

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

June 13, 2024, 8:50 – 11:25 am EDT

<b>Welcome</b>	8:50 - 9:00 am
<b>Nora Lim, PharmD, BCPS</b> <i>Lieutenant Commander</i>   United States Public Health Service <i>Pharmacist</i>   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)	
<b>OSIS 101</b>	9:00 - 9:15 am
<b>Tahseen Mirza, PhD</b> <i>Associate Director for Regulatory Affairs</i> Office of Study Integrity and Surveillance (OSIS)   Office of Translational Sciences (OTS) CDER   FDA	
<b>Collaboration, Risk Evaluation, and Surveillance Program (CREST)</b>	9:15 - 9:25 am
<b>Gabriel Davila, DVM Biologist</b> OSIS   OTS   CDER   FDA	
<b>BA/BE Analytical Program</b>	9:24 - 9:45 am
<b>Li-Hong (Paul) Yeh, PhD</b> <i>Interdisciplinary Scientist</i> Division of New Drug Study Integrity (DNDSI) OSIS   OTS   CDER   FDA	
<b>Q&amp;A Panel</b>	9:45 - 9:55 am
<b>Tahseen Mirza, Li-Hong (Paul) Yeh, and Clint Mitchell, PhD</b> <i>Lead Pharmacokineticist</i> OSIS   OTS   CDER   FDA	
<b>Break</b>	9:55 - 10:10 am
<b>BA/BE Clinical Program</b>	10:10 - 10:30 am
<b>Monica Javidnia, PhD</b> <i>Staff Fellow</i> Division of Generic Drug Study Integrity (DGDSI) OSIS   OTS   CDER   FDA	
<b>GLP Program</b>	10:30 - 10:50 am
<b>Mark Seaton, PhD, DABT</b> <i>Senior Pharmacokineticist</i> DNDSI   OSIS   OTS   CDER   FDA	

## 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