Version 5 – Updated April 3, 2023

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AGENDA

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

DAY ONE: Wednesday, April 12, 2023

8:00 – 8:15

Administrative Overview

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

8:15 – 8:30

CDER Keynote

Jacqueline Corrigan-Curay, JD, MD
Principal Deputy Center Director, CDER

8:30 – 8:45

Office of Generic Drugs (OGD) 2023 Outlook and Opportunities

Ilun Murphy, MD
Deputy Director of Clinical and Regulatory Affairs
Office of Generic Drugs (OGD) | CDER

8:45 – 9:00

Office of Pharmaceutical Quality (OPQ) 2023 Outlook and Opportunities

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

DAY ONE: Wednesday, April 12, 2023

Your SBIA Hosts for Day One

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

Renu Lal, PharmD
LCDR, USPHS, *Pharmacist*
DDI | OCOMM | CDER

Nora Lim, PharmD, BCPS
LT, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

9:00 – 9:30

Controlled Correspondence Program Updates under GDUFA III

This presentation will describe how controlled correspondence is used in the abbreviated new drug application process, how to submit correspondence, provide an overview key changes that relate to controlled correspondences under the Generic Drug User Fee Amendment III, and helpful tips with submissions

Marcia Fields, PharmD
LCDR, USPHS
Office of Regulatory Operations (ORO)
OGD | CDER

9:30 – 9:50

Submitting a Successful Controlled Correspondence for Quality-Related Questions

This presentation provides an overview of information to be submitted in controlled correspondences for quality-related questions. Best practices for applicants are highlighted.

Shanaz Read, PhD
Program Lead, Controlled Correspondence Team
Division of Internal Policies and Programs (DIPAP)
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

9:50 – 10:10

An Overview of the FDA Product-Specific Guidance (PSG) Program under GDUFA III

FDA will provide an overview of the Product-Specific Guidance (PSG) program with GDUFA III updates, including the new PSG teleconferences and PSG meetings.

Christine Le, PharmD, PMP
CDR, USPHS
PSG Program Director
Office of Research and Standards (ORS)
OGD | CDER

10:10 – 10:30

Questions & Panel Discussion

Shanaz Read, Christine Le, and
Malik Imam
CDR, USPHS, *Deputy Director*, ORO | OGD | CDER
Manina Singh, PharmD, PMP, RAC
Deputy Director, Division of Bioequivalence Process Management (DBPM) | Office of Bioequivalence (OB) | OGD | CDER
Peter Capella, PhD
Director, Division of Immediate and Modified Release Products II (DIMRP II)
Office of Lifecycle Drug Products (OLDP) | OPQ | CDER
Xiaoming Xu, PhD
Director, Division of Product Quality Research (DPQR); Office of Testing and Research (OTR) | OPQ | CDER
Lei K. Zhang, PhD
Deputy Director, Office of Research and Standards (ORS) | OGD | CDER
David Coppersmith, JD
Regulatory Counsel, Division of Policy Development (DPD), Office of Generic Drug Policy (OGDP) | OGD | CDER

10:30 - 10:40: BREAK

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DAY ONE: Wednesday, April 12, 2023

10:40 – 11:00

An Overview of Pre-ANDA meetings under GDUFA III

FDA will provide an overview of the pre-ANDA meetings (product-development and pre-submission) between the FDA and prospective ANDA applicants, including GDUFA III new features.

Savita Nigam, PhD
Senior Project Manager
ORS | OGD | CDER

11:00 – 11:20

Abbreviated New Drug Application (ANDA) Meeting Requests

This presentation will provide an overview of formal meetings between the FDA and the ANDA Applicants of Complex product under GDUFA III; (meeting types, meeting requests, meeting formats, meeting package content and submission).

