Small Business and Industry Assistance

Advancing Generic Drug Development 2024

September 24 & 25

Version 5 – Updated August 2, 2024

For files and resources, please visit

The Event Page on SBIAevents.com

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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

Robert M. Calif, MD, MACC
Commissioner of Food and Drugs
U.S. Food and Drug Administration

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.

All times shown are Eastern (UTC-5)

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

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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)