



**AIMBE/NIH Summit on
Validation and Qualification of New *In Vitro* Tools and Models for the
Pre-Clinical Drug Discovery Process**

March 19

- 8:00 – 8:45 AM Continental Breakfast and Check-In
- 8:45 – 9:00 AM **Welcome and Goals of the Summit**
James Hickman, Ph.D., University of Central Florida, AIMBE BOD member
- 9:00 – 9:15 AM **Welcome from the AIMBE President**
Raphael Lee, MD, Sc.D., University of Chicago Medicine
- 9:15 – 9:30 AM **Address from the NIBIB Director**
Roderic I. Pettigrew, Ph.D., MD, Director, NIBIB/NIH
- Session 1: Current Perspectives on Validation**
Moderator: Mohammed Heidarani, Ph.D., CBER/FDA
- 9:30 – 9:40 AM **Introduction**
Mohammed Heidarani, Ph.D., CBER/FDA
- 9:40 – 10:15 AM **Development and Validation of New Technologies for use in the Drug Discovery and Toxicology**
Christopher Austin, MD, NCATS/NIH
- 10:15 – 10:35 AM *Break*
- 10:35 – 11:10 AM **Validation/Qualification Issues for Enabling Technologies for Drug Discovery**
David Stresser, Ph.D., BD Biosciences
- 11:10 – 11:50 PM **From Engineering Validation to Qualification of Biomarkers, an FDA Success Story**
Federico Goodsaid, Ph.D., Vertex Pharmaceuticals
- 11:50 – 12:50 PM **Reception—Lister Hill Lobby**
- Session 2: Latest Technologies for Pre-clinical Regulatory Science.**
Moderator: Rosemarie Hunziker, Ph.D., NIBIB/NIH
- 12:50 – 1:00 PM **Introduction**
Rosemarie Hunziker, Ph.D., NIBIB/NIH
- 1:00 – 1:40 PM **Experience using PBPK Models in Clinical Pharmacology Reviews**
Ping Zhao, Clinical Pharmacology CDER/FDA
- 1:40 – 2:10 PM **Functional in vitro Systems for Drug Discovery**
Mike Shuler, Ph.D., Cornell University



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- 2:10 – 2:40 PM **Organs on Chips**
Donald Ingber, MD, Ph.D., Wyss Institute/Harvard
- 2:40 – 3:00 PM **Break**
- 3:00 – 3:30 PM **Liver Construct for Drug Screening and Toxicity**
Dawn Applegate, Ph.D., CEO RegeneMed
- 3:30 – 4:00 PM **Stem Cell Technologies for Pre-clinical Drug Discovery**
Nick Thomas, Ph.D., GE Healthcare
- 4:00 – 4:30 PM **Pre-clinical Imaging Technologies**
John Elliott Ph.D., NIST
- 4:30 – 5:20 PM **Session 3:**
Group Discussion of Validation and Qualification Requirements
Moderator: J. Hickman, AIMBE and Chris Kelley, NIBIB/NIH
- 5:20 – 5:30 PM Discuss topics and time frames for follow-on workshop on September 17th and 18th
- 5:30 PM *Adjourn*
- 5:30 – 7:30 PM Reception – Lister Hill Lobby