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

American Institute for Medical and Biological Engineering

March 19

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**
TBD

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**
TBD

11:05 – 11:25 AM **Validation/Qualification Issues for Enabling Technologies for Drug Discovery**
Mohammed Heldaran, FDA

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 PM ***Session 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 PM Discuss topics and time frames for follow-on workshop.

5:30 – 7:30 PM ***Reception—Lister Hill Lobby***

A report on the workshop will be generated