FDA M13B Webinar: Navigating the Draft ICH M13B Additional Strengths Biowaiver Guideline

September 11, 2025, 12:00 – 2:00 pm EDT

Link to Join the Event

12:00 – 12:05 pm — Welcome

Joseph Kotsybar, PharmD
Project Manager
Office of Research and Standard (ORS) | Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER), FDA

12:05 – 12:55 pm — Presentations

Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS) | OGD | CDER | FDA

Nilufer Tampal, PhD
Associate Director of Scientific Quality
Office of Bioequivalence (OB) | OGD | CDER | FDA

Kimberly Raines, PhD
Associate Director of Science
Office of Policy for Pharmaceutical Quality | Office of Pharmaceutical Quality (OPQ) | CDER | FDA

12:55 – 1:25 pm — Panel Discussion

Moderator:
Sarah A. Ibrahim, PhD
Associate Director for Stakeholder and Global Engagement
OGD | CDER | FDA

Presenters and Additional Panelists:

David Coppersmith, JD
Regulatory Counsel
Division of Policy Development (DPD) | Office of Generic Drug Policy (OGDP) | OGD | CDER | FDA

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

Bhagwant Rege, PhD
Division Director
Office of Pharmaceutical Quality Assessment I | OPQ | CDER | FDA

Partha Roy, PhD
Director
OB | OGD | CDER | FDA

1:25 – 1:55 pm — Question and Answer Session

Moderator:
Sarah A. Ibrahim, PhD

All presenters and panelists participate

1:55 – 2:00 pm — Closing Remarks

Robert Lionberger, PhD