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EVENTS LIST

Tougher Import Rules for FDA Imports in 2018

Date : Feb 15, 2018 - 09:00 AM - Feb 16, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/tougher-import-rules-for-fda-imports-in-2018-feb-2018

Organizer : GlobalCompliancePanel

Venue :

Location : 4949, Regent Blvd
Irving, TX, USA, ZIP: 75063

Background:

FDA and the Customs and Border Patrol 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. As of December 2016, 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 course covers detailed information about the roles and responsibilities of the various parties involved with an 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 thinking, negotiate with the FDA and offer anecdotal examples of FDA's import program curiosities.

Why you should attend:

What happens when your product is detained? FDA will begin a legal process that can become an expensive business debacle. You must respond fully within short timeframes. This is not the time for you to be on a learning curve. You need to have a plan in place and know what you are doing.

The FDA is steadily increasing the legal and prior notice information requirements. If you do not know what those requirements are and you initiate a shipment, your product is figuratively dead

in the water. You must be accurate with the import coding information and understand the automated and human review process. If not, you can expect detained shipments. CBP is implemented a new "Automated Commercial Environment" computer program that changes import logistics and information reporting for FDA regulated products. Your shipment may be stopped before it is even loaded at the foreign port.

When products are refused, you have different options. Some options may cost more than others. For example, your product can be seized and destroyed by the government. You may be fined if you do not act in a timely manner. These are common problems that become prohibitively expensive. You should know how to avoid common problems or at least how to mitigate the cost by using established and effective business planning.

Learn how to deal with common problems, such as returns for repair, importing QC samples, and investigational products

On a positive note, the FDA is implementing the Voluntary Qualification Importer Program under the FDA Food Safety and Modernization Act. One other perk is that FDA offers export certificates, for a modest fee, which may give you a competitive advantage in foreign markets. In some cases, a FDA export certificate is required by foreign governments. Finally, the new EU Medical Device Regulation will change how FDA manages foreign inspections and in your favor.

Who Will Benefit:

- Domestic importers
- Foreign exporter
- Initial importers
- International trade executives
- Venture Capitalists
- Marine insurance underwriters
- Import Brokers
- Regulatory affairs managers
- Import / Export consultants
- In-house counsel
- Contract specialists
- Logistics managers
- Third party establishment inspection entities
- Sales managers
- Investors

Day 1 Schedule

Lecture 1:

FDA Legal Authority Customs and Border Control (CBP) Import Process FDA Import

Process Registration and documentation

Lecture 2:

FDA Import Process (continued)

- Import Brokers
- Prior Notice Information
- CBP and FDA computer programs
- Import Codes
- Bonds and Bonded Warehouses
- FDA "Notice of Action"

Lecture 3:

Import Delays Import Alerts Detention Refusals

Day 2 Schedule

Lecture 1:

Foreign Inspections FDA 483 - Inspectional Observations

Lecture 2:

FDA Warning Letters and Automatic detention

Lecture 3:

Import Hypothetical FDA Import for Export Program FDA Export Program Export Hypothetical

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Lecture 4:

FDA Export Program Special Import Issues

- Trade Shows
- Personal Use
- Compassionate Use

Casper Uldriks

ex-FDA Expert and former Associate Center Director of CDRH

Casper (Cap) Uldriks owns Encore Insight LLC, which provides consulting services on FDA Law. He 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 as 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. He is recognized as an exceptional and energetic speaker. His comments are candid, straightforward and of practical value. He understands how FDA thinks, operates and where it is headed.

Event Categories :