# Small Business and Industry Assistance
# Generic Drugs Forum (GDF) 2024

Version 5 – Updated April 2, 2024

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 10, 2024

8:45 – 9:05

### Welcome & Administrative Overview

**Brenda Stodart, PharmD, MS, BCGP, RAC**
*Captain,* United States Public Health Service (USHPS)
*Director,* Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

9:05 – 9:25

### Office of Generic Drugs (OGD) Keynote

**Iilun Murphy, MD**
*Director*
Office of Generic Drugs (OGD) | CDER

9:25 – 9:45

### Office of Pharmaceutical Quality (OPQ) Keynote

**Susan Rosencrance, PhD**
*Deputy Director of Science, Acting*
Office of Pharmaceutical Quality (OPQ) | CDER

# DAY ONE: Wednesday, April 10, 2024

9:45 – 10:15

## Drug Shortages and Generic Drugs

Understand the ongoing reasons for generic drug shortages as well as challenges to the US drug supply.

**Emily Thakur**
*CDR*, USPHS
*Team Leader* | Drug Shortage Staff (DSS)
Office of the Center Director (OCD) | CDER

**10:15 - 10:30: BREAK**

10:30 – 11:00

## GDUFA III Policy Updates

An update on published policy documents for GDUFA III

**Tina Kiang**
*Director* | Division of Regulations and Guidance (DRGS) | Office of Policy for Pharmaceutical Quality (OPPQ) | OPQ | CDER

**Martha Nguyen**
*Director* | Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP) | OGD | CDER

11:00 – 11:20

## GDUFA III Suitability Petitions

This presentation will provide a refresher of the GDUFA III Commitments for Suitability Petitions as well as tips for submitting a complete suitability petition.

**Rosanne Pagaduan**
*Supervisory General Health Scientist*
Division of Filing Review (DFR)
Office of Regulatory Operations (ORO) | OGD | CDER

**Arlene Figueroa**
*Regulatory Counsel* | Division of Legal and Regulatory Support (DLRS) | OGDP | OGD | CDER

11:20 – 11:40

## Overview of the FDA's Product-Specific Guidance (PSG) Program

This presentation will provide an overview of the FDA's PSG Program including PSG development general principles, processes, resources on PSGs, and pertinent GDUFA III updates.

**Joe Kotsybar, PharmD**
*Regulatory Health Project Manager*
Office of Research and Standards (ORS)
OGD | CDER

All times shown are Eastern (EST UTC-4)

## DAY ONE: Wednesday, April 10, 2024

11:40 – 12:00

**Q&A Panel**

**Emily Thakur, Tina Kiang, Martha Nguyen, Rosanne Pagaduan, Arlene Figueroa, Joe Kotsybar and**

**Reynolds (Rey) Cantave, PharmD**
*Senior Regulatory Health Project Manager*
Enterprise Project Management Staff
Office of Quality Assurance (OQA) | OPQ | CDER

**12:00 – 1:00: LUNCH BREAK**

# DAY ONE: Wednesday, April 10, 2024

1:00 – 1:20

## An Overview of Controlled Correspondence: GDUFA III Updates and a Comprehensive Analysis of Controlled Correspondences Received by the Office of Bioequivalence

The Controls Team will present on changes in controlled correspondence since the implementation of GDUFA III and rejection rates of controlled correspondence since GDUFA III compared to GDUFA II. The Office of Bioequivalence will present on controls received by the Office of Bioequivalence.

**Marcia Fields**
*LCDR* | USPHS | *Regulatory Officer*
ORO | OGD | CDER | FDA

**Zhen Zhang, PhD**
Master Pharmacologist
Division of Bioequivalence I (DB I)
Office of Bioequivalence (OB) | OGD | CDER

1:20 – 1:40

## Overview of Quality Controlled Correspondence

What comprises of a complete and concise Quality Controlled Correspondence for submission to the FDA

**Jenn Anim**
*Pharmacologist - Policy Lead* | Division of Internal Policy and Communication | OPPQ | OPQ | CDER

1:40 – 2:00

## Overview and Considerations of Pre-ANDA (Abbreviated New Drug Application) Scientific Meetings Under GDUFA III

This presentation will provide an overview of the GDUFA III pre-ANDA scientific meetings, their process, and considerations for grant/deny decisions.

**Maria Monroy-Osorio**
*Regulatory Health Project Manager*
ORS | OGD | CDER

2:00 – 2:20

## Unveiling the Data: Post-Complete Response Letter Scientific Meeting Requests under GDUFA III

This presentation will provide the insights on the handling of post-CRL scientific meeting requests under GDUFA III and utilization of this platform in the most efficient manner.

**Hiren Patel, PhD**
*Senior Staff Fellow*
DB II | OB | OGD | CDER

# DAY ONE: Wednesday, April 10, 2024

2:20 – 2:50

## Q&A Panel

**Marcia Fields, Zhen Zhang, Jenn Anim, Maria Monroy-Osorio Hiren Patel** and **Karen Bengtson**
*Supervisory Regulatory Health Project Manager* | ORS | OGD | CDER

**2:50 – 3:05: BREAK**

3:05 – 3:25

## ANDA Program Statistics

This presentation will provide the sources and meaning of key ANDA Program statistics.

