

From: "RMRAS Programs" <programs@rmras.org>
Subject: Webinar - FDA's New PREDICT Import Screening Program
Date: September 14, 2011 2:45:27 PM MDT
To: "RMRAS Programs" <programs@rmras.org>

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WEBINAR

Surviving the FDA's New PREDICT Import Screening Program

Wednesday, September 28 2011

11:30 am – 1:00 pm

The program starts promptly at 11:30 am, so we would recommend arriving a little earlier. Our meeting room is available at 11:00 am. You are welcome to bring a lunch, if you wish. The webinar will be followed by an informal discussion

[Your registration is needed by September 23 - If there are fewer than 10 participants, this event not be held.]

The PREDICT system allows the FDA to take into consideration a whole array of new information to determine whether to examine a shipment – information that was not generally available to its inspectors before.

Now, when the agency looks at a shipment of your drugs or medical devices, it will be assessing:

- The risks inherent in the product, such as its potential harm to patients and susceptibility to adulteration
- Past inspection results, both foreign and US, related to the product
- Results of sample analyses from previous product entries, and
- News and informal accounts of problems with your products

All of this additional information will help the agency make the most of its inspections by targeting problem products.

So, from now on, you'll need to keep your company's profile as clean as possible so you aren't needlessly caught up in the new screening filter. For companies with a good track record, PREDICT will result in faster import clearances.

But, if you don't understand which practices can disrupt PREDICT, you won't be able to take advantage of it. In 90 fast-paced minutes, the program will go from the basics of PREDICT to compliance mastery.

Here's a brief summary of what will be covered:

- History of PREDICT and current roll-out status
- Why voluntary data (i.e. Affirmations of Compliance) becomes more important
- Toughened enforcement of proper registration and listing data
- Assuring your PREDICT profile doesn't raise red flags with the FDA
- How the PREDICT system will influence the import alert and hold process
- How the Food Safety Modernization Act may affect drugs and devices:
- Foreign Supplier Verification
- Mandatory Recall (drugs)
- Qualified Importer Program
- Foreign Inspection Targets

Instructor

Benjamin L. England Esq. is founding member of Benjamin L. England & Associates LLC. During a 17-year FDA career, he served as Regulatory Counsel to the Associate Commissioner for Regulatory Affairs. In private practice, he guides clients facing FDA and USDA inspection and enforcement actions, as well as FDA and Customs criminal investigations, inquiries and prosecutions; and helps clients leverage risk management programs for food, medical device or drug distribution against FDA and Customs import clearance processes.

Sponsor: For additional information about this webinar, see www.fdanews.com

Cost: The cost of this webinar is \$75.00

To register, please go to: https://www.paypal.com/cgi-bin/webscr?cmd=_s-xclick&hosted_button_id=LTWAC7Y2RSMEA

Note: Your credit card will be charged at registration, but you will be fully refunded if the event is cancelled.

Location:

Regus Business Center
10955 Westmoor Drive, 4th Floor
Westminster, CO 80021
303-379-2100

Follow the signs for the Golf Course and after you see the clubhouse, look for the blue building with the gazebo (approximately 0.9 miles from entrance of complex. (Warning: the building numbers are hard to see.)

Questions: Questions can be addressed to Evelyn Cadman at ecadman@biotransapp.com or to Webinars@RMRAS.org