CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

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Model-Integrated Evidence (MIE) Industry Meeting Pilot Program

January 18, 2024, 1:00 – 3:00 pm EDT

Welcome (5 min)	**Welcome and Overview** Forest "Ray" Ford, Jr., *Captain*, United States Public Health Service *Pharmacist* Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) | Office of Communications (OCOMM) | Center for Drug Evaluation and Research (CDER)	1:00 - 1:05 pm
Opening Remarks (15 min)	**Introduction to MIE Industry Meeting Pilot Program** Liang Zhao, PhD *Director* Division of Quantitative Methods and Modeling (DQMM) | Office of Research and Standards (ORS) Office of Generic Drugs (OGD) | CDER	1:05 - 1:20 pm
Talk 1 (15 min)	**MIE Pilot Program: Process Overview** Maria Monroy-Osorio *Regulatory Health Project Manager*, ORS|OGD|CDER	1:20 - 2:35 pm
Talk 2 (15 min)	**Potential Topics for Discussion Through the MIE Industry Meeting Pilot Program** Andrew Babiskin, PhD *Lead Pharmacokineticist*, DQMM | ORS | OGD | CDER	1:35 - 1:50 pm
Talk 3 (15 min)	**Considerations and expectations when meeting with the FDA under the Industry Meeting Pilot MIE program** Eleftheria Tsakalozou, PhD *Senior Pharmacologist (Acting TL),* DQMM | ORS | OGD | CDER	1:50 – 2:05 pm
Panel Discussion (20 min)	**Moderator:** Lanyan (Lucy) Fang, PhD, *Deputy Director*, DQMM | ORS | OGD| CDER **Panelists:** • Bhagwant Rege, PhD, *Division Director*, Division of Biopharmaceutics (DB) | Office of New Drug Products (ONDP) | Office of Pharmaceutical Quality (OPQ) | CDER • Partha Roy, PhD, *Director,* Office of Bioequivalence (OB) | OGD | CDER • Robert Lionberger, PhD, Director, ORS|OGD|CDER • Liang Zhao	2:05 - 2:25 pm
Speaker Q&A Discussion (30 min)	**Moderator:** Forest "Ray" Ford, Jr. **Panelists:** • Liang Zhao • Eleftheria Tsakalozou • Andrew Babiskin • Maria Monroy-Osorio • Fang Wu, PhD, *Senior Pharmacologist*, DQMM | ORS | OGD | CDER • Meng Hu, PhD, *Lead Engineer*, DQMM | ORS | OGD | CDER	2:25 - 2:55 pm
Closing Remarks (5 min)	**Closing Remarks** Robert Lionberger or Lei Zhang	2:55 - 3:00 pm