



**CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE**  
**CDER COMPLIANCE CONFERENCE**

VIA WEBCAST  
[www.fda.gov/CDERSBIA](http://www.fda.gov/CDERSBIA)

**JANUARY 14, 2021**

Version 3, December 9, 2020  
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# AGENDA

All times are Eastern (EDT UTC-4)

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**Thursday, January 14, 2020**

**9:00 - 9:15**

**Welcome and Overview**

**Brenda Stodart**

*Captain, United States Public Health Service (USPHS)  
 Director, Small Business and Industry Assistance (SBIA)  
 Division of Drug Information (DDI) | Office of Communications (OCOMM)  
 Center for Drug Evaluation & Research (CDER)*

**9:15 – 9:25**

**Keynote**

**Donald D. Ashley**

*Director  
 Office of Compliance (OC)  
 CDER*

**Your SBIA Hosts for Day One**

**Forest "Ray" Ford, Jr.**

*CAPT, USPHS, Pharmacist  
 DDI | OCOMM*

**Lisa Misevicz**

*Health Communications Specialist  
 SBIA | DDI | OCOMM | CDER*

**9:25 – 10:25**

**Compounding: Cleanrooms and Cleanroom Behaviors: Why they Matter**

This session will cover why cleanrooms and cleanroom behaviors are important for preventing insanitary conditions that can adversely impact the quality and safety of drug products. Includes live Q&A with the presenter.

**Djamila Harouaka**

*Microbiologist  
 Division of Drug Quality III (DDQIII)  
 Office of Manufacturing Quality (OMQ) | OC | CDER*

**10:25 - 10:45: BREAK**

Thursday, January 14, 2020

**10:45 – 11:45**

**Enhanced Drug Distribution Security – Drug Supply Chain Security Act (DSCSA) Implementation Updates**

We are in year seven of implementing the supply chain security requirements under the Drug Supply Chain Security Act (DSCSA). This session will provide implementation updates for achieving enhance drug distribution security by November 2023 across the pharmaceutical supply chain. Includes live Q&A with the presenter.

**Connie T. Jung**

*Captain, United States Public Health Service (USPHS)  
Senior Advisor for Policy  
Office of Drug Security, Integrity and Response (ODSIR)  
CDER*

**11:45 - 1:00 LUNCH BREAK**

**1:00 – 2:00**

**A Glance at Drug Importation Requirements**

This session will provide an overview of drug importation requirements and to cover recent changes impacting drug imports. Includes live Q&A with the presenter.

**Cristina Dar**

*Lieutenant Commander, United States Public Health Service (USPHS)  
Imports Team Lead  
Division of Global Drug Distribution & Policy (DGDDP)  
ODSIR | CDER*

**2:00 - 2:20: BREAK**

**2:20 – 3:20**

**Risk Evaluation and Mitigation Strategies (REMS) Compliance Program**

The session will provide stakeholders an overview of the REMS Compliance Program. The mission of the Office of Compliance is to shield patients from poor quality, unsafe and ineffective drugs. This is done by addressing patient risks that arrive from violations of FDA regulations and law. The REMS Compliance team develops risk-based enforcement and communication strategies that ensure that drugs approved have reliable evidence of safety and effectiveness by ensuring that they meet post-market safety requirements.

**Haley Seymour**

*Consumer Safety Officer  
Division of Enforcement and Postmarketing Safety (DEPS)  
Office of Scientific Investigations (OSI)  
CDER*

**3:20 – 3:30**

**Closing Remarks**

**3:30 p.m. - ADJOURN**