# Small Business and Industry Assistance
# Advancing Generic Drug Development 2024
September 24 & 25

Version 4 – Updated July 22, 2024

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**The Event Page on SBIAevents.com**
*Add Event to Your Calendar*

# AGENDA

All times are Eastern (UTC-5)
*View Start Time on World Clock*

## DAY ONE: Tuesday, September 24, 2024

8:30 – 8:45

### Welcome

**Brenda Stodart, PharmD, MS, BCGP, RAC**
*Captain (CAPT), 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)

8:45 – 9:00

### Keynote

**Speaker TBD**

### Your SBIA Hosts

**Brenda Stodart, PharmD, MS, BCGP, RAC**
*CAPT, USPHS, Pharmacist*
SBIA | DDI | OCOMM | CDER

**Nora Lim, PharmD, BCPS**
*Lieutenant Commander (LCDR), USPHS, Pharmacist*
SBIA | DDI | OCOMM | CDER

# DAY ONE: Tuesday, September 24, 2024

## Session 1: Scientific and Regulatory Considerations for In Vitro Release Test (IVRT) for Complex Products

Session Leads: **Wenlei Jiang, PhD**, *Senior Advisor for Innovation and Strategic Outreach*, Office of Research and Standards (ORS) | Office of Generic Drugs (OGD) | CDER and
**Yan Wang, PhD**, *Lead Pharmacologist / Acting Deputy Division Director*, Division of Therapeutic Performance I (DTP I) | ORS | OGD | CDER

9:00 – 9:15

### IVRT Methods for In Situ Depot-Forming Long-Acting Injectable Products

**Agm (Abu) Mostofa, PhD**
*Pharmacologist*
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB) | OGD | CDER

9:15 – 9:30

### Nano-Size Complex Products IVRT

**Thilak Mudalige, PhD**
*Research Chemist*
Arkansas Human & Animal Food Laboratory (ARLHAF) | Office of Human & Animal Food Laboratory Operations (OHAFLO) | Office of Regulator Science (ORS) Office of Regulatory Affairs (ORA)

9:30 – 9:45

### Application of Adaptive Perfusion as In Vitro Release Testing Method to Improve Understanding and Assessment of Complex Drug Products

**Dongkai Zhu, PhD**
*Visiting Associate*
Division of Pharmaceutical Quality Research VI (DPQR VI)
Office of Pharmaceutical Quality Research (OPQR)
Office of Pharmaceutical Quality (OPQ) | CDER

9:45 – 10:15

### Session 1: Q&A Panel

**Agm (Abu) Mostafa, Thilak Mudalige, Dongkai Zhu** and

**Hee Sun Chung, PhD**
*Lead Pharmacologist*
DBIDBI | OB | OGD | CDER

**Xiaoming Xu, PhD**
*Division Director*
Division of Pharmaceutical Quality Research V (DPQR V)
OPQR | OPQ | CDER

**10:15 – 10:30: BREAK**

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# DAY ONE: Tuesday, September 24, 2024

## Session 2: Research to Support Guidance Development for Topical Drug Products

Session Leads: **Ahmed Zidan, PhD,** *Senior Staff Fellow,* DPQR V | OPQR | OPQ | CDER and **Priyanka Ghosh, PhD,** *Lead Pharmacologist,* DTP I | ORS | OGD | CDER

10:30 – 10:45

### Current Trends in Product-Specific Guidance (PSG) Development & Revisions for Topical Products

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

10:45 – 11:00

### Enhanced Understanding of Structure Performance Relationship Using Modeling and Simulation- A Case Study with Dapsone Topical Gel

**Eleftheria Tsakalozou, PhD**
*Lead Pharmacologist*
Division of Quantitative Methods and Modeling (DQMM)
ORS | OGD | CDER

11:00 – 11:15

### Approaches for Evaluation of Formulation Differences on Performance of Topical Products

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

11:15 – 11:45

### Session 2: Q&A Panel

**Megan Kelchen, Eleftheria Tsakalozou, Tannaz Ramezanli** and

**Hiren Patel, PhD**
*Senior Staff Fellow*
Division of Bioequivalence II (DBIDBII) | OB | OGD | CDER

**Pahala Simamora, PhD**
*Division Director*
Division of Product Quality Assessment IX (DPQA IX) | Office of Product Quality Assessment II (OPQA II) | OPQ | CDER

**11:45 – 1:00 PM: LUNCH BREAK**

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# DAY ONE: Tuesday, September 24, 2024

## Session 3: Research to Support Guidance Development for Inhalation Drug Products

Session Leads: **Ke Ren, PhD,** *Acting Deputy Division Director,* Division of Bioequivalence III (DBIII) | OB | OGD | CDER and **Bettina McGraw, MD, FAAP,** *Physician,* Division of Clinical Review (DCR), Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

