

Advancing Generic Drug Development (AGDD): Bioequivalence Challenges for Patient-Centric Oral Formulations

June 11, 2026, 8:30am – 12:30pm 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)
- 8:35 – 8:45 am Current Landscape of Patient-Centric Formulations in Generic Drug Development: Gaps and Alternative Pathways
Karen Li, PharmD
Staff Fellow
Division of Therapeutic Performance II (DTP II)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER
- 8:45 – 9:00 am Developing Pediatric Formulations: Regulatory Considerations
Vilayat Sayeed, PhD
Division Director
Office of Product Quality Assessment II
Office of Pharmaceutical Quality (OPQ) | CDER
- 9:00 – 9:15 am Suitability Petitions: An Avenue for Patient-Centric Formulations
Andrew Fine, PharmD
Associate Director for Regulatory Affairs
Office of Safety and Clinical Evaluation
OGD | CDER
- 9:15 – 9:30 am Extrapolation Using PBPK Modeling to Support the Development of Pediatric Products
Fang Wu, PhD
Senior Pharmacologist
Division of Quantitative Methods and Modeling
ORS | OGD | CDER

- 9:30 – 10:00 am Question and Answer Session
Moderator:
To Be Announced
Karen Li
Vilayat Sayeed
Andrew Fine
Fang Wu
- 10:00 – 10:15 am Break
- 10:15 – 10:20 am Speaker Introduction
Kori Adair, PharmD
- 10:20 – 10:35 am Bioequivalence Strategies for Chewable Tablets: Regulatory Considerations
Hye Lim Lim, PharmD
Visiting Associate
DTP II | ORS | OGD | CDER
- 10:35 – 10:45 am Risk Assessment and Navigating the Regulatory Landscape for Immediate-Release Drug-Coated Sphere Formulations
Wen Cheng Yang, MD
Senior Staff Fellow
DTP II | ORS | OGD | CDER
- 10:45 – 10:55 am Dose Selection Consideration for Pharmacokinetic Bioequivalence Studies of Oral Suspension Products
Duyen Nguyen, PharmD
Staff Fellow
DTP II | ORS | OGD | CDER
- 10:55 – 11:05 am Scientific and Regulatory Considerations for Sublingual Products
Wei-Jhe Sun, PhD
Senior Staff Fellow
DTP II | ORS | OGD | CDER
- 11:05 – 11:20 am Bioequivalence Strategies for Orally Disintegrating Tablets: Regulatory Considerations
Heather Boyce, PhD
Lead Pharmacokineticist
DTP II | ORS | OGD | CDER

11:20 – 11:40 am In Vitro Feeding Tube Studies: Scientific and Regulatory Perspectives

Shamema Nasrin, PhD

Contractor

DTP II | ORS | OGD | CDER

Geng Tian, PhD

Research Officer

Division of Pharmaceutical Quality Research VI

Office of Pharmaceutical Quality Research

OPQ | CDER

11:40 – 12:20 pm Question and Answer Session

Moderator:

To Be Announced

Hye Lim Lim

Wen Cheng Yang

Duyen Nguyen

Wei-Jhe Sun

Heather Boyce

Shamema Nasrin

Geng Tian

2:20 – 12:30 pm Closing Remarks

To Be Announced