Tina Nhu, PharmD, Mc. PM, BS Pharm
CDR, USPHS
Team Leader, *Regulatory Project Manager*
Division of Project Management (DPM)
ORO | OGD | CDER

11:20 – 11:40

GDUFA III Mid-Cycle Review Meetings and Enhanced Mid-Cycle Review Meetings

This presentation will define and outline the changes and additions under GDUFA-III for mid-cycle review meetings and enhanced mid-cycle review meetings for complex generic drug products and competitive generic therapies. It will provide an outline of the criteria, expectations, and overall process for requesting MCRMs and EMCRMs. In addition to providing resources for reference.

April Braddy, PhD, RAC
Director, Division of Bioequivalence III (DBIII)
OB | OGD | CDER

11:40 – 12:00

A New GDUFA III Meeting: Post-CRL (Complete Response Letter) Scientific Meeting

This presentation will provide an overview of a GDUFA III new meeting: Post-CRL Scientific Meeting, including meeting criteria, and meeting process.

Tao Bai, PhD
Senior Advisor
OB | OGD | CDER

12:00 – 12:30

Questions & Panel Discussion

Savita Nigam, Tina Nhu, April Braddy, Tao Bai, and
Karen Bengtson
Supervisory Regulatory Health Project Manager, ORS | OGD | CDER
Parth Soni, PharmD, MBA, PMP
Regulatory Project Manager, DPM | ORO | OGD | CDER
Xuan-Mai Nguyen, PharmD
Regulatory Project Manager, DPM | ORO | OGD | CDER

12:30 – 1:00: LUNCH BREAK

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DAY ONE: Wednesday, April 12, 2023

1:00 – 1:30

GDUFA III Metrics

This presentation will provide an understanding of the layout of the new GDUFA III Generic Drugs Program Monthly and Quarterly Activities Report, and insights on the salient metrics of the GDUFA III program.

Russell Storms, PhD
Associate Director for Analytics
ORO | OGD | CDER

Edward Sherwood
Director, ORO | OGD | CDER

1:30 – 1:50

GDUFA III Impact on DMF Assessment

This presentation will highlight the impact of GDUFA III enhancements on Drug Master File (DMF) assessment.

Jayani Perera, PhD
Senior Chemist, Division of Lifecycle API (DLAPI)
Office of New Drug Products (ONDP)
OPQ | CDER

1:50 – 2:10

Facility Related Updates in GDUFA III

This presentation discusses facility related updates in GDUFA III including reclassification of facility-based major complete response letter amendments and submissions with facilities not ready for inspection.

Daniel Obrzut, PhD
Branch Chief
Division of Pharmaceutical Manufacturing Assessment I (DPMA I) | Office of Pharmaceutical Manufacturing Assessment (OPMA) | OPQ | CDER

2:10 – 2:30

Quality Considerations for Developing Complex Generics

This presentation will discuss best practices for successful pre-ANDA meetings and mid-cycle review meetings (MCRM), considered from the product quality perspective. GDUFA III enhancements will be highlighted.

Kumara Subramanian, PhD
Senior Pharmaceutical Quality Assessor
Division of Liquid-Based Drug Products I (DLBP I)
OLDP | OPQ | CDER

2:30 – 2:55

Risk Evaluation and Mitigation Strategies (REMS) for Generic Drugs: Use of a Drug Master File (DMF) and REMS Modifications

This presentation will discuss pre-market and post-market Risk Evaluation and Mitigation Strategy (REMS) requirements for generic drugs. Highlighting, proper submission of a REMS to a generic drug application, the various types of REMS modifications, use of a Drug Master File (DMF), and provide helpful tools and resources related to REMS.

Jennifer Sarchet
REMS Coordinator, Division of Clinical Safety and Surveillance (DCSS), Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

Charles Kerns
REMS Coordinator
DCSS | OSCE | OGD | CDER

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DAY ONE: Wednesday, April 12, 2023

2:55 – 3:15

Questions & Panel Discussion

Jayani Perera, Daniel Obrzut, Kumara Subramanian, Jennifer Sarchet, Charles Kerns, and **Rakhi Shah, PhD**
Associate Director for Science & Communications, OPMA | OPQ | CDER
Srinivas Behara, PhD
Chemist, Division of Immediate and Modified Release Products III (DIMRP III) | OLDP | OPQ | CDER

3:15 – 3:25: BREAK

3:25 – 3:45

Overview of CREATES Act and Covered Product Authorizations

This presentation will help product developers understand the CREATES Act, which established a pathway for generic and other developers to access the product samples they need to support their applications. It will also discuss Covered Product Authorizations, which are needed when product developers seek to use the CREATES pathway to obtain samples of products subject to REMS with ETASU.