**Edward (Ted) Sherwood**
*Director* | ORO | OGD | CDER | FDA

3:25 – 3:55

## ANDA Project Management Topics: Pre-Launch Activities Importation Requests (PLAIR) and Cover Letter Attachments

This presentation provides an overview of Pre-Launch Activities Importation Request (PLAIR) program and an overview of information to include with a cover letter to help the FDA route and manage each submission effectively.

**Andrew Kim**
*CDR* | USPHS | *Supervisory Project Manager*
Division of Project Management (DPM) | ORO | OGD | CDER

**Andrei Perlloni**
Branch Chief | Imports Compliance Branch (ICB) | Division of Global Drug Distribution and Policy (DGDDP) | Office of Drug Security, Integrity, and Response (ODSIR) | OC | CDER

**Tom Ching**
*Regulatory Project Manager*
DPM |ORO | OGD | CDER

3:55 – 4:15

## Quality ANDA Submission Best Practices and Communications

Best practices from project management prospective when submitting Pre and Post marketing ANDA applications.

**Steven Yang**
*LCDR* | USPHS | *Regulatory Business Process Manager*
Division of Regulatory & Business Process Management IV (DRBPM IV) | OPRO | OPQ | CDER

All times shown are Eastern (EST UTC-4)

# DAY ONE: Wednesday, April 10, 2024

4:15 – 4:45

**Q&A Panel**

**Edward (Ted) Sherwood, Andrew Kim**
**Andrei Perlloni, Tom Ching, Steven Yang**

**4:45: ADJOURN DAY ONE**

**5:00 – 6:00 PM: NETWORKING OPPORTUNITY**

Onsite attendees are invited to gather at The Bethesdan Lobby Bar to continue the conversation with fellow attendees.

All times shown are Eastern (EST UTC-4)

# DAY TWO: Thursday, April 11, 2024

8:30 – 8:40

## Administrative Overview

**Brenda Stodart, PharmD, MS, BCGP, RAC**
*Captain,* USHPS | *Director,* SBIA
DDI | OCOMM | CDER

8:40 – 9:00

## Pediatric Excipient Evaluation:  Bioequivalence (BE) Perspective

This presentation provides OGD's current thinking and procedures in assessing the safety of excipients/inactive ingredients (IIGs) for pediatric use during bioequivalence review in ANDA reviews.

**Yang Lu, PhD**
*Senior Staff Fellow* | DB III | OB | OGD | CDER

9:00 – 9:20

## GDSA-BE: Modernizing Bioequivalence Assessment for Abbreviated New Drug Applications (ANDAs)

This presentation provides an introduction of an intelligent generic drug bioequivalence assessment tool, GDSA-BE, which symbolizes OGD's modernization of drug assessment workflow to move from an unstructured narrative to structured data with dynamic and interactive collaboration capabilities.

**Tao Bai, PhD**
*Senior Advisor*
Office of Bioequivalence Immediate Office (OBIO)
OGD | CDER

9:20 – 9:50

## Bio-IND Best Practices: an Analysis of Common Clinical Safety Hold and Non-hold Issues and Comparative Analysis Update

This joint presentation will provide successful practices for IND submissions and updates on comparative analyses.

**Andrea Dugas, MD, PhD**
*Physician* | Division of Clinical Safety and Surveillance (DCSS) | Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

**Shabnam Foroughi, MD**
*Physician* | Division of Clinical Review (DCR) OSCE | OGD | CDER

All times shown are Eastern (EST UTC-4)

## DAY TWO: Thursday, April 11, 2024

9:50 – 10:10

### Successful Practices for Pharmacology/Toxicology (Pharm/Tox) Justification in ANDAs

This presentation will provide successful practices for Pharm/Tox justifications to support the safety of impurities and excipients in generic drug formulations.

**Jimena Dancy, PhD**
*Pharmacologist* | Division of Pharmacology/Toxicology Review (DPTR) | OSCE | OGD | CDER

10:10 – 10:40

### Q&A Panel

**Yang Lu, Tao Bai, Andrea Dugas**
**Shabnam Foroughi, Jimena Dancy**

**10:40 – 11:00: BREAK**

All times shown are Eastern (EST UTC-4)

## DAY TWO: Thursday, April 11, 2024

11:00 – 11:20

### Nitrosamine Risk Assessment in Type II Drug Master Files (DMFs) Supporting GDUFA Applications

Root causes of nitrosamine formation in the API manufacturing process and their mitigating strategies will be discussed.

