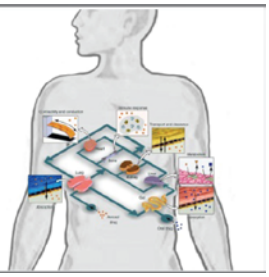
THIRD WORKSHOP ON VALIDATION AND QUALIFICATION OF

NEW IN VITRO TOOLS AND MODELS FOR THE PRE-CLINICAL DRUG DISCOVERY PROCESS

MARCH 14-15, 2013 | LISTER HILL AUDITORIUM, NIH CAMPUS | BETHESDA, MD



Agenda

Third Workshop on Validation and Qualification of New In Vitro Tools and Models for the Pre-Clinical Drug Discovery Process

March 14-15, 2013
Lister Hill Auditorium, NIH Campus, Bethesda, MD

March 14 Day 1

8:00-8:30 AM **Continental Breakfast and Check-In**

8:30-8:45 AM **Welcome from AIMBE and Goals of the Workshop**
James Hickman, PhD, AIMBE Fellow and Professor, University of Central Florida

8:45-9:00 AM **Welcome from the NIBIB Associate Director**
William Heetderks, MD, PhD, NIBIB/NIH

Session 1: **Current Government Perspectives on Validation and Qualification**
9:00-9:10 AM *Moderator: Christine A. Kelley, PhD, AIMBE Fellow and Director, Division of Discovery Science & Technology, NIBIB/NIH*

9:10-9:55 AM **New Strategies for Regulatory Approval of In Vitro Technologies for Drug Development**
Federico Goodsaid, PhD, Vice President for Strategic Regulatory Intelligence, Vertex Pharmaceuticals Inc.

9:55-10:25 AM *Break*

10:25-11:10 AM **Validation of New Technology for Use in Drug Discovery in Europe**
Sonja Beken, PhD, Belgian Federal Agency for Medicines and Health and the European Medicines Agency

11:10-11:55 AM **An FDA Point of View**
Tom Colatsky, PhD, Division of Drug Safety Research, FDA

11:55-1:05 PM **Lunch**

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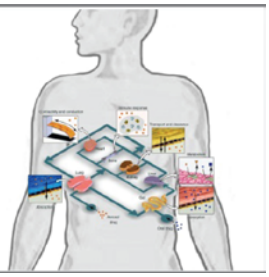

Session 2: **In Vitro Technologies for Draft Validation Guidelines**

1:05-1:15 PM *Moderator: Rosemarie Hunziker, PhD, Program Director, Tissue Engineering/Regenerative Medicine, NIBIB/NIH*

1:15-2:00 PM **NIH Technologies for Pre-clinical Regulatory Science**
Margaret Sutherland, PhD, NINDS,NIH, co-Director of the MPS Program

2:00-2:45 PM **Induced Pluripotent Stem Cell-Derived Tissues and their Role in Developing Novel Assays for Drug Discovery.**
Kyle Kolaja, PhD, DABT, Fellow, ATS, Vice President of Business Development, Cellular Dynamics International, Inc.

2:45-3:15 PM *Break*

3:15-3:45 PM **A Tissue Engineered Human Kidney Microphysiological System**
Jonathan Himmelfarb, MD, Director, Kidney Research Institute and Professor, Department of Medicine, University of Washington

3:45-4:30 PM **Validation of New Technology from a Developer Viewpoint**
Brett Blackman, PhD, Chief Scientific Officer, Hemoshear

4:30-5:00 PM **Group Discussion and Plans for Day 2**

5:30-7:30 PM **AIMBE Sponsored Reception - Share Wine Lounge**
Doubletree Hotel at 8120 Wisconsin Avenue, Bethesda, Maryland 20814

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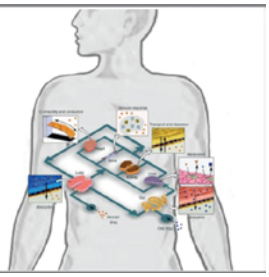

March 15 Day 2

8:00-8:30 AM **Continental Breakfast**

Session 3: **Development of Draft Validation Guidelines**

8:45-8:55 AM *James Hickman, PhD, AIMBE Fellow and Professor, University of Central Florida*
Moderator: Warren Grundfest, MD, FACS, AIMBE BOD and Professor, Bioengineering, Electrical Engineering, and Surgery, UCLA

8:55-9:25 AM **A 3D Model of Human Brain Development for Studying Gene/Environment Interactions**
Tom Hartung, PhD, Director, Center for Alternative to Animal Testing, and Professor, Johns Hopkins University, School of Public Health

9:25-9:55 AM **Circulatory System and Integrated Muscle Tissue for Drug and Tissue Toxicity**
George Truskey, PhD, AIMBE Fellow, Department of Biomedical Engineering, Duke University

9:55-10:25 AM **Disease-Specific Integrated Microphysiological Human Tissue Models**
Kevin Healy, PhD, AIMBE Fellow, Professor and Chair, Department of Biomedical Engineering, UC-Berkeley

10:25-10:55 AM *Break*

10:55-11:25 AM **Integrated Heart-Liver-Vascular Systems for Drug Testing in Human Health and Disease**
Karen Hirschi, PhD, Professor of Medicine (Cardiology), Internal Medicine, Yale University

11:25-11:55 AM **3D Biomimetic Liver Construct for Predicting Physiology and Toxicity**
Lansing D. Taylor, PhD, AIMBE Fellow, and Director Drug Discovery Institute and Professor, Computational & Systems Biology, University of Pittsburgh

11:55-1:00 PM **Lunch (move to Natcher Building for 1:00 pm breakout sessions)**

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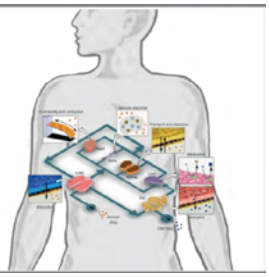

1:00-3:00 PM **Parallel Breakout Sessions (Natcher, Rooms A, D, and F)**
Discussion of Hemoshear Technology Platform (Natcher, Room D)
Presentation Leader – Luke Lee, PhD, AIMBE Fellow and Professor, Department of Bioengineering, University of California, Berkeley

Discussion of Berkeley Technology Platform (Natcher, Room A)
Presentation Leader - Warren Grundfest, MD, FACS, AIMBE BOD and Professor, Bioengineering, Electrical Engineering, and Surgery, UCLA

Discussion of Pittsburgh Technology Platform (Natcher, Room F)
Presentation Leader – Michael Shuler, PhD, AIMBE Fellow and Professor and Chair, Department of Biomedical Engineering, Cornell University

3:00-3:30 PM *Break (Return to Lister Hill Auditorium)*

3:30-3:45 PM **Breakout Group 1 Report**
Presentation Leader – Luke Lee, PhD, AIMBE Fellow

3:45-4:00 PM **Breakout Group 2 Report**
Presentation Leader – Warren Grundfest, PhD, AIMBE BOD

4:00-4:15 PM **Breakout Group 3 Report**
Presentation Leader – Michael Shuler, PhD, AIMBE Fellow

4:15-5:00 PM **Final Discussion**
Further development of validation and qualification guidelines for microphysiological systems. These guidelines will be used by the steering committee to meet with the FDA to determine next steps based on FDA requirements and to set the agenda for the next workshop.

5:00 PM **Adjourn**