

Coping with FDA Import Delays, Including COVID-19, Expedited Imports and Detentions: ComplianceOnline Seminar

"Coping with FDA Import Delays, including COVID-19, Expedited Imports and Detentions" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES, July 9, 2021 /EINPresswire.com/ --ComplianceOnline, the world's leading provider of training for regulated companies, is hosting the Seminar entitled 'Coping with FDA Import Delays, including COVID-19, Expedited Imports and Detentions.' The Seminar will be held on August 12-13, 2021, and will be presented by Casper E. Uldriks,



Former Associate Center Director of FDA's CDRH.

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 at an expensive disadvantage.

Learning Objectives:

- •EDA's new cost-saving import programs
- •Understand how U.S. Customs and FDA legal requirements intersect
- •Inow how to manage foreign suppliers
- Understand FDA's internal procedures

•Dearn how to mitigate and resolve import detentions

- •Dearn how to avoid common problems
- •Develop practical ways to improve your import and export business

•Mou 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?
- •Bow 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?

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
- •Dwners of New or Developing Import/Export Firms
- International Trade Managers
- •Import Brokers
- Investors
- •Dogistics Managers
- •Bales Managers

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 offshore operations, managing imported products can and does present obvious and hidden

For more information or to register for this seminar, <u>please click here</u>. Virtual Training Through WebEx Date: August 12-13, 2021 (8:30 AM to 2:30 PM PDT)

About the Speaker:

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.

About ComplianceOnline.com:

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Priyabrata Sahoo ComplianceOnline + +1-888-717-2436 email us here Visit us on social media: Facebook Twitter LinkedIn

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