FDA Acronyms & Abbreviations

CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

CDER COMPLIANCE CONFERENCE

VIA WEBCAST
www.fda.gov/CDERSBIA
JANUARY 14, 2021

U.S. FOOD & DRUG ADMINISTRATION

Version 4, January 9, 2021
(use link below to check for updates)

For files and resources, please visit
The Event Page on SBIAevents.com

Add to Your Calendar

AGENDA

All times are Eastern (EDT UTC-4)
View Start Time on World Clock

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 | CDER

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

9:25 – 10:35

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

10:35 - 10:55: BREAK

Thursday, January 14, 2020

10:55 – 11:55

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

11:55 - 1:00 LUNCH BREAK

1:00 – 2:05

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

2:05 - 2:25: BREAK

2:25 – 3:25

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

3:25 – 3:30

Closing Remarks

3:30 p.m. - ADJOURN