CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

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OSIS Workshop: CDER Bioavailability/Bioequivalence Study Sites and Inspections of Good Laboratory Practice

June 13, 2024, 8:50 – 11:25 am EDT

Welcome — 8:50 - 9:00 am

Nora Lim, PharmD, BCPS
Lieutenant Commander | 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)
U.S. Food and Drug Administration (FDA)

OSIS 101 — 9:00 - 9:15 am

Tahseen Mirza, PhD
Associate Director for Regulatory Affairs
Office of Study Integrity and Surveillance (OSIS) | Office of Translational Sciences (OTS)
CDER | FDA

Collaboration, Risk Evaluation, and Surveillance Program (CREST) — 9:15 - 9:25 am

Clint Mitchell, PhD
Lead Pharmacokineticist
OSIS | OTS | CDER | FDA

Gabriel Davila, DVM *Biologist*
OSIS | OTS | CDER | FDA

BA/BE Analytical Program — 9:24 - 9:45 am

Li-Hong (Paul) Ye, PhD
Interdisciplinary Scientist
Division of New Drug Study Integrity (DNDSI)
OSIS | OTS | CDER | FDA

Q&A Panel — 9:45 - 9:55 am

Tahseen Mirza, Clint Mitchell, Gabriel Davila, Li-Hong (Paul) Ye

Break — 9:55 - 10:10 am

BA/BE Clinical Program — 10:10 - 10:30 am

Monica Javidnia, PhD
Staff Fellow
Division of Generic Drug Study Integrity (DGDSI)
OSIS | OTS | CDER | FDA

GLP Program — 10:30 - 10:50 am

Mark Seaton, PhD, DABT
Senior Pharmacokineticist
DNDSI | OSIS | OTS | CDER | FDA

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Q&A Panel

10:50 - 11:00 am

Seongeun (Julia) Cho, Mark Seaton

Discussion Panel

11:00 - 11:25 am

Moderator:**Tahseen Mirza, PhD**
Associate Director for Regulatory Affairs
OSIS | OTS | CDER | FDA

Seongeun (Julia) Cho, PhD
Division Director
DGDSI | OSIS | OTS | CDER | FDA

Kimberley Benson, PhD
Deputy Division Director
DGDSI | OSIS | OTS | CDER | FDA

Arindam Dasgupta, PhD
Deputy Division Director
DNDSI | OSIS | OTS | CDER | FDA

Charles Bonapace, PharmD
Division Director
DNDSI | OSIS | OTS | CDER | FDA