Sharon Coleman
Senior Regulatory Counsel
Division of Regulatory Policy II (DRP II)
ORP | CDER

3:45 – 4:10

Considerations for Application Pathway: 505(b)(2) or ANDA

The presentation will help potential applicants understand the different application approval pathways and determine the best fit for their particular drug product and to understand the differences between the 505(b)(2) and ANDA application pathways.

David Coppersmith, JD
Regulatory Counsel
DPD |
OGDP | OGD | CDER

4:10 – 4:25

Resources Available on the Orange Book Website

This presentation will provide information on: 1) How to Navigate the Orange Book website; 2) Available information in the Additional Resources Page; 3) How to download a copy of the monthly CS files to view in Excel or other Software, and; 4) Orange Book FAQs.

Truong Quach, PharmD
Acting Team Lead
Division of Orange Book Publication and Regulatory Assessment (DOBPRA) | OGDP | OGD | CDER

4:25 – 4:40

The Global Generic Drug Supply Chain and Need for International Dialogue

This presentation will discuss:

- Generic drug global impact
- The global nature of the US generic drug supply chain
- Overview of OGD's global regulatory strengthening and capacity building engagements
- Update on Generic Drug cluster and the Pilot Parallel Scientific Advice (PSA)

Sarah Ibrahim, PhD
Associate Director for Stakeholder and Global Engagement
OGD | CDER

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DAY ONE: Wednesday, April 12, 2023

4:40 – 5:00

Quality Management Maturity

This presentation provides an overview of FDA's Quality Management Maturity (QMM) program, highlighting the importance to Industry and the Agency.

Djamila Harouaka, PhD
Senior Scientific Advisor
Office of Quality Surveillance (OQS)
OPQ | CDER

5:00 – 5:20

Questions & Panel Discussion

Sharon Coleman, David Coppersmith, Truong Quach, Djamila Harouaka, and **Andrew Fine, PharmD, BCPS**
CDR, USPHS
Senior Advisor, Division of Clinical Review (DCR)
OSCE | OGD | CDER

5:20 – 5:30

Day One Closing

5:30: DAY ONE ADJOURN

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DAY TWO: Thursday, April 13, 2023

8:00 – 8:10

Administrative Overview

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

8:10 – 8:40

Best Practices for Abbreviated New Drug Applications (ANDAs) in GDUFA III

This presentation focuses on ways to engage with the Office of Bioequivalence and Office of Pharmaceutical Quality during the ANDA lifecycle; bioequivalence (BE) and quality communications during ANDA assessment cycles; and best practices for ANDAs from a BE and quality perspective.

Chitra Mahadevan, PharmD, MS, BCPS, PMP
CDR, USPHS
Director, Division of Bioequivalence Process Management (DBPM) | OB | OGD | CDER

Craig Kiester
CAPT, USPHS
Director, Division of Regulatory Business Project Management II (DRBPMII) | OPRO | OPQ | CDER

8:40 – 8:50

Submission of In Vitro Release Test (IVRT) Data and Information for Topical Drug Products under ANDAs (3) Products

This presentation focuses on Agency's expectations of IVRT data and information submitted for generic topical products under ANDAs, as well as submission-related common deficiencies for the IVRT study.

