
Version 8 – Updated September 18, 2021

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# AGENDA

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

## DAY ONE: Tuesday, September 21, 2021

8:30 – 8:45

### Welcome

**Brenda Stodart, PharmD, BCGP, RAC**
CAPT, USPHS
*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 – 9:00

### Keynote

**Janet Woodcock, MD**
*Acting Commissioner of Food and Drugs*
Food and Drug Administration

### Your SBIA Hosts for Day One

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

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

# DAY ONE: Tuesday, September 21, 2021

## Session 1: COVID-19 Impact on Generic Drug Regulation and Evaluation

Session Leads: **Liang Zhao, PhD** (Division of Quantitative Methods & Modeling (DQMM) | Office of Research and Standards (ORS) | Office of Generics Drugs (OGD) | CDER) and **Bing Li, PhD** (Office of Bioequivalence (OB) | OGD | CDER)

9:00 – 9:20

### Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency

**Mitchell Frost, MD**
*Acting Deputy Director*
Division of Therapeutic Performance II (DTP II)
ORS | OGD | CDER

9:20 – 9:40

### Alternative Bioequivalence Approaches for Data Analysis Due to COVID-19 Related Study Interruptions

**Yuqing Gong, PhD**
*Pharmacologist*
DQMM | ORS | OGD | CDER

9:40 – 10:00

### Quality Consideration in the Development of FDA Guidance "Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency"

**Gloria Huang, PhD**
*Lead Chemist*
Division of Liquid-Based Products II (DLBP II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ) | CDER

10:00 – 10:20

### Applications and Lessons Learned for Conducting Adaptive Designs in Generic Drug Development

**Kairui (Kevin) Feng, PhD**
*Staff Fellow*
DQMM | ORS | OGD | CDER

10:20 – 10:50

### Session 1: Q&A Panel

**Mitchell Frost, Yuqing Gong, Gloria Huang, Kairui (Kevin) Feng,** and
**Kimberly Witzmann, MD**
*Acting Director*
Division of Clinical Review (DCR)
*Deputy Director*
Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER
**Stella C. Grosser, PhD**
*Director*
Division of Biometrics VIII
Office of Biostatistics (OB)
Office of Translational Sciences (OTS) | CDER

**10:50 - 11:05: BREAK**

# DAY ONE: Tuesday, September 21, 2021

## Session 2: Considerations in Assessing Generic Drug Products of Oral Dosage Forms

Session Leads: **Wei-Jhe Sun, PhD** (Division of Bioequivalence | ORS | OGD | CDER), **Fang Wu, PhD** (DQMM | ORS | OGD | CDER), and **Rong Wang, PhD** (Division of Biometrics I (DB I) | OB | OGD | CDER)

11:05 - 11:25

**Nasal Pharmacokinetic Study of Abuse-Deterrent Oxycodone HCl ER Products Following Insufflation of Physically Manipulated Products**

**Saeid Raofi, MS**
*Pharmacologist*
DTP II | ORS | OGD | CDER

11:25 – 11:45

**Advancement in the In-Vitro Evaluation of Abuse-Deterrent Formulations for Opioid Analgesics: Research and Assessment Perspectives**

**Manar Al-Ghabeish, PhD**
*Staff Fellow*
Division of Product Quality Research (DPQR)
OTR | OPQ | CDER

11:45 – 12:05

**Physiological Based Pharmacokinetic Modeling and Simulation Absorption Modeling and Virtual Bioequivalence to Support Generic Drug Development and Regulatory Decision Making for Oral Products**

**Fang Wu, PhD**
*Acting Team Lead*
DQMM | ORS | OGD | CDER

12:05 – 12:25

**Safety Assessment of Flavors in Generic Drug Products**

**Melanie Mueller, PharmD, PhD**
*Team Lead*
Division of Pharmacology/Toxicology Review (DPTR)
OSCE | OGD | CDER

12:25 – 12:55

**Session 2: Q&A Panel**

**Saeid Raofi, Manar Al-Ghabeish, Fang Wu, Melanie Mueller,** and

**Xiaoming Xu, PhD**
*Supervisory Chemist*
DPQR | OTR | OPQ | CDER

**Heather Boyce, PhD**
*Acting Team Lead*
DTP II | ORS | OGD | CDER

**12:55 - 1:30 PM: LUNCH BREAK**

# DAY ONE: Tuesday, September 21, 2021

## Session 3: Complex Generics: Complex Injectables, Ophthalmic and Otic Products, Part 1

Session Leads: **Pahala Simamora, PhD** (DLBP II | OLDP | OPQ | CDER) and **Darby Kozak, PhD** (DTP I | ORS | OGD | CDER)

