Advancing Generic Drug Development 2025
October 7 – 8, 2025

AGENDA

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

DAY ONE: Tuesday, October 7, 2025

9:00 – 9:15
Welcome

Maria Monroy-Osorio
Regulatory Health Project Manager
ORS | OGD | CDER | FDA

9:15 – 9:30
Keynote Speaker

Darby Kozak, PhD
Deputy Director
OGD | CDER | FDA

DAY ONE: Tuesday, October 7, 2025

Session 1: Insights to Product-Specific Guidance for Complex Products: From Research to Standards

Session Leads
Wenlei Jiang, PhD, *Senior Advisor for Innovation and Strategic Outreach,*
ORS | OGD | CDER | FDA
Nahid Kamal, PhD, *Pharmacologist,* DPQRV | OPQR | OPQ | CDER | FDA

9:30 – 9:35
Session Introduction

Wenlei Jiang, PhD
Senior Advisor for Innovation and Strategic Outreach
ORS | OGD | CDER | FDA

9:35 – 9:55
SME Triage Team: Office of Pharmaceutical Quality Research & Office of Research and Standards Product-Specific Guidance Development

Rangeeta Kumari
Project Manager
OPQR | OPQ | CDER | FDA

9:55 – 10:15

SME Triage Team Case Study: Complex Implant Products – Excipient Sameness, Characterization and Bioequivalence Challenges

Nahid Kamal, PhD
Pharmacologist
DPQRV | OPQR | OPQ | CDER | FDA

10:15 – 10:35

Product-Specific Guidance Revisions: Update on Metered Dose Inhaler & Dry Powder Inhaler

Liangfeng Han, MD, PhD
Clinical Analyst
DTPI | ORS | OGD | CDER | FDA

10:35 – 10:55

Streamlining Recommendations for Topical and Mucosal Products

Megan Kelchen, PhD
Senior Pharmacologist
DTPI | ORS | OGD | CDER | FDA

10:55 – 11:15: BREAK

11:15 – 12:00

Session 1: Q&A Panel

Rangeeta Kumari
Project Manager
OPQR | OPQ | CDER | FDA

Megan Kelchen, PhD
Senior Pharmacologist
DTPI | ORS | OGD | CDER | FDA

Nahid Kamal, PhD
Pharmacologist
DPQRV | OPQR | OPQ | CDER | FDA

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

Liangfeng Han, MD, PhD
Clinical Analyst
DTPI | ORS | OGD | CDER | FDA

Xiaoming Xu, PhD
Division Director
DPQRV | OPQR | OPQ | CDER | FDA

Wenlei Jiang, PhD
Senior Advisor for Innovation and Strategic Outreach
ORS | OGD | CDER | FDA

12:00 – 1:00: Lunch

All times shown are Eastern (UTC-5)

DAY ONE: Tuesday, October 7, 2025

Session 2: Novel Bioequivalence Study Design Recommendations

Session Leads

Angelique Besold, PhD, *Senior Pharmacologist,* DBII | OB | OGD | CDER | FDA
Andrew Babiskin, PhD, *Lead Pharmacokineticist,* DQMM | ORS | OGD | CDER | FDA

1:00 – 1:05

Session Introduction

Angelique Besold, PhD
Senior Pharmacologist
DBII | OB | OGD | CDER | FDA

1:05 – 1:25

Biopharmaceutics Classification System Waiver Option in Product-Specific Guidances

CDR Yi Zhang, PhD
Senior Scientific Advisor
DTPII | ORS | OGD | CDER | FDA

1:25 – 1:50

Addressing Degradation Challenges in BCS Class III Biowaiver Applications Through Physiologically Based Pharmacokinetic (PBPK) Modeling

Usha Katragadda, PhD
Senior Pharmacologist
DBIII | OB | OGD | CDER | FDA

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

1:50 – 2:15

Using Modeling and Simulation to Correct Carryover for Long Half-Life Drug with Incomplete Washout

