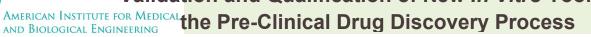
AIMBE/NIH Summit on

Validation and Qualification of New *In Vitro* Tools for





March 19

March 17	
8:00 – 8:45 AM	Continental Breakfast and Check-In
8:45 – 9:00 AM	Welcome and Goals of Workshop James Hickman, PhD, University of Central Florida, AIMBE BOD member
9:00 – 9:10 AM	Welcome from AIMBE President Raphael Lee, MD, ScD, University of Chicago Medicine
9:10 – 9:25 AM	Address from NIBIB Director Roderic I. Pettigrew, PhD, MD, Director, NIBIB, NIH
9:25 – 12:00 AM	Session 1: Current Perspectives on Validation by FDA, NIH, Industry and European EMA. Moderator: Christine A. Kelley, PhD, NIBIB/NIH
9:25 AM	Pre-Clinical Validation and Qualification at the FDA <i>TBD</i>
9:55 AM	NIH Perspective on Validation of New Technology for use in Drug Discovery Research as Part of the Regulatory Science Initiative Christopher Austin, MD, NCATS/NIH
10:25 – 10:45 AM	Break
10:45 – 11:05 AM	EMA speaker on validation <i>TBD</i>
11:05 – 11:25 AM	$\begin{tabular}{ll} \textbf{Validation/Qualification Issues for Enabling Technologies for Drug Discovery} \\ \textit{Mohammed Heldaran}, \ FDA \end{tabular}$
11:25 – 12:00 PM	From Engineering Validation to Qualification of Biomarkers, an FDA Success Story Frederico Goodsaid, PhD, Vertex Pharmaceuticals
12:00 – 1:00 PM	Lunch on your own
1:00 – 4:20 PM	Session 2: Latest Technologies for Pre-clinical Regulatory Science. Moderator: Rosemarie Hunziker, PhD, NIBIB/NIH
1:00 PM	Introduction Rosemarie Hunziker, PhD, NIBIB/NIH
1:10 PM	Stem Cell Technologies for Pre-clinical Drug Discovery

	Nick Thomas, PhD, GE Healthcare
1:50 PM	Liver Construct for Drug Screening and Toxicity Dawn Applegate, Ph.D., CEO RegeneMed
2:20 – 2:40 PM	Break
2:40 – 3:05 PM	Organs on Chips Donald Ingber, MD, PhD, Wyss Institute/Harvard
3:05 – 3:30 PM	Functional in vitro Systems for Drug Discovery Mike Shuler, PhD, Cornell University

3:30 - 3:55 PM **Pre-clinical Imaging Technologies**

John Elliott PhD, NIST

3:55 - 4:20 PM**Experience using PBPK in Clinical Pharmacology Reviews**

Ping Zhao, Clinical Pharmacology CDER/FDA

4:20 - 5:20 PMSession 3:

Discussion of Validation and Qualification Pathways.

Moderator: J. Hickman, AIMBE

- Discussion of the drug development process from the previous session for discussion.
- What needs to occur for validation of the identified technologies?
- How can we REPLACE existing requirements?

5:20 - 5:30 PMDiscuss topics and time frames for follow-on workshop.

5:30 - 7:30 PMReception—Lister Hill Lobby

A report on the workshop will be generated