1:30 - 1:50

### Advances in Iron Colloid Products: Product-Specific Guidance (PSG) Discussion

**Wenlei Jiang, PhD**
*Senior Science Advisor*
Immediate Office (IO)
ORS | OGD | CDER

1:50 – 2:10

### Advances in Iron Colloid Products: Quality Considerations When Conducting Comparability Studies

**Yiwei Li, PhD**
Branch Chief
Division of Pharmaceutical Manufacturing IV (DPMAIV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

2:10 – 2:30

### Injectable Suspensions: Tools and Methods Bridging the In Vivo and In Vitro Gap

**Bin Qin, PhD**
Staff Fellow
DTP I | ORS | OGD | CDER

2:30 – 3:00

### Session 3, Part 1: Q&A Panel

**Wenlei Jiang, Yiwei Li, Bin Qin,** and

**Bruce Lerman, PhD**
*Lead Pharmacologist*
DB I | OB | OGD | CDER

**Darby Kozak, PhD**
*Deputy Director*
DTP I | ORS | OGD | CDER

**3:00 – 3:15 PM: BREAK**

# DAY ONE: Tuesday, September 21, 2021

## Session 3: Complex Generics: Complex Injectables, Ophthalmic and Otic Products, Part 2

Session Leads: **Pahala Simamora, PhD** (DLBP II | OLDP | OPQ | CDER) and **Darby Kozak, PhD** (DTP I | ORS | OGD | CDER)

3:15 – 3:35

### Challenges in the Approval of Complex Otic and Ophthalmic Generic Products: Bioequivalence Perspectives

**Chunsheng Zhao, PhD**
*Bioequivalence Reviewer*
Division of Bioequivalence III (DB III)
OB | OGD | CDER

3:35 - 3:55

### Challenges in the Approval of Complex Otic & Ophthalmic Generic Products: Quality Perspectives

**Poonam Chopra, PhD**
*Review Chemist*
DLBP II | OLDP | OPQ | CDER

3:55 – 4:15

### Physiological Based Pharmacokinetic Modeling and Simulation to Support Generic Ophthalmic Drug Product Development and Regulatory Decision Making

**Mingliang Tan, PhD**
*Staff Fellow*
DQMM | ORS | OGD | CDER

4:15 – 4:45

### Session 3, Part 2: Q&A Panel

**Chunsheng Zhao, Poonam Chopra, Mingliang Tan, Yan Wang**, and

**Asif Rasheed, PhD**
*Senior Chemist*
DLBPI | OLDP | OPQ | CDER

**Kai Kwok, PhD**
*Senior Pharmaceutical Quality Assessor*
DLBPII | OLDP | OPQ | CDER

4:45 – 4:50

### Day 1, Closing Remarks

**Lei Zhang, PhD**
Deputy Director
ORS | OGD | CDER

**4:50 PM: DAY ONE ADJOURN**

## DAY TWO: Wednesday, September 22, 2021

8:30 – 8:40

### Day Two Welcome

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

### Your SBIA Hosts for Day Two

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

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

## Session 4: Cutting Edge Science in Complex Generics

Session Leads: **Lei Zhang, PhD** (ORS | OGD | CDER) and **Lucy Fang, PhD** (DQMM | ORS | OGD | CDER)

8:40 – 9:00

### Utility of Artificial Intelligence to Facilitate the Development and Regulatory Assessment of Complex Generic Drugs

**Meng Hu, PhD**
*Acting Team Lead*
DQMM | ORS | OGD | CDER

9:00 – 9:20

### Model-Integrated Evidence for Bioequivalence Assessment of Complex Generic Drugs

**Miyoung Yoon, PhD**
*Acting Team Lead*
DQMM | ORS | OGD | CDER

9:20 – 9:40

### Scanning Electron Cryomicroscopy (Cryosem) for Characterization of Complex Drug Products

**Huzeyfe Yilmaz, PhD**
*Staff Fellow*
Division of Complex Drug Analysis (DCDA)
OTR | OPQ | CDER

9:40 – 10:00

### Advanced Imaging and Data Analysis to Support Compositional Structure Similarity of Polymeric Formulations

**Yan Wang, PhD**
*Acting Team Lead*
DTP I | ORS | OGD | CDER

## DAY TWO: Wednesday, September 22, 2021

10:00 – 10:30

**Session 4: Q&A Panel**

**Meng Hu, Miyoung Yoon, Huzeyfe Yilmaz, Yan Wang,** and

**Robert Lionberger, PhD**
*Director*
ORS | OGD | CDER

**Daniel Willett, PhD**
*Chemist*
DCDA | OTR | OPQ | CDER

**10:30 – 10:45 AM: BREAK**

## Session 5: Complex Generics: Nasal and Inhalation Products

Session Leads: **Changning Guo, PhD** (DCDA | OTR | OPQ | CDER)**, Michael Spagnola, MD** (Division of Clinical Safety and Surveillance (DCSS) | OSCE | OGD | CDER)**,** and **Sneha Dhapare, PhD** (DTP I | ORS | OGD | CDER)

