Version 1 – Updated September 10, 2023

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AGENDA

All times are Eastern (UTC-5)

View Start Time on World Clock

DAY ONE: Tuesday, October 31, 2023

9:00 – 9:10

Welcome

Brenda Stodart, PharmD, MS, BCGP, RAC
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 and Research (CDER)

9:10 – 9:20

FDA Keynote

Robert Califf, MD (Invited)
Commissioner of Food and Drugs
Food and Drug Administration

9:20 – 9:30

Office of Pharmaceutical Quality Keynote

Michael Kopcha, PhD, RPh
Director
Office of Pharmaceutical Quality (OPQ) | CDER

Your SBIA Host for Day One

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

DAY ONE: Tuesday, October 31, 2023

9:30 – 9:50

State of Pharmaceutical Quality

This presentation will share findings that help to characterize the state of pharmaceutical quality for U.S. consumers and patients and describe OPQ's role in assuring pharmaceutical quality.

Neil Stiber, PhD
Associate Director for Science and Communication
Office of Quality Surveillance (OQS)
OPQ | CDER

Session 1 (9:50 AM – 12:00 PM)
The Quality Assessment

9:50 – 10:20

Quality Assessment Updates

This talk will present a broad overview of the quality assessment process and describe how OPQ is advancing this process.

Sau "Larry" Lee, PhD
Deputy Director of Science
OPQ | CDER

10:20 – 10:40

Patient - Focused Specifications

This presentation will discuss the role that patient focused specifications play in the patient-focused drug development approach and discuss considerations for setting specifications.

Susan Kirshner, PhD, MSc
Division Director
Office of Biotechnology Products (OBP)
OPQ | CDER

10:40 – 10:55: BREAK

10:55 – 11:15

Modernizing Quality Assessment of New Drugs

This presentation will describe the Knowledge-Aided Assessment and Structured Application (KASA) initiative for Investigational New Drug and New Drug Applications to improve consistency and efficiency of quality assessments.

Hong Cai, PhD
Division Director
Office of New Drug Products (ONDP)
OPQ | CDER

11:15 – 11:35

Collaborating for Generic Drug Development and Approval Success: A Regulatory Perspective

This talk will discuss challenges faced by the generic industry and regulatory authorities and the value of collaboration between them, as well as the efforts to ensure success.

Yue "Helen" Teng, PhD
Division Director
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

11:35 – 12:00

Q&A Panel

Sau "Larry" Lee, Susan Kirshner, Hong Cai, and **Yue "Helen" Teng**

12:00 – 1:00 PM: LUNCH BREAK

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DAY ONE: Tuesday, October 31, 2023

1:00 – 1:15

Inspections in a Post-Pandemic World

This talk will discuss lessons learned during the COVID-19 public health emergency and how they will shape the future of inspections moving forward.

Alonza Cruse
Director
Office of Pharmaceutical Quality Operations (OPQO)
Office of Regulatory Affairs (ORA) | FDA

1:15 – 1:30

Pre-license Inspections: What Industry Should Know

This talk will cover the pre-license inspection (PLI) process for CDER-regulated Biologics License Applications, including common deficiencies observed.

Christopher Downey, PhD
Supervisory Chemist
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

1:30 – 1:50

Q&A Panel

Alonza Cruse and **Christopher Downey**

1:50 – 2:00 PM: BREAK

Session 2 (2:00 – 4:30)
Quality Policy

2:00 – 2:20

Overview of Policy Document Options, Development, and Oversight

This presentation will give an overview of policy development concepts, policy tools and their scope, and policy finalization for implementation.

Leila Wieser, BA, Master's Certification (Publications)
Supervisory Senior Advisor
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

2:20 – 2:35

International Harmonization: Ensuring Availability of Quality Medicine

This talk will explain the vital role that international harmonization plays in ensuring the availability of quality medicines.

Theresa Mullin, PhD
Associate Director for Strategic Initiatives
CDER

2:35 – 3:00

ICH Q12 Implementation: What Does Industry Need to Know

This presentation will introduce key concepts from International Council on Harmonisation (ICH) Q12 such as the lifecycle approach, control strategies, and documentation as well as communicating regulatory considerations for comparability protocols.

Mahesh Ramanadham, PhD
CDR | USPHS
Deputy Director
OPPQ | OPQ | CDER

3:00 – 3:15: BREAK

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DAY ONE: Tuesday, October 31, 2023

3:15 – 3:30

Nitrosamines Guidance: How Policy Can Address and Mitigate Future Problems

This talk will present an overview of nitrosamine drug substance related impurities as an emerging issue and mitigation strategies.

Dongmei Lu, PhD
Pharmacologist
OPPQ | OPQ | CDER

3:30 – 3:45

USP & FDA: A Symbiotic Relationship to Ensure Quality

This presentation will provide an overview of FDA-U.S. Pharmacopeia collaboration in the development of standards, as well as the role of industry stakeholders in the development of USP monographs and other standards.

Pallavi Nithyanandan, PhD
Director
OPPQ | OPQ | CDER

3:45 – 3:55

Not So Complex? Product-Specific Guidance Updates

This talk will cover how OPQ research informs product-specific guidances and supports the development of generic drugs.

