CDER Small Business and Industry Assistance

Webinars 2025

Model Master Files: *Advancing Modeling and Simulation in Generic Drug Development and Regulatory Submissions*

March 13, 2025, 1:00 – 3:00 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 - 1:15: **Introduction and Overview of the Model Master File**

Lanyan (Lucy) Fang, PhD
Deputy Division Director | Division of Quantitative Methods and Modeling (DQMM) | Office of Research and Standards (ORS) | Office of Generic Drugs (OGD) | CDER

1:15 - 1:35: **Model Master Files: How to Develop and Submit One?**

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

1:35 - 1:50: **Cross-Comparison to Other Drug Master Files and Lessons Learned**

Erin Skoda, PhD
Supervisory Chemist | Division of Product Quality Assessment XVIII (DPQA XVIII)
Office of Product Quality Assessment III (OPQA III) | Office of Pharmaceutical Quality (OPQ)

1:50 - 2:25: **Discussion Panel**

Moderator: Andrew Babiskin, PhD, *Lead Pharmacokineticist,* DQMM | ORS | OGD| CDER

Panelists:

- **Robert Lionberger, PhD** | *Director*, ORS|OGD|CDER
- **Lanyan (Lucy) Fang, PhD**, *Deputy Division Director*, DQMM | ORS | OGD | CDER
- **Partha Roy, PhD** | *Director,* Office of Bioequivalence (OB) | OGD | CDER
- **Bhagwant Rege, PhD** | *Division Director*, Division of Product Quality Assessment VI (DPQA VI) Office of Product Quality Assessment I (OPQA I) | OPQ | CDER
- **Stella Grosser, PhD** | *Division Director*, Division of Biometrics VIII (DBVIII) Office of Biostatistics (OB) | Office of Translational Sciences (OTS) | CDER
- **Rajanikanth Madabushi, PhD** | *Director,* CDER Quantitative Medicine Center of Excellence (QM CoE) *Associate Director* for Guidance and Scientific Policy Office of Clinical Pharmacology (OCP) | OTS | CDER
- **Martha Nguyen, JD** | *Division Director* | Division of Policy Development (DPD) Office of Generic Drug Policy (OGDP) | OGD | CDER

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

Moderator: Kori Adair, PharmD

Panelists:

- **Eleftheria Tsakalozou, PhD** | *Lead Pharmacologist*, DQMM | ORS | OGD | CDER
- **Ross Walenga, PhD** | *Senior Chemical Engineer,* DQMM | ORS | OGD | CDER
- **Fang Wu, PhD** | *Senior Pharmacologist*, DQMM | ORS | OGD | CDER
- **Meng Hu, PhD** | *Lead Engineer*, DQMM | ORS | OGD | CDER
- **Yuqing Gong, PhD** | *Acting Lead Pharmacologist,* DQMM | ORS | OGD | CDER
- **Ethan Stier, PhD** | *Associate Director for Lifecycle Management,* OCP | OTS | CDER
- **Hao Zhu, PhD** | *Division Director, Division* of Pharmacometrics (DPM) | OCP | OTS | CDER
- **Rebecca Moody, PhD** | *Pharmaceutical Scientist,* Office of Product Quality Assessment II (OPQA II) | OPQ

2:55 - 3:00: **Closing Remarks**

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