1:00 – 1:15

### Orally Inhaled Drug Product PSGs: General Considerations Using the Alternative Bioequivalence (BE) Approach In Lieu of Comparative Clinical Endpoint (CCEP) BE Study for Suspension-Based Metered Dose Inhalers

**Liangfeng Han, MD, PhD**
*Clinical Analyst*
DTP I | ORS | OGD | CDER

1:15 – 1:30

### Orally Inhaled Drug Product PSGs: Considerations for Using Modeling and Simulation with Alternative BE Approaches

**Ross Walenga, PhD**
*Senior Chemical Engineer*
DQMM | ORS | OGD | CDER

1:30 – 1:45

### OPQR Testing & Research to Support Guidance Development of Inhalation Products

**Changning Guo, PhD**
*Supervisory Chemist*
Division of Pharmaceutical Quality Research II (DPQR II)
OPQR | OPQ | CDER

1:45 – 2:15

### Session 3: Q&A Panel

**Liangfeng Han, Ross Walenga, Changning Guo** and
**Elizabeth Bielski, PhD**
*Senior Pharmacologist*
DTP I | ORS | OGD | CDER

**Zhen Xu, PhD**
*Senior Staff Fellow*
DBIII | OB | OGD | CDER

**2:15 – 2:30 PM: BREAK**

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# DAY ONE: Tuesday, September 24, 2024

## Session 4: Outlook for Drug-Device Combination Products

Session Leads: **William Chong, MD**, *Director*, OSCE | OGD | CDER and **Andrew Babiskin, PhD**, *Lead Pharmacokineticist*, DQMM | ORS | OGD | CDER

2:30 – 2:50

### Drug-Device Combination Products – A New Methodology for Evaluation

**Christina Streets, MD**
*Senior Physician*
DCR | OSCE | OGD

**Betsy Ballard, MD**
*Medical Officer*
DTP I | ORS | OGD | CDER

2:50 – 3:10

### Approaches to Analyzing Comparative Use Human Factors Studies

**Jing (Jenny) Wang, PhD**
*Visiting Associate*
DQMM | ORS | OGD | CDER

3:10 – 3:30

### Session 4: Q&A Panel

**Christina Streets, Betsy Ballard, Jing (Jenny) Wang** and

**Somesh Chattopadhyay, PhD**
*Lead Mathematical Statistician*
Division of Biometrics VIII (DB VIII) | Office of Biostatistics (OB)
Office of Translational Sciences (OTS) | CDER

**William Chong, MD**
*Director*
OSCE | OGD | CDER

3:30 – 3:35

### Day One Closing Remarks

**Sau (Larry) Lee, PhD**
*Deputy Director of Operations*
OPQ | CDER

**3:35 PM: Broadcast for Virtual Attendees Ends**

3:35 – 4:35

### Poster Sessions / Walkthrough for In-Person Attendees / Presenters Available for Q&A

4:35 – 5:30 PM:
**NETWORKING OPPORTUNITY**

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

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## DAY TWO: Wednesday, September 25, 2024

9:00 – 9:10

### Welcome

**Brenda Stodart, PharmD, MS, BCGP, RAC**
*CAPT*, USPHS, *Pharmacist*
*Director,* Small Business, and Industry Assistance (SBIA)
DDI | OCOMM | CDER

## Session 5A: Spotlight Generic Drug Review Challenges and Solutions

Session Leads: **Sheela Rajesh, PhD,** *Senior Pharmaceutical Quality Assessor*, DPQA IX | OPQA II | OPQ | CDER and **Eric Pang, PhD,** *Senior Chemist,* DTP I | ORS | OGD | CDER

9:10 – 9:30

### Teriparatide Injection First Generic Approval: Quality-Related Review Considerations

**Tina Jiao, MS**
*Chemist*
Division of Product Quality Assessment IV (DPQA IV) | OPQA I | OPQ | CDER

9:30 – 9:50

### Quality Considerations for First Generic Oral Solutions

**Maria Flynn, PhD**
*Senior Pharmaceutical Quality Assessor*
Division of Product Quality Assessment VIII (DPQA VIII) | OPQA II | OPQ | CDER

9:50 – 10:10

### Quality Considerations for First Generic Tiotropium Bromide Capsule-Based Dry Powder Inhalers (DPIs)

**Nashwa El-Gendy, PhD**
*Senior Pharmaceutical Quality Assessor*
Division of Product Quality Assessment V (DPQA V) | Office of Product Quality Assessment I (OPQA I) | OPQ | CDER

10:10 – 10:40

### Session 5A: Q&A Panel

**Tina Jiao, Maria Flynn, Nashwa El-Gendy** and

**Yili Li, PhD**
*Senior Pharmaceutical Quality Assessor*
Division of Product Quality Assessment XI (DPQA XI) | OPQA II | OPQ | CDER

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

**10:40 – 11:00 AM: BREAK**

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## DAY TWO: Wednesday, September 25, 2024

