your product is detained?
- What happens if a foreign manufacturer is in trouble with the FDA?
- How do you inter-act with the FDA to work out problems?
- Why are import and export rules different or does it even matter?

COURSE DESCRIPTION

The FDA continues to change its import program to better manage new problems and to use new procedures to make the whole process easier. The FDA and U.S. Customs and Border Protection (CBP) are relying more and more on computer programs to expedite the import process. When and how you use these programs can make a big difference in the net profit derived from even a single shipment. The new Voluntary Qualified Importer Program (VQIP) is one such example. Another example is CBP's and FDA's implementation of the Automated Commercial Environment (ACE) program became mandatory for importers in 2016. If you fail to correctly use new import procedures and programs, you will be operating under an expensive disadvantage.

You will be able to answer the following questions with this course without saying, "I don't know?"

- ✓ What are the FDA's import legal requirements and policy?
- ✓ How do you deal with the FDA and the U.S. Customs and Border Patrol procedures?
- ✓ What happens when your product is detained?
- ✓ What happens if a foreign manufacturer is in trouble with the FDA?
- ✓ How do you inter-act with the FDA to work out problems?
- ✓ Why are import and export rules different or does it even matter?

Seminar Instructor Casper Uldriks is an "Ex-FDA Official" who has spent 32 years in FDA and his engagements focus on advertising and promotion, recalls, corrections and removals and enforcement. He currently trains FDA personnel and counsels clients on wide range of topics, including: FDA inspections; import operations; advertising and promotion; corrective and preventive actions; medical device reporting and corporate reorganization to improve conformance to the FDA's requirements.

WHO WILL BENEFIT

The FDA's regulatory controls for imported and exported devices have become increasingly pervasive and stringent. Foreign manufacturers, foreign exporters and domestic initial importers face greater scrutiny and are subject to expensive consequences if they do not plan carefully. Attendees need to understand the FDA's and the US Customs Border Patrol's regulatory criteria, inter-agency agreements and intra-agency procedures. The conference provides attendees with the opportunity to understand their work's inter-relationship with other attendees' roles.

- Business Planning Executives
- Regulatory Managers
- In-house Legal Counsel and Contract Specialists
- Venture Capitalists
- Business Acquisition Executives
- Owners of New or Developing Import/Export Firms
- International Trade Managers
- Import Brokers
- Investors
- Logistics Managers
- Sales Managers



AGENDA

DAY ONE (8:30 AM – 4:30 PM)

08.30 AM - 09.00 AM: Registration

09.00 AM: Session Start

Day 1 – Morning

FDA's legal requirements

- Statutory authority
- Regulations

Foreign manufacturers obligations

- U.S. initial importers obligations
- User Fees
- How does FDA do its job
- What is CPB and how do they do their job

Selecting foreign suppliers

- Inspection history
- Samples analyzed
- Vendor Audit

Day 1 / Afternoon

Product Import Procedures

- Entry Process (U.S. Customs/FDA)
- How to Pick the right Custom House Broker
- Documentation
  - FDA Form 2877
  - CPB Form 3461
  - Medical Device Affirmations of Compliance (AofC)
  - Electronic Entry Filing
    - FDA's PREDICT computer screening program
    - U.S. Customs Automated Commercial Environment (ACE) program
    - Product sampling / testing
    - Detention, block list, automatic detention
  - Quality standards
  - Country of origin
  - Product type

(Case Study)

DAY TWO (8:30 AM – 4:30 PM)

Day 2 / Morning

Foreign Inspections by the FDA and EU Notified Bodies

Detention

- Options for a detained shipment
- Negotiating with FDA and U.S. Customs
  - What to say
  - What not to say
  - When to give up
- Release from Detention and Government Refusal Remedies
- Reducing the risk of detention

(Group study for mitigating detention risks)

Day 2 / Afternoon

Enforcement

- U.S. Customs and FDA authority
- Burden of proof
- Assistant U.S. attorney
- Government remedies

Special provisions

- Counterfeit
- Import for export
- International trade shows
- Investigational device
- "Compassionate Use"

New and Special Issues for Imports and Exports in 2020

- EU Medical Device Regulation (MDR) program for imported products
- Inspection of personal mail
- Personal use exception
- Trade shoes and promotional marketing
- Compassionate use.



Registration Form

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- **Register Online**. Click Here Use your American Express, Visa or MasterCard.
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Seminar Topic: Preparing for FDA's New Import/Export Trauma in 2020

Date & Location: .....

Attendee Details:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

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Address .....

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City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed,

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

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(Payment is required by the date of the conference.)
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