Min Tzu Chung, PharmD
Pharmacokineticist
DBIII | OB | OGD | CDER | FDA

Deniz Ozdin, PhD
Pharmacologist
DQMM | ORS | OGD | CDER | FDA

2:15 – 2:40

Updates and Current Landscape for Study Population Selection and Additional Mitigation Strategies in Bioequivalence Studies

Karen Li, PharmD
Pharmacologist
DTPII | ORS | OGD | CDER | FDA

Duyen Nguyen, PharmD
Pharmacologist
DTPII | ORS | OGD | CDER | FDA

All times shown are Eastern (UTC-5)

2:40 – 3:00

Extrapolation of PK Bioequivalence to an Alternative Comparator due to RLD/RS Unavailability

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

3:00 – 3:10: BREAK

3:10 – 3:55

Session 2: Q&A Panel

CDR Yi Zhang, PhD
Senior Scientific Advisor
DTPII | ORS | OGD | CDER | FDA

Duyen Nguyen, PharmD
Pharmacologist
DTPII | ORS | OGD | CDER | FDA

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

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

Min Tzu Chung, PharmD
Pharmacokineticist
DBIII | OB | OGD | CDER | FDA

Diana Vivian, PhD
Associate Division Director
DBII | OB | OGD | CDER | FDA

Wanjie Sun, PhD
Master Mathematical Statistician
DBVIII | OB | OTS | CDER | FDA

3:55 – 4:00

Day One Closing Remarks

Yan Wang, PhD
Deputy Division Director
DTPI | ORS | OGD | CDER | FDA

End Day 1 of Workshop

Join us tomorrow, October 8, 2025, at 9 a.m. ET for Day 2!

All times shown are Eastern (UTC-5)

DAY TWO: Wednesday, October 8, 2025

9:00 – 9:10

Welcome

Irfan Memon, PharmD
Regulatory Health Project Manager
ORS | OGD | CDER | FDA

DAY TWO: Wednesday, October 8, 2025

Session 3: Common Deficiencies and Resolutions: Complex Drug Substances, Complex/Critical Excipients, and Complex Products

Session Leads
Yan Wang, PhD, *Deputy Director,* DTPI | ORS | OGD | CDER | FDA
Dominick Roselle, PhD, *Supervisory Chemist*, DPQAIV | OPQAI | OPQ | CDER | FDA

9:10 – 9:15

Session Introduction

Yan Wang, PhD
Deputy Director
DTPI | ORS | OGD | CDER | FDA

9:15 – 9:35

Compositional Sameness for Complex Polymeric Excipients: Progress and remaining challenges

Bin Qin, PhD
Senior Staff Fellow
DTPI | ORS | OGD | CDER | FDA

9:35 – 10:05

Navigating Complexity: Key Considerations in Developing the Oral Semaglutide Product-Specific Guidance

Sami Nazzal, PhD
Senior Pharmacologist
DTPII | ORS | OGD | CDER | FDA

Jinhui Zhang, PhD
Senior Pharmaceutical Scientist
OPQR | OPQ | CDER | FDA

10:05 – 10:30

Case Studies: Glatiramer Acetate Subcutaneous Injectable and Pentosan Polysulfate Oral Capsules

Maotang Zhou, PhD
Division Director
DPQAXVII | OPQAIII | OPQ | CDER | FDA

Keduo Qian, PhD
Chemist
DPQAXIX | OPQAIII | OPQ | CDER | FDA

All times shown are Eastern (UTC-5)

10:30 – 10:50

Comparative Physicochemical Characterization of Iron Products

Dahui Liu, PhD
Senior Pharmaceutical Quality Assessor
DPQAIV | OPQAI | OPQ | CDER | FDA

10:50 – 11:05: BREAK

11:05 – 12:00

Session 3: Q&A Panel

Bin Qin, PhD
Senior Staff Fellow
DTPI | ORS | OGD | CDER | FDA

Maotang Zhou, PhD
Division Director
DPQAXVII | OPQAIII | OPQ | CDER | FDA

Sami Nazzal, PhD
Senior Pharmacologist
DTPII | ORS | OGD | CDER | FDA

Keduo Qian, PhD
Chemist
DPQAXIX | OPQAIII | OPQ | CDER | FDA

Jinhui Zhang, PhD
Senior Pharmaceutical Scientist
OPQR | OPQ | CDER | FDA

Dahui Liu, PhD
Senior Pharmaceutical Quality Assessor
DPQAIV | OPQAI | OPQ | CDER | FDA