## Session 5B: Spotlight Generic Drug Review Challenges and Solutions

Session Leads: **Deyi Zhang, PhD,** *Senior Chemist,* DTP I | ORS | OGD | CDER and **Ross Walenga, PhD,** *Senior Chemical Engineer,* DQMM | ORS | OGD | CDER

11:00 – 11:20

### Totality of Evidence Including Physiologically Based Pharmacokinetic (PBPK) Modeling to Support BE Assessment and Approval of Mesalamine Delayed Release Tablets

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

**Fang Wu, PhD**
*Senior Pharmacologist*
DQMM | ORS | OGD | CDER

11:20 – 11:40

### Challenges and Progress in Emerging Complex Generic Oligonucleotide Products

**Likan Liang, PhD**
*Supervisory Chemist*
Division of Product Quality Assessment X (DPQA X) | OPQA II | OPQ | CDER

11:40 – 12:00

### The Journey of First Approvals of Complex Generic Long-acting Injectable Products

**Yan Wang, PhD**
*Lead Pharmacologist / Acting Deputy Division Director*
DTP I | ORS | OGD | CDER

12:00 – 12:30

### Session 5B: Q&A Panel

**Yang Lu, Fang Wu, Likan Liang, Yan Wang** and

**Hansong Chen, PharmD**
*Senior Interdisciplinary Scientist*
Division of Product Quality Assessment XII (DPQA XII) | OPQA II | OPQ | CDER

**12:30 – 2:00 PM: LUNCH BREAK & POSTER VIEWING**

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## DAY TWO: Wednesday, September 25, 2024

## Session 6: Ensuring Efficient and Consistent High Quality Generic Drug Development

Session Leads: **Manar Al-Ghabeish, PhD,** *Staff Fellow,* Division of Therapeutic Performance II (DTP II) | ORS | OGD | CDER and **Diana Vivian, PhD,** *Associate Director,* DBII | OB | OGD | CDER

2:00 – 2:20

### Guidance for Industry: Content and Format of Composition Statement and Corresponding Statement of Ingredients in Labeling in NDAs and ANDAs

**Greg Huang, PhD**
*Senior Chemist*
DPQA IX | OPQA II | OPQ | CDER

2:20 – 2:40

### Analysis of First Cycle ANDA Approval and Major Deficiencies Encountered from In Vitro and In Vivo Bioequivalence Study Perspectives

**Fang Lu, PhD**
*Lead Pharmacologist*
DBI | OB | OGD | CDER

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

2:40 – 3:00

### ICH M13A: First ICH Guideline for Bioequivalence

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

3:00 – 3:20

### Model-Integrated Evidence (MIE) Industry Meeting Pilot Program for Generic Drugs: First-Year Review

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

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# DAY TWO: Wednesday, September 25, 2024

3:20 – 4:00

## Session 6: Q&A Panel

**Greg Huang, Fang Lu, Priyanka Ghosh, Lei Zhang, Yuqing Gong** and

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

**Rachel Erdman, JD**
*Regulatory Counsel*
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP) | OGD | CDER

4:00 – 4:15

## Closing Remarks

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

**4:15 PM: WORKSHOP ADJOURN**

All times shown are Eastern (UTC-5)

## List of Acronyms Used in This Document:

Board Certified Geriatric Pharmacist (BCGP)

Board Certified Pharmacotherapy Specialists (BCPS)

Captain (CAPT)

Center for Drug Evaluation and Research (CDER)

Division of Bioequivalence I (DBI)

Division of Bioequivalence II (DBII)

Division of Bioequivalence III (DBIII)

Division of Biometrics VIII (DB VIII)

Division of Clinical Safety and Surveillance (DCSS)

Division of Drug Information (DDI)

Division of Pharmaceutical Quality Research (DPQR)

Division of Product Quality Assessment (DPQA)

Division of Quantitative Methods & Modeling (DQMM)

Division of Therapeutic Performance I (DTP I)

Division of Therapeutic Performance II (DTP II)

Doctor of Medicine (MD)

Doctor of Pharmacy (PharmD)

Doctor of Philosophy (PhD)

Food and Drug Administration (FDA)

Lieutenant Commander (LCDR)

Master of Science (MS)

Office of Bioequivalence (OB)

Office of Biostatistics (OB)

Office of Communications (OCOMM)

Office of Generic Drugs (OGD)

Office of Pharmaceutical Quality (OPQ)

Office of Pharmaceutical Quality Research (OPQR)

Office of Product Quality Assessment (OPQA)

Office of Regulatory Affairs (ORA)

Office of Research and Standards (ORS)

Office of Safety & Clinical Evaluation (OSCE)

Office of Translational Sciences (OTS)

Regulatory Affairs Certification (RAC)

Small Business and Industry Assistance (SBIA)

United States Public Health Service (USPHS)