**Tougher Import Rules for FDA Imports in 2015**

**Casper Uldriks**

Ex-FDA Expert and former Associate Center Director of CDRH, Olsson

Casper Uldriks through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. As an investigator, he was responsible for countless 483s, scores of Warning Letters, injunctions, individual seizures, mass seizures and was coined by industry as FDA's "Darth Vader." He inspected foods, drugs, methadone clinics and clinical investigators, but specialized in the FDA's medical device program. He served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health.

**Overview:**

FDA's and the Customs and Border Patrol Service (CBP) have become increasingly sophisticated and equally demanding in the submission of information and adherence to government procedures. Firm's that fail to understand and properly execute an import and export program find that their shipment is delayed, detained or refused. A number of factors can derail the expectation of a seamless import 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 and offer anecdotal examples of FDA's import program curiosities.

**Seminar Price Includes (with Stay)**

<table>
<thead>
<tr>
<th>1</th>
<th>Two Days Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Pick-up and Drop Facility (Nearest Airport)</td>
</tr>
<tr>
<td>3</td>
<td>Break-Fast and Lunch</td>
</tr>
<tr>
<td>4</td>
<td>High Tea</td>
</tr>
<tr>
<td>5</td>
<td>Pack of 3 Webinars will be provided which has been done in the past on similar subject</td>
</tr>
</tbody>
</table>
Agenda:

Day 1 Schedule

1. FDA Legal Authority Customs and Border Control (CBP) Import Process
   - FDA Import Process Registration and documentation

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"

3. Import Delays Import Alerts Detention Refusals

Day 2 Schedule

1. Foreign Inspections FDA 483 - Inspectional Observations

2. FDA Warning Letters and Automatic detention

3. Import Hypothetical FDA Import for Export Program
   - FDA Export Program Export Hypothetical

4. FDA Export Program Special Import Issues
   - Trade Shows
   - Personal Use
   - Compassionate Use

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.

What happens when FDA decides you should bring the products back to the port of entry after you received a release but you cannot locate the product that has been sold? CBP may fine you three times the value of the shipment. FDA may have other adverse legal concerns and strategies.
2 Days in persons Seminar

**Group Participation**

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Attendees to get offer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>2</td>
</tr>
<tr>
<td>20%</td>
<td>3 to 6</td>
</tr>
<tr>
<td>25%</td>
<td>7 to 10</td>
</tr>
<tr>
<td>30%</td>
<td>10+</td>
</tr>
</tbody>
</table>

**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

**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

Contact Information: Event Coordinator

NetZealous LLC, DBA TrainHR
161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@trainhr.com

Kindly get in touch with us for any help or information. Look forward to meeting you at the seminar GlobalCompliancePanel

www.globalcompliancepanel.com