Xiaoming Xu, PhD
Division Director
Office of Testing and Research (OTR)
OPQ | CDER

3:55 – 4:25

Q&A Panel

Leila Wieser, Mahesh Ramanadham, Dongmei Lu, Pallavi Nithyanandan, and **Xiaoming Xu**

4:25: ADJOURN DAY ONE

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DAY TWO: Wednesday, November 1, 2023

9:00 – 9:10

Day Two Welcome

Forest "Ray" Ford, PharmD, BCPS
Captain | United States Public Health Service (USPHS)
Pharmacist | Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

9:10 – 9:30

Featured Presentation: Project ORBIS

This presentation will provide the history and current status of Project ORBIS and give insight into the future directions of the program.

Angelo De Claro, MD
Division Director
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND) | CDER

Session 1 (9:30 AM – 12:00 PM)
Supply Chain Quality

9:30 – 9:50

Testing of High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol

FDA will discuss recent compliance actions taken in the wake of reports of fatal poisonings of consumers (outside of the U.S. only) who ingested drug products that were manufactured with DEG- or EG-contaminated components.

Matthew Dionne, PharmD
CAPT, USPHS
Compliance Officer
Office of Manufacturing Quality (OMQ)
Office of Compliance (OC) | CDER

9:50 – 10:10

Microbiological Quality Considerations in Non-Sterile Drug Manufacturing

FDA will discuss recent compliance cases involving microbial contamination as well as a draft guidance to assist manufacturers of active ingredients and finished dosage forms with establishing and meeting appropriate quality standards in accord with CGMP requirements.

Timothy Pohlhaus, PhD
Consumer Safety Office
OMQ | OC | CDER

10:10 – 10:30

Q&A Panel

Matthew Dionne and **Timothy Pohlhaus**

10:30 – 10:45: BREAK

DAY TWO: Wednesday, November 1, 2023

10:45 – 11:05

Quality Management Maturity

This presentation will discuss quality management maturity (QMM), the reasons for developing a QMM program, and program development to date.

Nandini Rakala, PhD, MS,
Visiting Associate & Data Scientist
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ) | CDER

11:05 – 11:20

Drug Quality Sampling and Testing

This talk will provide an overview of the Office of Quality Surveillance's Drug Quality Sampling and Testing Program, including the process for selecting products and firms for sampling, key accomplishments, and the future of the program.

Stephen Cahill, MBA
Operations Research Analyst
OQS | OPQ | CDER

11:20 – 11:40

CDER Site Selection Model

This presentation will discuss CDER's Site Selection Model, which prioritizes sites for surveillance inspections, including its purpose and objectives and the factors it considers, such as site type and compliance history.

John Wan, MBA
Supervisory Operations Research
OQS | OPQ | CDER

11:40 – 12:00

Q&A Panel

Nandini Rakala, Stephen Cahill, and **John Wan**

12:00 – 1:00: LUNCH BREAK

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DAY TWO: Wednesday, November 1, 2023

Session 1 (1:00 – 3:25)
Advancing Manufacturing

1:00 – 1:20

CDER's Emerging Technology Program

This talk will provide updates on CDER's Emerging Technology Program, which provides engagement opportunities for developers of emerging technologies, including the formalization of the program.

Tom O'Connor, PhD
Deputy Director
Office of Testing and Research (OTR)
OPQ | CDER

1:20 – 1:40

FRAME: Supporting Advanced Manufacturing Technologies

This presentation will describe the progress of CDER's Framework for Regulatory of Advanced Manufacturing Evaluation (FRAME) Initiative, which provides clarity and reduces uncertainty for developers of advanced manufacturing technologies.

Adam Fisher, PhD
Director of Science Staff
OPQ | CDER

1:40 – 1:45: BREAK

1:45 – 2:15

Implementation of ICH Q13 Continuous Manufacturing Guidance

This presentation will give an overview of the ICH Q13 guidance and considerations for implementing continuous manufacturing processes.

Rapti Madurawe, PhD
Division Director
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

2:15 – 2:30

Continuous Manufacturing to Improve Pharmaceutical Quality: Research Examples and Opportunities

This talk will cover OPQ's scientific research supporting advanced manufacturing, such as research in process modelling. In addition, this talk will highlight how drug product manufacturers might benefit from process intensification.

Geng "Michael" Tian, PhD
LCDR | USPHS
Branch Chief
OTR | OPQ | CDER

2:30 – 2:45

AI in Manufacturing of Pharmaceutical Products: Challenges and Opportunities

This talk will cover scientific research related to the implementation of artificial intelligence (AI) for manufacturing process control, product development, and quality assessment, as well as the impact of data architecture.

Jayanti Das, PhD
Research Scientist
OTR | OPQ | CDER

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DAY TWO: Wednesday, November 1, 2023

2:45 – 3:15

Q&A Panel

Tom O'Connor, Adam Fisher, Rapti Madurawe, Geng "Michael" Tian, and **Jayanti Das**

3:15 – 3:25

Closing Remarks

3:25: ADJOURN SYMPOSIUM

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