

CASA/FDA PHARMACEUTICAL INDUSTRY SEMINAR

**PHILADELPHIA AIRPORT HILTON HOTEL
PHILADELPHIA, PA
MAY 11, 2009**

7:30am – 8:30am	Registration	
8:30am – 8:45am	Welcome and Program Overview	Melinda Plaisier , Regional Food & Drug Director/Central Region
8:45am – 9:30am	FDA's Foreign Drug Inspection Program -New Dedicated Foreign Cadre -Offices Beyond Our Borders	Susan Laska , Supervisor, Dedicated Foreign Drug Cadre/Office of Reg. Affairs/Div. of Field Inv.
9:30am – 10:30am	Basic Import-Export Drug Requirements	William Nychis , Senior Compliance Officer/CDER/OC/Import-Export Team Huascar Batista , Team Leader CDER/OC/Import-Export Team
10:30am – 10:45am	BREAK	
10:45am – 11:00am	Imports in Philadelphia District	Rhonda Walley-Wade , Compliance Officer/Philadelphia District
11:00am - 11:30am	Pre/Post Approval Inspection Program	Tara Gooen , Team Leader (Acting) CDER/OC/Div. of Mfg. Product Quality/New/Generic Drug Mfg. Team
11:30am – 12:00pm	Recall Root Cause Analysis	Lynn Torbeck , Consultant to FDA CDER/OC/Div. of Mfg. Product Quality
12:00pm – 1:15pm	LUNCH (provided)	
1:15pm – 2:15pm	Prevention of Cross Contamination with Hazardous Compounds	Edwin Melendez , Compliance Officer CDER/OC/Division of Manufacturing Product Quality/ICB
2:15pm – 3:15pm	Drug Quality Reporting System -NDA Field Alert Reports -Adverse Drug Experience Reports	Seongjin (Cindy) Cho , Pharm D CDER/OC/Div. of Compliance Risk Management & Surveillance
3:15pm – 3:30pm	BREAK	
3:30pm – 4:30pm	Draft Process Validation Guide: A Field Perspective	Karyn M. Campbell , Director, Investigations Branch FDA/Philadelphia District
4:30pm – 5:00pm	Questions and Answers	Panel

**Moderators: Karyn M. Campbell, Director, Investigations Branch, FDA/Philadelphia District and
CASA Drug Committee Chairperson**

Brooke Higgins, Pre-Approval Program Manager, FDA/Baltimore District/Richmond Resident Post

Conference Information Sheet

Seminar Pre-Registration

Those arriving early on Sunday, May 10th, may pre-register for the seminar and receive their seminar materials from 4:00 to 6:00 PM at the Philadelphia Airport Hilton Hotel. Pre-registration room location will be posted in the hotel lobby.

Location

The CASA/FDA Pharmaceutical Seminar will be held at the Philadelphia Airport Hilton Hotel, 4509 Island Avenue, Philadelphia, PA 19153. The hotel is just off I-95, adjacent to the Philadelphia International Airport and just seven miles from downtown Historic Philadelphia.

Hotel Information

CASA is holding a block of rooms at the hotel (telephone 215-365-4150). The room rate for the seminar is \$ 155.00 per night (double); be sure to tell the hotel that you are attending the CASA/FDA seminar when making your reservation.

The hotel has 331 beautifully appointed deluxe guest rooms and 3 executive suites. Each room is complete with superior amenities, including complimentary high-speed internet. Overnight guests also enjoy the convenience of complimentary parking, airport shuttle service which is available 24 hour a day, state-of-the-art fitness center, and an indoor heated pool. In addition, the hotel is just five minutes from Citizens Bank Park, home of the 2008 Philadelphia Phillies-World Series Champions, who just happen to be in town during the seminar! For more information, please visit the hotel's website at <http://www.hilton.com/en/hi/groups/personalized/PHLAHHF-ANN-20090510/index.jhtml> and click on the CASA site.

REGISTRATION FORM

**CASA/FDA Pharmaceutical Seminar
May 11, 2009
Philadelphia Airport Hilton Hotel, Philadelphia, PA
REGISTRATION DEADLINE IS APRIL 27, 2009**

Name _____
(Please staple your business card to this registration)

Title _____

Affiliation _____

Address _____

Telephone _____ Email _____

REGISTRATION FEE (includes technical session, lunch, and refreshment breaks)

- \$400
- \$450 (*Late Registration Fee/After April 27th)

Please mail this form and your CHECK (No credit cards accepted), made payable in US dollars to "CASA" no later than April 27, 2009 to:

**Central Atlantic States Association of Food and Drug Officials
U.S. Food and Drug Administration
Attn: Megan Lauff
U.S. Customhouse, Room 900
2nd & Chestnut Streets
Philadelphia, PA 19106**

***Those registering after the deadline will be accepted pending space availability

CASA Membership Information

CASA is the Central Atlantic States Association of Food and Drug Officials, a regional affiliate of AFDO. Founded in 1916, it is an organization of food and drug officials working to improve coordination among local, state, and federal government agencies. If you would like to become a member of CASA, please check the membership category box below and include the membership dues with your registration check.

- \$35 Associate (industry representatives)

**For more information, please visit our website at www.casafdo.org.

TOTAL Enclosed \$ _____