



# CDER Small Business and Industry Assistance Webinars 2025



## Navigating Controlled Correspondences to Support Generic Drug Development

February 27, 2025, 1:00 – 3:30 pm EDT

**1:00 - 1:05: Welcome and Overview**

**Kori Adair, PharmD**

*Pharmacist* | Small Business and Industry Assistance (SBIA) | Division of Drug Information (DDI)  
Office of Communications (OCOMM) | Center for Drug Evaluation and Research (CDER)

**1:05 - 1:20: Mastering Controlled Correspondences: What, When, and How**

**Yan Wang, PhD**

*Deputy Director*

Division of Therapeutic Performance I (DTP I) | Office of Research and Standards (ORS)  
Office of Generic Drugs (OGD) | CDER

**1:20 - 1:35: Controlled Correspondence on Clinical Pharmacology Topics in Generic Drug Development**

**Mark Donnelly, PhD**

*Senior Pharmacologist*

Division of Quantitative Methods and Modeling (DQMM) | ORS | OGD | CDER

**1:35 - 1:50: Navigating Formulation Assessment: Considerations When Preparing the Q1/Q2  
Sameness Inquiry**

**Qiangnan Zhang, PhD**

*Staff Fellow*

DTP I | ORS | OGD | CDER

**1:50 – 2:05: Navigating Formulation Assessment: Considerations For Products that are Not  
Required to be Q1/Q2**

**Ying Jiang, PhD**

*Chemist*

DTP I | ORS | OGD | CDER

**2:05 – 2:20: Exploring Bioequivalence Considerations for Controlled Correspondences:  
Assessment and Best Practices**

**Pamela Dorsey, PhD**

*Senior Pharmacologist*

Division of Bioequivalence III (DB III) | Office of Bioequivalence (OB) | OGD | CDER

**2:20 – 2:35: The Role of Controlled Correspondences in Supporting Safety Assessments in  
Generic Drug Development**

**Christopher Morgan, PhD**

*Pharmacologist*

Division of Pharmacology/Toxicology Review (DPTR) | Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

**2:35 - 2:55: Discussion Panel**

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

**Panelists:**

- **Robert Lionberger, PhD** | *Director, ORS* | OGD | CDER
- **Partha Roy, PhD** | *Director, Office of Bioequivalence (OB)* | OGD | CDER
- **Bill Chong, MD** | *Director, OSCE* | OGD | CDER

2:55 - 3:25: **Question and Answer Session**

**Moderator: Kori Adair, PharmD**

**Panelists:**

- **Yan Wang, PhD** | *Deputy Director, DTP I* | ORS | OGD | CDER
- **Mark Donnelly, PhD** | *Senior Pharmacologist, DQMM* | ORS | OGD | CDER
- **Qiangnan Zhang, PhD** | *Staff Fellow, DTP I* | ORS | OGD | CDER
- **Ying Jiang, PhD** | *Chemist, DTP I* | ORS | OGD | CDER
- **Pamela Dorsey, PhD** | *Senior Pharmacologist, DB III* | OB | OGD | CDER
- **Christopher Morgan, PhD** | *Pharmacologist, DPTR* | OSCE | OGD | CDER

3:25 - 3:30: **Closing Remarks**

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