Hui Zheng, PhD
Pharmacologist, Division of Bioequivalence (DBI)
OB | OGD | CDER

8:50 – 9:05

Submission of In Vitro Permeation Test (IVPT) Data and Information for Topical Drug Products under ANDAs

This presentation focuses on Agency's expectations of IVPT information and data to be submitted in ANDA submissions when IVPT studies are intended to support a demonstration of bioequivalence. Specifically, the presentation elucidates some key aspects of a high quality IVPT submission in terms of: (a) the information and data relevant to each stage of an IVPT study to be submitted, (b) their expected level of detail, and (c) their recommended organization within the electronic common technical document (eCTD) submission.

Archana A. Manerikar, PharmD, MS
Pharmacologist
DBI | OB | OGD | CDER

9:05 – 9:15

Considerations for Alternative Bioequivalence (BE) In Vitro Study Information Submitted in Nasal Drug

The presentation focuses on Agency's expectations of alternative bioequivalence (BE) study information submitted for nasal suspension drug products, as well as submission related common deficiencies for the alternative BE study.

Vipra Kundoor, PhD
Pharmacologist
DBI | OB | OGD | CDER

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DAY TWO: Thursday, April 13, 2023

9:15 – 9:50

Structured Submission and Review (Module 3)

This presentation gives high level information about Agency plans to receive module 3 quality data in structured format. The relation of structured data to OPQ's KASA (Knowledge-aided Assessment and Structured Application) will be highlighted.

G. Scott Gordon, PhD
Senior Health Informatics Officer
Data Standards Staff (DSS)
Office of Strategic Programs (OSP) | CDER

Norman Schmuff, PhD
Associate Director for Science
OPMA | OPQ | CDER

9:50 – 10:20

Information to Include with Cover Letters

This presentation provides recommendations regarding the pertinent information that should be included in the cover letters accompanying each submission.

Nimmy Mathews, PharmD, MS, BCSPC, CPGP
LCDR, USPHS
Regulatory Project Manager
ORO | OGD | CDER

10:20 – 10:50

Questions & Panel Discussion

Chitra Mahadevan, Craig Kiester, Hui Zheng, Archana A. Manerikar, Vipra Kundoor, G. Scott Gordon, Norman Schmuff, Nimmy Mathews, and **Malik Imam, Andrew Fine**

10:50 – 11:00: BREAK

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DAY TWO: Thursday, April 13, 2023

11:00 – 11:30

GDUFA III Labeling Updates and Tips

This presentation will highlight GDUFA III updates that impact Abbreviated New Drug Application (ANDA) labeling and provide tips on ANDA labeling submissions.

Julie Neshiewat, PharmD, BCPS, CPH
CDR, USPHS
Supervisor, Division of Labeling Review (DLR)
ORO | OGD | CDER

Oluwakemi "Kemi" Odesina, PharmD, BCPS, CPH
Labeling Reviewer
DLR | ORO | OGD | CDER

Kodilichi (Kodi) Echeozo, PharmD, MBA, BPCS, BCACP
LCDR, USPHS
Senior Labeling Reviewer
DLR | ORO | OGD | CDER

11:30 – 11:50

Overview of Major Quality Deficiencies and Approaches Available in GDUFA III

This presentation presents identification and communication of major quality deficiencies to applicants. Approaches available to applicants to address these deficiencies, including new avenues from GDUFA III, will be highlighted.

Karen Ireland, MS, PMP, RAC-Drugs
Senior Regulatory Health Project Manager
DRBPMII | OPRO | OPQ | CDER

11:50 – 12:10

Drug Product Quality Tips: Drug-Device Combination Products

This presentation discusses key considerations for applicants when submitting ANDAs for drug-device combination products.

Kai Kwok, PhD
Senior Pharmaceutical Quality Assessor
Division of Liquid-Based Drug Products II (DLBP II)
OLDP | OPQ | CDER

12:10 – 12:30

Questions & Panel Discussion

Julie Neshiewat, Oluwakemi "Kemi" Odesina, Kodilichi (Kodi) Echeozo, Karen Ireland, Kai Kwok

12:30 - 1:00: LUNCH BREAK

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DAY TWO: Thursday, April 13, 2023

1:00 – 1:10

Change in API Supplier: Drug Substance Quality Tips

This presentation discusses quality considerations for applicants when changing API supplier, focused on the drug substance perspective.

