CDER Small Business and Industry Assistance

Webinars 2024

M13A: Bioequivalence for Immediate-Release Solid Oral Dosage Forms - *Implementing the Final Guidance*

November 21, 2024, 1:00 – 3:00 pm EDT

1:00 – 1:05 pm — 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 – 2:00 pm — Presentations

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

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

Myong-Jin (MJ) Kim, PharmD
Director | Division of Therapeutic Performance II (DTPII) | ORS | OGD

2:00 – 2:30 pm — Discussion Panel

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

Speakers and Additional Panelists:
Robert Lionberger, PhD
Director | ORS | OGD

Partha Roy, PhD
Director | OB | OGD

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

Qi Zhang, PhD
Immediate Release Drug Products Team Leader | DTPII | ORS | OGD

2:30 – 2:55 pm — Question and Answer Session

Moderator:
Kori Adair, PharmD

All presenters and panelists participate

2:55 – 3:00 pm — Closing Remarks

Robert Lionberger, PhD
Director | ORS|OGD