

CASA/FDA PHARMACEUTICAL INDUSTRY SEMINAR

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

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| 7:30am – 8:30am | Registration | |
| 8:30am – 8:45am | Welcome and Program Overview | Kirk Sooter , Acting District Director, Philadelphia District/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 – 9:45am | BREAK | |
| 9:45am – 10:45am | Basic Import-Export Drug Requirements | William Nychis , Senior Compliance Officer/CDER/OC/Import-Export Team Huascar Batista , Team Leader CDER/OC/Import-Export Team |
| 10:45am – 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