



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



Version 3 – Updated March 11, 2024

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AGENDA

All times are Eastern (EST UTC-4)

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DAY ONE: Wednesday, April 10, 2024

8:30 – 8:45

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)

8:45 – 9:05

CDER Keynote

9:05 – 9:25

Office of Generic Drugs (OGD) Keynote

lilun 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

Your SBIA Host for Day One

Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS, Pharmacist
 DDI | OCOMM | CDER

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

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*

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.



DAY TWO: Thursday, April 11, 2024

8:30 – 8:40

Administrative Overview

Forest “Ray” Ford, Jr., PharmD, BCPS
CAPT, USPHS, Pharmacist
 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

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

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

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

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

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