**Govindaraj Kumaran, PhD**
*Chemist* | Division of Product Quality Assessment XIX (DPQA XIX)| Office of Product Quality Assessment III (OPQA III) OPQ | CDER

11:20 – 11:40

### Post approval changes in Complex Generics from Drug Product/Chemistry Manufacturing & Controls (CMC) Perspectives

A presentation on the best practices for post-Approval CMC changes in complex dosage forms such as Transdermal Patches, MDI, DPI, and Peptide drug Products

**David Awotwe-Otoo, PhD**
*Senior Pharmaceutical Quality Assessor*
DPQA III | OPQA I | OPQ | CDER

11:40 – 12:00

### Quality Considerations for Topical Ophthalmic Drug Products - Guidance for Industry

This presentation will discuss quality considerations for topical Ophthalmic drug products as provided in the FDA Guidance for Industry (GFI) published in 2023.

**Asif Rasheed, PhD**
*Senior Review Chemist* | DPQA VIII | OPQA II | OPQ | CDER

12:00 – 12:30

### Q&A Panel

**Govindaraj Kumaran, David Awotwe-Otoo, Asif Rasheed**

**12:30 - 1:30: LUNCH BREAK**

All times shown are Eastern (EST UTC-4)

## DAY TWO: Thursday, April 11, 2024

1:30 – 1:50

### ANDA Submissions: Risk-Based Extractable and Leachable Quality Information

This combined talk will cover (i) Evaluation of manufacturing process-related leachables information in generic drug applications, and (ii) Evaluation of container closure system related extractables and leachables.

**Kshitij Patkar, PhD**
*Senior Pharmaceutical Quality Assessor*
Division of Pharmaceutical Manufacturing Assessment I (DPMA I) | Office of Pharmaceutical Manufacturing Assessment (OPMA) | OPQ | CDER

**Jin Xu, PhD**
*Senior Pharmaceutical Quality Assessor*
DPQA IX | OPQA II | OPQ | CDER

1:50 – 2:10

### Facility Assessment for Pre-Marketing Applications

This combined talk will cover (i) Pre-approval inspections and use of regulatory remote assessments for pre-marketing applications; (ii) GDUFA-III commitments related to facilities evaluation- Major to minor and facilities not ready for inspection.

**Derek Smith, PhD**
*Deputy Director* | OPMA | OPQ | CDER

**Rakhi Shah, PhD**
*Associate Director* | OPMA | OPQ | CDER

2:10 – 2:30

### Emerging Technology Program (ETP) and Advanced Manufacturing Technologies Designation Program (AMTDP): Which Advanced Manufacturing Program is Right for Me?

Overview of the Emerging Technology Program and the Advanced Manufacturing Technologies Designation Program.

**Elisa Nickum, PhD, PMP**
*Senior Regulatory Health Project Manager*
DRBPM IV | OPRO | OPQ | CDER

2:30 – 2:50

### Q&A Panel

**Kshitij Patkar, Jin Xu, Derek Smith, Rakhi Shah, Elisa Nickum**

**2:50 – 3:05: BREAK**

All times shown are Eastern (EST UTC-4)

## DAY TWO: Thursday, April 11, 2024

3:05 – 3:25

### Improving the Sterility Assurance Application to the FDA

Discussion of common deficiencies and concepts to improve the sterility assurance portion of an application.

**John Arigo, PhD**
*Division Director*
DPMA II
OPMA | OPQ | CDER

3:25 – 3:45

### The Bacterial Endotoxins Specification - Points to Consider

A description of risks and mitigation strategies for the presence of bacterial endotoxins in drug products. Case studies on the endotoxins release/stability specification will be shared.

**Erika Pfeiler, PhD**
*Unit Supervisor* | DPMA VI | OPMA | OPQ | CDER

3:45 – 4:05

### General Overview of ANDAs Labeling Requirements for Rx to OTC Switched Products

This presentation will go over what ANDA applicants need to do when there RLD goes from Rx to OTC.

**Sunny Pyon**
*Labeling Project Manager*
Division of Labeling Review (DLR)
Office of Regulatory Operations (ORO) | OGD | CDER

**Bayli Larson, PharmD**
*Pharmacist*
Patent and Exclusivity Team (PET)
Division of Legal & Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP) | OGD | CDER

4:05 – 4:25

### Regulatory Reminders at the Finish Line

This presentation will provide Industry with the required documents needed moving toward approval.

**Vincent Sansone**
*CAPT* | USPHS | *Director* | DPM
ORO | OGD | CDER

**Rinku Patel**
*Program Management*
DLRS | OGDP | OGD | CDER

All times shown are Eastern (EST UTC-4)

## DAY TWO: Thursday, April 11, 2024

4:25 – 4:55

### Questions & Panel Discussion

**John Arigo, Erika Pfeiler, Sonny Pyon, Bayli Larson**
**Vincent Sansone, Rinku Patel**

4:55 – 5:00

### Closing Remarks

**Tawni B. Schwemer**
*Senior Advisor*
Office of Generic Drugs

**5:00: ADJOURN FORUM**

All times shown are Eastern (EST UTC-4)