Advancing Generic Drug Development (AGDD): Leveraging Model-Integrated Evidence (MIE) in the Development & Approval of Generic Drugs

August 27, 2026, 8:30 am – 12:30 pm EDT

8:30 – 8:35 am — Welcome and Overview

Kori Adair, PharmD
Pharmacist
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research (CDER) | FDA

Session 1 — **Regulatory Expectations of Using Model-Integrated Evidence (MIE) in Generic Drug Development**

8:35 – 8:50 am — Overview of Recent MIE Submissions to Support Generic Drug Development: What We've Received and What It Tells Us

Yuqing Gong, PhD
Lead Pharmacologist
Division of Quantitative Methods and Modeling (DQMM)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

8:50 – 9:05 am — Quantitative Clinical Pharmacology Tools to Support Generic Drug Development: Regulatory Expectations and Case Examples

Mark Donnelly, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER

9:05 – 9:20 am — Maximizing the Regulatory Impact of MIE Submissions of Mechanistic Models for Generic Non-orally Administered Drug Products

Eleftheria Tsakalozou, PhD
Lead Pharmacologist
DQMM | ORS | OGD | CDER

9:20 – 9:35 am — Physiologically Based Pharmacokinetics (PBPK) Modeling for Oral Drug Products — Regulatory Expectations and Recommendations for Generic Drug Submissions

Arindom Pal, PhD
Pharmacokineticist
DQMM | ORS | OGD | CDER

9:35 – 9:50 am

MIE in Abbreviated New Drug Application (ANDA) Submissions: Regulatory Expectations, Frequent Pitfalls, and How to Avoid Them

Ja Hye Myung, PhD
Pharmacologist
Division of Bioequivalence III (DB III) | Office of Bioequivalence (OB)
OGD | CDER

9:50 – 10:20 am

Question and Answer Session

Moderator:
Lanyan (Lucy) Fang, PhD
Division Director
DQMM | ORS | OGD | CDER

Panelists:
Yuqing Gong, PhD
Mark Donnelly, PhD
Eleftheria Tsakalozou, PhD
Arindom Pal, PhD
Ja Hye Myung, PhD

10:20 – 10:30 am

Break

10:30 – 10:35 am

Welcome Back

Kori Adair, PharmD

Session 2

Successful MIE Case Studies Supporting Guidance Development

10:35 – 10:40 am

Overview: Role of MIE in Shaping FDA Product-Specific Guidances

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

10:40 – 10:55 am

In Silico Modeling to Guide Charcoal Block PK BE Study Recommendations for Orally Inhaled Drug Products

Ross Walenga, PhD

10:55 – 11:10 am

PBPK Modeling to Support Product-Specific Guidance Revision for Cabotegravir Long-Acting Injectable Suspension

Khondoker Alam, PhD
Senior Pharmacologist
DQMM | ORS | OGD | CDER

11:10 – 11:25 am

PBPK/Pharmacodynamic Modeling to Support Product-Specific Guidance Development for Ophthalmic Drugs

Mingliang Tan, PhD
Senior Pharmacokineticist
DQMM | ORS | OGD | CDER

11:25 – 11:40 am PBPK Absorption Modeling to Support General and Product-Specific Guidance Development

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

11:40 – 11:55 am The ICH M15 Guidance: Assessment of Model-Informed Drug Development (MIDD) Evidence

Colleen Kuemmel, PhD
Policy Analyst
Office of Clinical Pharmacology |Office of Translational Sciences | CDER

11:55 am – 12:25 pm Question and Answer Session

Moderator:
Andrew Babiskin, PhD
Deputy Division Director
DQMM | ORS | OGD | CDER

Panelists:
Ross Walenga, PhD
Mingliang Tan, PhD
Fang Wu, PhD
Colleen Kuemmel, PhD
Yuqing Gong, PhD

and joined by:
Yan Wang, PhD
Deputy Division Director
Division of Therapeutic Performance I (DTP I) | ORS | OGD | CDER

Jihong Shon, MD, PhD
Associate Director for Clinical Safety
Division of Therapeutic Performance II (DTP II) | ORS | OGD | CDER

12:25 – 12:30 pm Closing Remarks

Robert Lionberger, PhD
Director
ORS | OGD | CDER