3D Cell Culture Models for Drug PK, Safety, and Efficacy Assessment

Co-Sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and U.S. Food and Drug Administration (FDA)

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Webex Online Event
Aug. 14, 2020

TIME	ACTIVITY
Noon – 12:05 p.m.	**Welcome and Logistics** Hongbing Wang, PhD (Professor, UMSOP) Shiew-Mei Huang, PhD, FCP (FDA)
Session One	**3D Models in Drug Safety and Risk Assessment** Session Chair: Ed Chow (FDA)
12:05 – 12:15 p.m.	**Overview of 3D Cellular Model Research at FDA** Suzy Fitzpatrick, PhD Senior Advisor for Toxicology Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration
12:15 – 12:25 p.m.	**Organ-on-Chips Application in Drug PK and Efficacy Evaluation** Lorna Ewart, PhD EVP European Scientific Liaison Emulate
12:25 – 12:35 p.m.	**Considerations About 3D Culture Models for Nonclinical Safety Evaluation** Ronald Wange, PhD, and Paul Brown, PhD Associate Directors for Pharmacology and Toxicology Center for Drug Evaluation and Research U.S. Food and Drug Administration
12:35 – 12:40 p.m.	**Break**

Session Two	**3D In Vitro Liver Models for DILI** Session Chair: Qi Liu (FDA)
12:40 – 12:50 p.m.	**Liver-on-Chip Model for Toxicity and PK** Alexandre Ribeiro, PhD Staff Fellow Division of Applied Regulatory Science Office of Clinical Pharmacology Office of Translational Sciences Center for Drug Evaluation and Research U.S. Food and Drug Administration
12:50 – 1 p.m.	**HepaRG 3D Spheroids in Comparison to 2D Models** Steve Ferguson, PhD Chemist Molecular Toxicology and Genomics Group National Institute of Environmental Health Sciences
1 – 1:10 p.m.	**Predicting DILI Risk Using Hepatic Spheroid Co-Culture Models** Will Proctor, PhD Director, Predictive Toxicology Genentech
1:10 – 1:15 p.m.	**Break**
1:15 – 2:10 p.m.	**Panel Discussion I** Chair: Shiew-Mei Huang (FDA) **Panelists:** Speakers and Moderators for Sessions One and Two, and Jerry Lee and Shannon Mumenthaler
2:10 – 2:15 p.m.	**Break**
Session Three	**Multi-Organ 3D Models Intestine, Liver, and Beyond** Session Chair: Grace Guo (Rutgers)
2:15 – 2:25 p.m.	**Novel In Vitro Hepatic and Enteric Technologies for Drug Metabolism, DDI, and Safety Evaluation** Albert Li, PhD, MBA President and Chief Executive Officer In Vitro ADMET Laboratories, Inc.

2:25 – 2:35 p.m.	**Intestinal Oganoids: An Excellent Ex Vivo Model for Mucosal Regeneration and Defense** Jian-Ying Wang, MD, PhD Joseph and Corinne Schwartz Professor in General Surgery University of Maryland School of Medicine
2:35 – 2:45 p.m.	**Use of Vascularized Human Kidney Proximal Tubule Microphysiological System and PBPK Modeling to Predict Renal Clearance in Subjects with Variable Kidney Function** Nina Isoherranen, PhD Professor and Milo Gibaldi Endowed Chair in Pharmaceutics Department of Pharmaceutics University of Washington School of Pharmacy
2:45 – 2:50 p.m.	**Break**
Session Four	**3D Spheroids/Organoids for Disease Modeling** Session Chair: William Hedrich (BMS)
2:50 – 3 p.m.	**Kidney Organoids for Disease Modeling and HTS** Benjamin Freedman, PhD Assistant Professor of Medicine and Nephrology Institute for Stem Cell & Regenerative Medicine University of Washington
3 – 3:10 p.m.	**Neuronal Multi-organ-on-Chip Models for Disease Modeling and Risk Assessment** James Hickman, PhD Professor of Nanoscience Technology, Chemistry, Biomolecular Science, Physics, and Electrical Engineering Head, Hybrid Systems Laboratory University of Central Florida
3:10 – 3:15 p.m.	**Break**
3:15 – 3:55 p.m.	**Panel Discussion II** Chair: Hongbing Wang (UMSOP) **Panelists:** Speakers and Moderators for Sessions Three and Four, and Scott Heyward

3:55 – 4 p.m.	**Summary** Hongbing Wang, PhD Professor and Program Chair, Experimental and Translational Therapeutics Department of Pharmaceutical Sciences University of Maryland School of Pharmacy Shiew-Mei Huang, PhD, FCP Deputy Director, Office of Clinical Pharmacology Center for Drug Evaluation and Research U.S. Food and Drug Administration