10:45 – 11:05

**Product-Specific Considerations for Alternative Bioequivalence (BE) Approaches to Comparative Clinical Endpoint BE Studies**

**Susan Boc, PhD**
*Scientific Researcher*
DTP I | ORS | OGD | CDER

11:05 – 11:25

**Approaches for studies interrupted due to COVID-19 for Nasal and Inhalation Products**

**Vipra Kundoor, PhD**
*Pharmacologist*
DB I | OB | OGD | CDER

11:25 – 11:45

**Demonstrating Bioequivalence with Inhalation Spray Drug Products**

**Sneha Dhapare, PhD**
*Visiting Associate*
DTP I | ORS | OGD | CDER

11:45 – 12:05

**Comparative Analyses for Generic Oral Inhalers**

**Michael Spagnola, MD**
*Lead Physician*
DCSS | OSCE | OGD | CDER

## DAY TWO: Wednesday, September 22, 2021

12:05 – 12:35

**Session 5: Q&A Panel**

**Susan Boc, Vipra Kundoor, Sneha Dhapare, Michael Spagnola,** and

**Bryan Newman, PhD**
*Acting Team Lead*
DTP I | ORS | OGD | CDER

**Changning Guo, PhD**
Supervisory Chemist
DCDA | OTR | OPQ | CDER

**Bing Cai, PhD**
Director
DLBP I | OLPD | OPQ | CDER

**12:35 - 1:10: LUNCH BREAK**

## Session 6: Complex Generics: Topical Products, Part 1

Session Leads: **Ying Fan, PhD** (DCR | OSCE | OGD | CDER), and **Tannaz Ramezanli, PhD, PharmD** (DTP I | ORS | OGD | CDER)

1:10 – 1:30

**"No Difference" Standard vs. Q1|Q2 Sameness for Topical Drug Products**

**Megan Kelchen, PhD**
*Pharmacologist*
DTP I | ORS | OGD | CDER

1:30 – 1:50

**Use of Q3 Characterization Tests for Topical Semisolid Drug Products**

**Sam Raney, PhD**
*Associate Director for Science*
IO | ORS | OGD | CDER

1:50 – 2:10

**Recent Research Related to Q3 Characterization of Topical Products Containing Porous Microparticles**

**Ahmed Zidan, PhD**
*Senior Pharmacologist*
DPQR | OTR | OPQ | CDER

2:10 – 2:40

**Challenges and Considerations with Model-based Virtual Bioequivalence Assessments for Generic Dermatological Products**

**Eleftheria Tsakalozou, PhD**
*Staff Fellow*
DQMM | ORS | OGD | CDER

**Khondoker Alam, PhD**
*Staff Fellow*
DQMM | ORS | OGD | CDER

## DAY TWO: Wednesday, September 22, 2021

2:40 – 3:10

**Session 6, Part 1: Q&A Panel**

**Megan Kelchen, Sam Raney, Ahmed Zidan, Khondoker Alam, Eleftheria Tsakalozou,** and **Markham Luke, MD, PhD**
*Director*
DTP I | ORS | OGD | CDER

**3:10 – 3:20 PM: BREAK**

## Session 6: Complex Generics: Topical Products, Part 2

Session Leads: **Ying Fan, PhD** (DCR | OSCE | OGD | CDER), and **Tannaz Ramezanli, PhD, PharmD** (DTP I | ORS | OGD | CDER)

3:20 – 3:40

**Common Issues Identified in In-vitro Release Test (IVRT) and In-vitro Permeation Test (IVPT) Studies Submitted in ANDA to Support Bioequivalence for Topical Products**

**Josephine Aimiuwu, PhD**
*Pharmacologist*
DB II | OB | OGD | CDER

3:40 – 4:00

**Theoretical Principles and Best Practices: In Vitro Release Test**

**Tannaz Ramezanli, PhD, PharmD**
*Pharmacologist*
DTP I | ORS | OGD | CDER

4:00 – 4:20

**Theoretical Principles and Best Practices: In Vitro Permeation Test**

**Priyanka Ghosh, PhD**
*Acting Team Lead*
DTP I | ORS | OGD | CDER

4:20 – 4:50

**Session 6, Part 2: Q&A Panel**

**Josephine Aimiuwu, Tannaz Ramezanli, Priyanka Ghosh, Markham Luke,** and **Sam Raney**

4:50 – 5:00

**Closing Remarks**

**Robert Lionberger, PhD**
*Director*
ORS | OGD | CDER

**5:00: ADJOURN WORKSHOP**