Multi-attendee discounts are available!

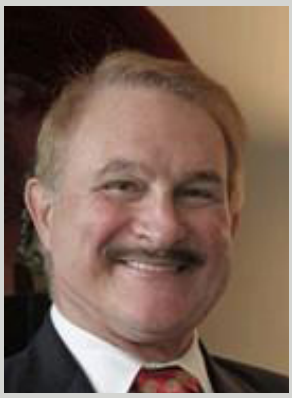
FDANEWS PRESENTS THE

SUCCESSFUL IMPORT/EXPORT PROGRAMS:

FORMER FDA EXPERT SHOWS THE WAY

AN INTERACTIVE WORKSHOP PRESENTED BY ENCORE INSIGHT LLC AND FDANEWS

YOUR EXPERT SPEAKER:



CASPER "CAP" ULDRIKS

Casper "Cap" Uldriks, founder of Encore Insight LLC provides consulting and training on FDA law and operations. Most recently he was counsel at Olsen Frank Weeda Law. With more than 30 years at the FDA he held a number of positions within the agency, such as an investigator in FDA's New England office, in the Office of the Commissioner in Legislative Affairs and in CDRH, where he served as CDRH's Associate Director for Regulatory Guidance and Government Affairs. He helped to guide CDRH to develop and implement various medical device related amendments to the Food, Drug, and Cosmetic Act, regulations and guidance documents. For years he has trained FDA staff on medical law and has been a featured speaker at many professional conferences involving FDA's medical device program.

He graduated with his B.A. in 1973 from Albion College, his Master of Divinity from Boston University in 1976, and his J.D. from Suffolk University Law School in 1986. He was admitted to the Massachusetts Bar in 1986 and the DC Bar in 2011.

OCT. 20-21, 2015 DOUBLETREE, BETHESDA, MD

Having FDA-regulated products held at ports costs time, money and your competitive edge. *But it doesn't have to.*

Instead of risking containment—or even destruction—of products, let an FDA insider show you how to implement a trouble-shooting import/export program.

Here's the one interactive workshop that arms you with a full program of today's best compliance strategies for speeding your products out of Customs and into U.S. and global markets.

No more guesswork about FDA priorities, processes or technologies; no more wondering about special provisions for trade shows, personal baggage and more. Former FDA import/export expert Casper "Cap" Uldriks lays out everything you need to know to take the risks—and delays—out of importing and exporting FDA-regulated products, including:

- How to negotiate with the FDA
- Registering and listing with the FDA
- Selecting an import broker
- FDA's and U.S. Custom's dual role
- Procedural fundamentals
- PREDICT: the FDA's computer screening program
- U.S. Custom's process and computer link to the FDA
- OASIS: the FDA's computer tracking program
- FDA automatic detention/import alert list
- Special provisions: trade shows, return for repair, compassionate use, personal baggage
- Options when your imports or exports are detained

WHO WILL BENEFIT?

This intensive hands-on training workshop is of immediate value to drug, biologics, device and diagnostics companies, as well as contract drug manufacturers, OTC companies, API suppliers, excipient suppliers, freight-forwarders and customs brokers. Personnel who will benefit the most include:

- Regulatory compliance officers
- Manufacturing directors and supervisors
- Supply chain managers
- Executive management

DAY ONE

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. – 10:15 a.m.

FDA Imports

- FDA import history and pirates
- Current legal authority
- Registering and listing with the FDA
- Selecting an import broker
- FDA's and U.S. Custom's dual role
- Procedural fundamentals
  - Required notice
  - Required information
- Documentation
  - Required and voluntary forms
  - FDA Form 2877
  - CPB Form 3461
  - Affirmation of compliance
  - Electronic Filing

10:15 a.m. – 10:30 a.m.

Break

10:30 a.m. – 12:00 p.m.

FDA's Import/Export Technologies

- FDA computer screening program (PREDICT)
- U.S. Custom's process and computer link to the FDA
  - Harmonized tariff
  - Invoice and shipping records
  - Entry number and what it means
  - Bonded warehouses for possession/control
  - FDA's notice of action and what to do
  - Sampling
  - Detention
  - Refusal
- FDA computer tracking program (OASIS)
  - Internal database
  - Violation codes

12:00 p.m. – 1:00 pm

Lunch Break

1:00 p.m. – 2:30 p.m.

Detention Process and Best Practices

- FDA automatic detention / import alert list
  - Detention by:
  - Country
  - Product type
  - Manufacturer
- Options for detained products
  - Reconditioning procedures
  - Form FDA 766 — reconditioning agreement
  - Re-export
  - Destruction and added government fees

2:30 p.m. – 2:45 p.m.

Break

2:45 p.m. – 4:30 p.m.

