Microphysiological Systems (MPS): Bridging Human and Animal Research
January 19 -20, 2021
Virtual-only

Workshop Overview: Microphysiological systems (MPS) are in vitro platforms composed of 3-D constructs (including spheroids, organoids, bioprinted, and tissue/organs-on-chips) of human or animal origin in micro-bioreactors that mimic the biochemical, electrical, mechanical properties of organ or tissue function. MPS are predictive tools enabling more physiologically meaningful pharmacology, toxicology and efficacy assessments in drug development. Workshop will discuss current MPS landscape, particularly in developing animal organs-on-chips and establishment of sustainable animal chip banks for large-scale use. MPS will be explored for a range of animal species/strains, including pathogen-free and gene-edited animals, and for optimizing animal model selection where whole animal models are necessary. Our goal is to build awareness and sensitize government, academia, industry, research scientists and developers throughout the stakeholder communities, share knowledge across the aisle and identify follow-on action items that will bridge human and animal research for societal impacts in human, animal and environmental health.

DAY ONE	
11:00-11:10 AM	Welcome and Brief Introductions – Teresa Sylvina and PJ Devine
11:10 AM – 12:05 PM (55 min)	**Session 1: Welcome remarks** **Rear Admiral Denise Hinton, M.S.** (U.S. Food and Drug Administration) • *FDA's Study of Alternative Assays* *Case Study: Microphysiological Systems (MPS)* **Rear Admiral Estella Z. Jones, B.S., D.V.M.** (U.S. Food and Drug Administration) • *MCM One Health and Animal Welfare* **Ekaterina Breous-Nystrom, Ph.D.** (Roche pRED-Pharmaceutical Sciences) • *Microphysiological systems in pharmaceutical safety* **Christopher P. Austin, M.D.** (National Center for Advancing Translational Sciences at the National Institutes of Health) • *Microphysiological Systems at NCATS: Increasing the Predictivity of Translational Assays* **Russell S. Thomas, Ph.D.** (U.S. Environmental Protection Agency) • *EPA's work plan for reducing animal testing: Role of organotypic, microphysiological, and in silico models.* Moderators: PJ Devine and Dan Tagle

12:05-12:15 PM (10 min)	Break/Buffer
12:15-2:00 PM (1 hr. 45 min)	**Session 2: MPSs for Toxicology Testing** **Amy M. Avila, Ph.D.** (Center for Drug Evaluation and Research, U.S. Food and Drug Administration) • *FDA/CDER perspective* **Raja Settivari, BVSc AH, Ph.D., DABT** (Corteva Agriscience) • *Agrochemical perspectives on utility of Microphysiological systems* **Gary Gintant, Ph.D.** (AbbVie) • *Lessons Learned from the Comprehensive In Vitro Proarrhythmia Assay (CiPA) Initiative for Safety/Toxicology Testing with Microphysiological Systems* **David Strauss, M.D., Ph.D.** (Center for Drug Evaluation and Research, U.S. Food and Drug Administration) • *Advancing Translational Models & Tools into the Drug Review Process: Opportunities for MPS* **Ivan Rusyn, M.D., Ph.D.** (Texas A&M) • *If you build it, will they come? Testing the "value proposition" for tissue chips in drug and chemical safety assessment* **Panel Q&A** (30 minutes) Moderator: Suzanne Fitzpatrick
Objectives	• Discuss current and projected applications for advancing in vitro predictive toxicology • Characterize pressing issues related to advancing MPSs in predictive toxicology • Discuss pathways for translating Chip data for regulatory use • Discuss major hurdles to adopting these technologies and translating them into information needed to make research and public policy decisions
2:00-2:10 PM (10 min)	Break/Buffer

2:10-3:15 PM (1 hr. 5 min)	**Session 3: Going from *in vitro* to *in silico* – data and developmental tools** **D. Lansing Taylor, Ph.D.**, (University of Pittsburgh) • *Harnessing Human Biomimetic Liver MPS Combined with Quantitative Systems Pharmacology to Predict Drugs/Combinations for Treating MAFLD* **Tom Knudsen, Ph.D.** (U.S. Environmental Protection Agency) • *Synthetic Microsystems, Computational Intelligence, and Artificial Life* **Mark E. Schurdak, Ph.D.** (University of Pittsburgh) • *The Microphysiology Systems Database (MPS-Db): A platform for aggregating, analyzing, sharing and modeling of in vitro and in vivo safety and efficacy data* **Panel Q&A** (20 minutes) **Moderator**: John Rogers
Objectives	• Optimize characterization of *in vitro* models • Enabling MPS data use in *in silico* models • Discuss ways to use *in vitro* data and *in silico* models for human prediction
3:15-4:35 PM (1 hr. 25 min)	**Session 4: Panel Discussion on topics of public health importance (COVID)** **Simon Funnell, Ph.D.** (Public Health UK) • *The role of MPSs in addressing the 3Rs in research involving Zoonoses in protected species.* **Diane Bimczok, D.V.M., Ph.D.** (Montana State University) • *Bat and human gastrointestinal organoids as in vitro models to define pathogenic and protective responses to SARS-CoV-2 infection* **Vivek Thacker, Ph.D.** (Global Health Institute) • *Lung-on-chip model systems to study host-pathogen interactions in respiratory infections* **Donald E. Ingber, M.D., Ph.D.** (Wyss Institute at Harvard University) • *Human Organ Chip-enabled discovery of therapeutics and prophylactics for viral pandemics* **Panel Q&A** (20-30 minutes) **Moderators:** Milica Radisic/PJ Devine
Objectives	• Develop rapid responses to recent epidemics

