Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Tougher Import Rules for FDA Imports in 2019

Washington, DC

April 4th & 5th, 2019

9:00 AM to 6:00 PM

Price

Price: **$2,000.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$10,000.00**

Register for 10 attendees

Price: **$20,000.00**

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Casper Uldriks

ex-FDA Expert & 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.

Overview :

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.

AGENDA:

Day One

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 Two

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

Lecture 4: FDA Export Program Special Import Issues

- Trade Shows
- Personal Use
- Compassionate Use

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

Why should you 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.

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel