Version 7 – Updated April 18, 2021

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

Add Event to Your Calendar

AGENDA

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

DAY ONE: Wednesday, April 28, 2021

7:40 – 8:00

Administrative Overview

Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM) | CDER

8:00 – 8:20

Office of Generic Drugs (OGD) Keynote

Sally Choe
Director
Office of Generic Drugs (OGD)
CDER

8:20 – 8:40

Office of Pharmaceutical Quality (OPQ) Keynote

Sau (Larry) Lee
Deputy Director of Science
Office of Pharmaceutical Quality (OPQ) | 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

DAY ONE: Wednesday, April 28, 2021

8:40 – 9:00

Global Generic Drug Landscape

Sarah Ibrahim
Associate Director of Global Generic Drug Affairs
OGD | CDER

9:00 – 9:20

Data Integrity Issues in Bioequivalence Studies

FDA will provide an overview of bioequivalence data expectations.

Nilufer Tampal
Acting Deputy Director
Office of Bioequivalence (OB)
OGD | CDER

9:20 – 9:40

Bioavailability/Bioequivalence Site Evaluation During the Pandemic

FDA will provide an overview of clinical site evaluation during the pandemic.

Makini Cobourne-Duval
Office of Study Integrity and Surveillance (OSIS)
Office of Translational Sciences (OTS)
CDER

9:40 – 10:00

Impact of Data Integrity Issues on Pharmacology/Toxicology Studies in ANDAs

FDA will discuss what types of studies are impacted, the common types of data integrity issues FDA encounters, what are key collaborations in identifying/investigating these issues, what the impact of data integrity on review process is, particularly when multiple DMFs and ANDAs are affected (pending and approved), and what are approaches to manage the impact.

Victoria Keck
Division of Clinical Review
OGD | CDER

10:00 – 10:30

Questions & Panel Discussion

Sarah Ibrahim, Nilufer Tampal, Makini Cobourne-Duval, Victoria Keck

10:30 - 10:50: BREAK

10:50 – 11:10

OPQ Policy Update

Ashley Boam
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

All times shown are Eastern (EST UTC-4)

DAY ONE: Wednesday, April 28, 2021

11:10 – 11:30

Update on CDER's Quality Management Maturity Program

FDA will provide background on Quality Management Maturity (QMM) and will highlight CDER's journey to date as we build this new program.

Jennifer Maguire
Office of Quality Surveillance (OQS)
OPQ | CDER

11:30 – 11:50

Questions & Panel Discussion

Ashley Boam, Jennifer Maguire

11:50 – 12:50: LUNCH BREAK

12:50 – 1:20

Pre-ANDA Program

FDA will provide an overview of the pre-ANDA process to include research, controlled correspondence, PSG, meetings.

Caliope Sarago
Office of Research and Standards (ORS)
OGD | CDER

1:20 – 1:40

Pre-ANDA Program Update and Tips for Success - OPQ Perspective

FDA will provide an update of GDUFA II pre-ANDA metrics and recommendations to prepare pre-ANDA development and submission meeting requests.

Fang Yuan
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

1:40 – 2:00

Controlled Correspondence Related to Pharmaceutical Quality

FDA will provide:

- an overview of the controlled correspondence (CC) process in the Office of Pharmaceutical Quality,
- recommendations for submitting CCs,
- frequently asked questions and answers, and
- an analysis of controlled correspondence with potential solutions.

Janice T. Brown
Chief, Policy Development and Evaluation Branch
Division of Internal Policies and Programs (DIPAP)
OPPQ | OPQ | CDER

2:00 – 2:20

Questions & Panel Discussion

Caliope Sarago, Fang Yuan, Janice T. Brown and Lei Zhang

2:20 – 2:40: BREAK

All times shown are Eastern (EST UTC-4)

DAY ONE: Wednesday, April 28, 2021

2:40 – 3:00

Division of Filing Review: Helpful Tips for Submission of an ANDA or Controlled Correspondence

The Division of Filing Review will provide an overview of common deficiencies found during the filing review and recommend best practices for submitting controlled correspondences and substantially complete ANDAs.

Nnenna Nzelibe

Bijal Patel

Division of Filing Review (DFR)
Office of Regulatory Operations (ORO)
OGD | CDER

3:00 – 3:20

ANDA Labeling: Recommendations and Helpful Resources

The Division of Labeling Review will provide an overview of the labeling review process, helpful hints, and challenge questions with answers.

Charlene Peterson

Esther Chuh
CDR, USPHS

Division of Labeling Review (DLR)
ORO | OGD | CDER

3:20 – 3:35

Questions & Panel Discussion

Nnenna Nzelibe, Bijal Patel, Charlene Peterson, Esther Chuh, and Julia Lee

3:35 – 3:55

Addressing Common Challenges in Bioequivalence Studies Due to COVID-19: OGD's Approach for Timeliness, Clarity, and Consistency

The COVID-19 pandemic has significantly affected BE study operations, leading to unexpected protocol deviations and study interruptions. As a result, the in vivo BE evaluation can be challenging due to lot expiration during the study, PK profile truncations, subjects dropping out and partial PK information in a crossover study, among other factors

Tao Bai

OB | OGD | CDER

3:55 – 4:15

Learnings and Insight from Records Requests under § 704(a)(4) of the FD&C Act in lieu of Pre-Approval Inspections

With the COVID-19 pandemic came travel restrictions limiting the FDA's ability to perform Pre-Approval Inspections. In response to this, Office of Manufacturing Assessment (OPMA) has implemented use of Records Requests under the provisions of § 704(a)(4) of the FD&C Act to aid in manufacturing assessments. OPMA has performed over 100 of these assessments with firms across the globe with much success. This talk will highlight the process and lessons learned from these remote facility assessments.

Cassie Abellard

Jonathan Swoboda

Division of Microbiology Assessment
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

DAY ONE: Wednesday, April 28, 2021

4:15 – 4:35

Questions & Panel Discussion

Tao Bai, Cassie Abellared, Jonathan Swoboda

4:35 – 4:40

Day One Closing

4:40: DAY ONE ADJOURN

DAY TWO: Thursday, April 29, 2021

8:35 – 8:45

Administrative Overview

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

Your SBIA Hosts for Day Two

Forest "Ray" Ford, Jr.
CAPT, USPHS, *Pharmacist*
DDI | OCOMM | CDER

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

8:45 – 9:05

Mid-Review Cycle Meeting Overview

FDA will explain who is eligible for MRCMs, what the process pitfalls are as well as FDA's expectations.

Lakeeta Carr
CAPT, USPHS

Nicholas Daniel
LCDR, USPHS

Division of Project Management (DPM)
ORO | OGD | CDER

9:05 – 9:25

Information to Include with Cover Letters

FDA will provide an explanation of the components that should be included in the cover letter.

Cassandra Metu
LCDR, USPHS
DMP | ORO | OGD | CDER

9:25 – 9:45

Application Communications - Quality Assessment Perspective

This presentation will focus on ANDA communications during the quality assessment, best practices for submitting responses to the communications, and frequently asked questions and answers.

Heidi Lee
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER

9:45 – 10:15

Questions & Panel Discussion

Lakeeta Carr, Nicholas Daniel, Cassandra Metu, Heidi Lee

10:15 – 10:35: BREAK

All times shown are Eastern (EST UTC-4)

DAY TWO: Thursday, April 29, 2021

10:35 – 10:50

Fostering Innovation Through OPQ's Emerging Technology Program

FDA will describe OPQ's Emerging Technology Program, including:

- Perspective on what technologies OPQ is encountering through the program and the current progress in emerging technology, and
- Case studies of how collaboration through the Emerging Technology Program can support the implementation of innovations in the pharmaceutical industry.

Tom O'Connor
Office of Testing and Research (OTR)
OPQ | CDER

10:50 – 11:10

Lab Science to Support Generic Complex Drug Product Assessment

FDA will provide an overview of laboratory research contributions from the OPQ/Office of Testing and Research that support the evaluation of generic complex drug products.

Rachel Dunn
OTR | OPQ | CDER

11:10 – 11:40

Assessment of Extractables/Leachables Data in ANDA Submissions

FDA will focus on the common review issues encountered in ANDA applications on extractables/leachables studies, the kind of information FDA is looking for and how FDA evaluates extractables/leachables data in ANDA applications.

Patricia Onyimba
OLPD | OPQ | CDER

Kshitij (Kris) Patkar
OPMA | OPQ | CDER

11:40 – 12:00

Questions & Panel Discussion

Tom O'Connor, Changning Guo, Patricia Onyimba, Shin (Grace) Chou, Kris Patkar, and Melanie Mueller

12:00 - 1:00: LUNCH BREAK

1:00 – 1:20

Biopharmaceutics Risk Assessment to Guide Dissolution Method Development for Solid Oral Dosage Forms

This presentation will provide insight into the scientific and risk-based framework associated with the Agency's evaluation of in vitro dissolution method development for generic immediate-release, extended-release and delayed-release solid oral drug products.

Min Li
Division of Biopharmaceutics
ONDP | OPQ | CDER

1:20 – 1:40

Integrated Manufacturing Assessment: Expectations

This presentation will highlight common manufacturing issues and deficiencies for generic applications and illustrate typical approaches to resolve the same using sample case studies.

Vidya Pai
OPMA | OPQ | CDER

All times shown are Eastern (EST UTC-4)

DAY TWO: Thursday, April 29, 2021

1:40 – 2:00

Building a Better Sterility Assurance Application

This presentation will discuss some common application issues that often result in additional product quality microbiology information being requested from applicants. Additionally, some best practices and references to use when preparing the sterility assurance information for an application will be described.

Marla Stevens-Riley
OPMA | OPQ | CDER

2:00 – 2:20

Questions & Panel Discussion

Min Li, Vidya Pai, Marla Stevens-Riley, and **Mayra Pineiro-Sanchez**

2:20 – 2:40: BREAK

2:40 – 3:00

Postmarketing Safety and Surveillance of Generic Drugs Update

FDA will provide an update on generic drug safety issues over the past year and review data analysis.

Howard Chazin
Clinical Safety and Surveillance Staff
OGD | CDER

3:00 – 3:30

Premarket Review of Expedited Serious Adverse Event Reports of BA/BE Studies

FDA will provide an overview of premarket safety review for premarket BA/BE serious adverse events in support of ANDAs. FDA will also discuss aids in communicating good clinical practice during BE studies that support ANDAs.

Linda Forsyth
Clinical Safety and Surveillance Staff
OGD | CDER

3:30 – 3:50

Update on Shared System REMS for Generic Drugs

FDA will provide information regarding REMS requirements for generic drugs and an update on shared system REMS under the CREATES Act.

Lauren Gilles
REMS Team
OB | OGD | CDER

3:50 – 4:10

ANDA Postapproval Changes: Best Practices and Strategies to Avoid Common Quality Assessment Issues

FDA will address common post-marketing quality assessment issues and discuss best practices and strategies to avoid them.

Niles Ron
OLDP | OPQ | CDER

All times shown are Eastern (EST UTC-4)

DAY TWO: Thursday, April 29, 2021

4:10 – 4:30

Questions & Panel Discussion

Howard Chazin, Linda Forsyth, Lauren Gilles, Niles Ron, and Debra Catterson

4:30 – 4:35

Day Two Closing

4:35: ADJOURN

All times shown are Eastern (EST UTC-4)