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FDA's New Import Program for 2018 - Strict Precision (com) A

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Organizer : NYMT

Venue :

Location : San FranciscoSan Francisco, CAUnited States,
San Francisco, CA, US, ZIP: 0001

FDA's New Import Program for 2018 - Strict Precision

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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.

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?

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- 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

Seminar Fee Includes:

Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar

Topic Background:

FDA's import and export program is complex and keeps changing. The FDA's and the U.S. Custom's new import and enforcement program operates with a streamlined computer system and can leave firms at a loss to understand the short term and long term effects of a detained shipment. The law now requires foreign firms to register and submit specific information to enter U.S. commerce.

Foreign establishments are subject to FDA inspections and quality testing. Failing either FDA activity typically prevents a foreign firm's product from entering U.S. commerce. If product is detained, resolving the problem with FDA is time consuming, expensive and uncertain. Without an adequate or informed approach to your import program, the specialized federal government process and roadblocks can seem impossible to overcome. To compound the problems, working with foreign establishments presents inherent difficulties based on cultural differences business practices and language barriers.

Other foreign and domestic and legal requirements intersect with FDA's import and export program, some for the better, some not. For example, not all foreign firms are treated the same under the FDA's law. A clear example is the FDA's uses of automatic detention based on the country of origin, type of product or an establishment's history. With the growing use of off-shore operations, managing imported products can and does present obvious and hidden

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AGENDA

DAY 01(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 02(8:30 AM - 4:00 PM)

- Day 2 / Morning
- 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”

SPEAKER

Casper (Cap) 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.

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