	• Discuss needs for animal MPS (which species and when?) • Highlight resource/research barriers with animal models and regulations • Describe benefits of MPSs systems versus animal models • Rapid production of MPSs of alternative species
4:35 PM	Adjourn Day One

DAY TWO	
11:00 -11:10 AM	Welcome and Brief Introductions
11:10 AM - 12:15 PM (1 hr. 5 min)	**Session 5: Commercialization/engineering/collaborations** **Thomas Neumann, M.D.** (Nortis) • *Learning from Tissue Chips in Space: Development and Commercialization of Next Generation MPS Platforms* **Clive Roper, BSc Ph.D. CBiol CSci FRSB** (Charles River Laboratories) • *The Use and Applications of 3D Tissue Models for Respiratory Toxicology and Efficacy Testing within the CRO Industry* **Michael J. Moore, Ph.D.** (AxoSim) • *Addressing the Opioid Crisis: A Microphysiological Model of Synaptic Transmission of Pain* **Panel Q&A** (20 minutes) Moderator: Szczepan Baran
Objectives	• Leveraging animal MPS data to build confidence for human MPS • Considerations for end users • Requirements for future MPS platforms • Commercialization to move to translation • Collaboration between pharma CRO and innovator
12:15-12:25 PM	Break/buffer
12:25-2:45 PM (2 hrs. 20 min)	**Session 6: Multi-organ chips and emerging applications for biologics studies** **Integrated multi-organ systems** **Uwe Marx, M.D.** (TissUse) • *Emulating human organ interactions on a universal multi-organ-chip platform* **Gordana Vunjak-Novakovic, Ph.D.** (Columbia University) • *Integrated human multi-organ platforms for modeling systemic pathologies*

	Linda Griffith, Ph.D. (Massachusetts Institute of Technology) • *Humanizing Models of Systemic Inflammatory Diseases with Multi-Organ Platforms and Systems Biology* **Joanna Burdette, Ph.D.** (University of Illinois, Chicago) • *Multi-organ, integrated female reproductive system for disease modeling and environmental exposure toxicity testing.* **Kyung Sung, Ph.D.** (CBER, U.S. Food and Drug Administration) • *Microphysiological Systems to assess the functional capacity of regenerative medicine cellular products* **Kevin Kit Parker, Ph.D.** (Wyss Institute at Harvard University) • *Exosomal Cardiotherapies on a Chip* **Thomas Hartung, M.D., Ph.D.** (CAAT/Johns Hopkins University) • *The challenge of disease modeling, quality assurance and validation of organ-on-chip models* **Panel Q&A** (35 minutes) Moderators: Ashutosh Agarwal and Milica Radisic
Objectives	• Discuss hurdles and opportunities in connecting multiple tissues • Evaluate timelines and role(s) for establishment of multi-organ chips • Characterize needs and capabilities of evaluating complex modalities • Discuss need for animal vs human systems for gene engineering and biologics • Functionalities of emerging animal OOC technologies for optimizing animal studies/research • Integrated human-animal OOC approaches for optimizing species selection and predictive power of OOC's and integrated OOC systems
2:45–2:55 PM	Break/buffer
2:55–4:40 PM (1 hr. 45 min)	**Session 7: Perspectives and strategies on the need for animal cell and chip-banks** **Kevin Greenlees, Ph.D., DABT** (Center for Veterinary Medicine, U.S. Food and Drug Administration) • *Animal Drugs, Animal Studies, and MicroPhysiological Systems* **Bernadette Dunham, D.V.M., Ph.D.** (Food and Drug Administration, GWU) • *Looking at Microphysiological Systems through the One Health Lens.*

	PJ Devine, Ph.D. (Novartis) • *Pharma Perspective on Animal Microphysiological Systems* **E. Sidney Hunter, III, Ph.D** (Environmental Protection Agency) • *Microphysiological systems: A cellular dilemma* **Lorna Ewart, Ph.D.** (Emulate) • *Development of Human, Rat and Dog Liver-Chips to facilitate safety assessment of candidate drugs* **Panel Q&A** (30 minutes) Moderators: Sean Gehen and David Kurtz
Objectives	• Discuss various perspectives on the needs for and uses of animal chips • Strategic goals to advance or improve access to animal cells and chips • Discuss gaps and limitations in available animal chips and strategies for filling those gaps/limitations • Discuss approaches for establishing animal chip banks
4:40-4:50 PM	Closing Remarks – Dan Tagle
4:50 PM	Closing of meeting - Teresa Sylvina Adjourn Day Two