Keduo Qian, PhD
Chemist
DLAPI | ONDP | OPQ | CDER

1:10 – 1:30

Change in API Supplier: Drug Product Quality Tips

This presentation discusses quality considerations for applicants when changing API supplier, focused on the impact on drug product quality from drug product assessment and facility assessment perspective.

Rajib Paul, PhD
Senior Pharmaceutical Quality Assessor
Division of Post-Marketing Activities II (DPMA II) | OLDP | OPQ | CDER

Bo Jiang, PhD
Senior Pharmaceutical Quality Assessor
DPMA I | OPMA | OPQ | CDER

1:30 – 1:50

Managing Quality Post-Approval

This presentation provides an overview of submission of post-approval supplements for quality-related changes. GDUFA III enhancements are highlighted.

Paul Schwartz, PhD
Director, DPMA II | OLDP | OPQ | CDER

Olugbenga (Gbenga) Okubadejo, PharmD
Director, DRBPM III | OPRO | OPQ | CDER

1:50 – 2:10

Inspection Tips: Best Practices for Remote Interactive Evaluations and Other Alternative Inspection Approaches

This presentation discusses the best practices interacting with the Agency during remote interactive evaluations. Other alternative inspection approaches are highlighted for ANDA applicants.

Lane Christensen, PhD
Branch Chief, Division of Pharmaceutical Manufacturing Assessment IV (DPMA IV) | OPMA | OPQ | CDER

Michael Chasey
Supervisory Consumer Safety Officer
Division of Pharmaceutical Quality Programs (DPQP)
Office of Pharmaceutical Quality Operations (OPQO)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Regulatory Affairs (ORA) | FDA

2:10 – 2:40

Questions & Panel Discussion

Keduo Qian, Rajib Paul, Bo Jiang, Paul Schwartz, Olugbenga (Gbenga) Okubadejo, Lane Christensen, Michael Chasey, and

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

2:40 – 2:50: BREAK

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DAY TWO: Thursday, April 13, 2023

2:50 – 3:15

Submitting in eCTD: Most Common submission issues and FDA plans for eCTD v4.0

Latest on eCTD validations that apply to study data; How FDA's eCTD v4 Implementation is going

Jonathan Resnick
Project Management Officer
Office of Business Informatics (OBI) | CDER

3:15 – 3:30

CDER NextGen Portal: What's New?

Seyoum Senay
Supervisory Operations Research
OBI | CDER

3:30 – 3:50

Impact Assessment of the 2021 Data Integrity Notifications to Sponsors

The presentation will provide an overview of the assessment of the impact on relevant stakeholders, following notifications to the sponsors in September 2021, related to data integrity concerns at 2 CRO facilities. Lessons learned and steps for mitigating similar occurrences will be discussed.

Nilufer Tampal, PhD
Associate Director for Scientific Quality
OB | OGD | CDER

3:50 – 4:05

Risk Factors for Benzene Contamination

This presentation highlights the Agency's interpretation of ICH Q3C with regards to proper control of benzene. Recent communications on benzene contamination by the Agency will be summarized.

Pallavi Nithyanandan, PhD
Director, Compendial Operations and Standards Staff (COSS) | OPPQ | OPQ | CDER

4:05 – 4:25

Approaches to Mitigate The Risk of Nitrosamine Impurities in Pharmaceuticals

This presentation highlights advances in assessing and mitigating the risk of nitrosamine contamination in drug products.

David Keire, PhD
Director, Office of Testing and Research (OTR)
OPQ | CDER

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DAY TWO: Thursday, April 13, 2023

4:25 – 4:45

Questions & Panel Discussion

Jonathan Resnick, Seyoum Senay, Nilufer Tampal, Pallavi Nithyanandan, David Keire and **Likan Liang, PhD**
Branch Chief, DLBP II | OLDP | OPQ | CDER

4:45 – 4:55

Day Two Closing

4:55: ADJOURN FORUM

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