Group Break Out Interactive Exercises

- Import Hypothetical I — Technical Problems (short term issues)
  - What are your options if the FDA detains a product because the product code and other qualifier information is incorrect? What if the product requires a certificate of analysis? Who gets involved with the detention and what do they do? Many companies are either clueless or confused about what can to be done immediately to get the product released by FDA. What is your plan of action? Will you wing it? What are your options for storage in the meantime and what can you expect with that?
- Import Hypothetical II — Enforcement Problems (long term issues)
  - What are your options if the FDA detains your product because it is "filthy?" What are your options and what do you do? What if you tried to clean the product, but failed. Next the FDA issues you a Notice of Action for refusal. What will the FDA do and what will you do next? Your next shipment of the same product is detained for the same reason. Your boss wants an explanation and how you are going to fix the problem. What is your game plan? Quitting your job is not an option.

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. – 10:15 a.m.

Interacting with the FDA

- How to negotiate with the FDA
  - What to say and what not to say
  - How to set up a telephone call or face-to-face meeting
  - How to prepare for and conduct yourself at a meeting with the FDA

10:15 a.m. – 10:30 a.m.

Break

10:30 a.m. – 12:00 p.m.

Managing Import Problems with the FDA

- Mitigating regulatory risk and FDA enforcement damage
  - Shipping strategies and cargo options
  - Foreign supplier options
  - Third party laboratories
  - Insurance
- Inspection of foreign manufacturers
  - Third party audit
  - FDA inspection
- Foreign inspection damage control
  - Responding to FDA's inspectional observations ("Form FDA 483")
    - When to respond
    - What to say and not say
    - Verification
  - Responding to the FDA's warning letter and manage automatic detention
    - When to respond
    - What to say and not say
    - Documentation
    - F/U inspection by the FDA

12:00 p.m. – 1:00 pm

Lunch Break

1:00 p.m. – 2:30 p.m.

FDA Exports

- Legal authority
  - Adulteration and misbranding exemption
  - Criteria requirements for using the export exemption
    - Basic criteria (Sec. 801(e)(1) of the FD&C Act)
    - New criteria and Tier I countries (Sec. 802 of the FD&C Act)
    - Special criteria for high-risk products that do not meet new export criteria (Sec. 801(e)(2) of the FD&C Act)
- Export certificates
  - Types and qualifications for use
  - How to obtain an export certificate

Group Break Out Interactive Exercises

- Export Hypothetical I — Selling a Recalled Product Abroad
  - Your firm's recalled some OTC product in the U.S. because the instructions for use on the label left out storage instructions. You have lots of this product in your warehouse just waiting to be shipped. What are your options?
- Export Hypothetical II — Shipping a Product Abroad Before Approval by a Foreign Country
  - Your new prescription product is made for your market in France. You expect to receive your CE mark in a few days. What

continued

FDANEWS PRESENTS THE

SUCCESSFU IMPORT/ EXPORT PROGRAMS:

FORMER FDA EXPERT SHOWS THE WAY

Workshop Agenda | Day 2 (cont.)

will you do with the product now? Your next market will be Japan and you expect approval in a few months. What can you do now? To your surprise, France does not issue a CE mark and a cargo ship will arrive in France in about 1 week. What will you do now? This shipment was valued for $2,000 when it left Miami, now it is worth a token amount of $1,000. What are your options.

2:30 p.m. – 2:45 p.m.

Break

2:45 p.m. – 4:30 p.m.

FDA Import-for-Export

- Purpose and legal criteria
- Foreign Trade Zone status is for U.S. Customs, not FDA
- Procedures
  - Notification
  - Accountability
  - What is the "for further processing" criteria mean?

FDA's Special Import Provisions

- Trade Shows
- Return for Repair
- Compassionate Use
- Personal baggage

4:30 p.m.

Adjourn Workshop

☐ **Yes!** Sign me up for the **Successful Import/Export Programs**

I understand the fee of $1,797 includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments. Please call (888) 838-5578 or fax to (703) 538-7676.

INFORMATION:

Name _____

Title _____ Company _____

Address _____

City _____ State _____ ZIP_____

Phone _____ Fax _____

Email _____

PAYMENT OPTIONS:

☐ **Check Enclosed:** payable in U.S. funds to FDAnews

☐ **Charge my**: ☐ Visa ☐ MasterCard ☐ AmEx

Card # _____ Exp. Date _____

Signature _____

HOTEL INFORMATION:

Doubletree Bethesda Hotel
8120 Wisconsin Avenue
Bethesda, MD 20814
Toll free: (800) 560-7753
Tel: +1 (301) 652-2000
www.doubletreebethesda.com
Room rate: $209 plus 13% tax
Reservation cut-off: Oct. 1, 2015

TUITION: $1,797

Tuition includes all conference presentations, conference materials, two breakfasts, two luncheons, and refreshments.

TEAM DISCOUNTS:

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Multi-attendee discounts are available and will be calculated at check out.

2-4 attendees – 10%
5-6 attendees – 15%
7-9 attendees – 20%
10+ attendees – 25%

CANCELLATION AND SUBSTITUTION

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.