12:00 – 1:00: Lunch

DAY TWO: Wednesday, October 8, 2025

Session 4: Nitrosamines: Known Issues and Practical Advice

Session Leads
Reynolds (Rey) Cantave, PharmD *Senior Regulatory Health Project Manager, Enterprise Project Management Staff, OQA* | OPQ | CDER | FDA
Christopher Morgan, PhD, *Pharmacologist,* DPTR | OSCE | OGD | CDER | FDA

1:00 – 1:05

Session Introduction

Christopher Morgan, PhD
Pharmacology
DPTR | OSCE | OGD | CDER | FDA

1:05 – 1:25

Nitrosamine Impacted Drug Products Containing BCS IV Drug Substances

Gang Zhao, PhD
Research Fellow
DTPII | ORS | OGD | CDER | FDA

All times shown are Eastern (UTC-5)

1:25 – 1:45

Addressing Potential Pitfalls in Nitrosamine Risk Assessment and Control

Matthew Vera, PhD
Supervisory Chemist
DPQAII | OPQAI | OPQ | CDER | FDA

1:45 – 2:05

Pharm/Tox Considerations for the Safety Evaluation of Nitrosamine Impurities

Xin Fu, PhD, DABT
Pharmacologist
DPTR | OSCE | OGD | CDER | FDA

2:05 – 2:50

Session 4: Q&A Panel

Gang Zhao, PhD
Research Fellow
DTPII | ORS | OGD | CDER | FDA

Rong Wang, PharmD, PhD
Associate Division Director
DBI | OB | OGD | CDER | FDA

Matthew Vera, PhD
Supervisory Chemist
DPQAII | OPQAI | OPQ | CDER | FDA

Xin Fu, PhD, DABT
Pharmacologist
DPTR | OSCE | OGD | CDER | FDA

Ee-Sunn (Joanne) Chia, PhD
Division Director
DPQAX | OPQAII | OPQ | CDER | FDA

2:50 – 3:00

Day Two Closing Remarks

Lei Zhang, PhD
Deputy Office Director
ORS | OGD | CDER | FDA

WORKSHOP ADJOURN

Thank you for joining us for this year's Advancing Generic Drug Development: Translating Science to Approval Workshop!

All times shown are Eastern (UTC-5)

List of Acronyms Used in This Document:

Center for Drug Evaluation and Research (CDER)
Division of Biometrics VIII (DBVIII)
Division of Bioequivalence I (DBI)
Division of Bioequivalence II (DBII)
Division of Bioequivalence III (DBIII)
Division of Pharmaceutical Quality Research V (DPQRV)
Division of Pharmacology/Toxicology Review (DPTR)
Division of Product Quality Assessment II (DPQAII)
Division of Product Quality Assessment IV (DPQAIV)
Division of Product Quality Assessment X (DPQAX)
Division of Product Quality Assessment XIX (DPQAXIX)
Division of Product Quality Assessment XVII (DPQAXVII)
Division of Quantitative Methods and Modeling (DQMM)
Division of Therapeutic Performance I (DTPI)
Division of Therapeutic Performance II (DTPII)
Food and Drug Administration (FDA)
Office of Bioequivalence (OB)
Office of Biostatistics (OB)
Office of Generic Drugs (OGD)
Office of Pharmaceutical Quality (OPQ)
Office of Pharmaceutical Quality Research (OPQR)
Office of Product Quality Assessment I (OPQAI)
Office of Product Quality Assessment II (OPQAII)
Office of Product Quality Assessment III (OPQAIII)
Office of Quality Assurance (OQA)
Office of Research and Standards (ORS)
Office of Safety & Clinical Evaluation (OSCE)
Office of Translational Sciences (OTS)