Microphysiological Systems (MPS): Bridging Human and Animal Research
Speaker Biographies

Session 1: Welcome Remarks

Rear Admiral Denise Hinton, M.S.

RADM Denise Hinton is FDA's Chief Scientist. She is responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts.

The Office of the Chief Scientist works closely with FDA's product centers, providing strategic leadership and support for FDA's regulatory science and innovation initiatives, including the Advancing Regulatory Science and Medical Countermeasures Initiatives, health informatics, scientific professional development, scientific integrity, laboratory safety, and technology transfer.

RADM Hinton previously served as Deputy Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER), where she concurrently served as Acting OMP Director from 2014 to 2016. There, she led the development, coordination, and implementation of medical policy programs and strategic initiatives, including the efficient integration of rapidly evolving science and new technologies into the drug development and regulatory review processes. RADM Hinton's work involved close collaboration with other CDER program areas, FDA product centers, and a broad variety of stakeholders.

RADM Hinton joined FDA in 2002, serving in CDER's Division of Cardiovascular and Renal Products and, later, served in the center's former Division of Training and Development. Before coming to FDA, she was an officer in the U.S. Air Force. RADM Hinton earned her Bachelor of Science in Nursing from Florida State University and her Master of Science degree from Boston University.

Rear Admiral Estella Z. Jones, B.S., D.V.M.

As Deputy Director of the Office of Counterterrorism and Emerging Threats, Office of the Chief Scientist, Office of the Commissioner, Rear Admiral (RADM) Estella Z. Jones provides strategic and executive direction on programs that continually combat global health threats. She safeguards the development and availability of critical medical countermeasures to mitigate and respond to public health emergencies involving chemical, biological, radiological, nuclear, and emerging infectious disease threats, such as Ebola virus outbreaks, pandemic influenza, Zika virus and SARS. RADM Jones advises and supports the Assistant Commissioner for Counterterrorism Policy at the U.S. Food and Drug Administration (FDA) to aid with the coordination of FDA's Medical Countermeasures Initiative, a significant component of broad government programs to increase and improve the Unites States' capacity to prepare for and improve government responses to public health emergencies. She advises and supports the U.S. Surgeon General on policy and procedures for responses to public health emergencies. RADM Jones has effectively established many sustainable countermeasure programs to support the preclinical review of crucial data such as the National Interagency Confederation for

Biological Research with the Fort Detrick Biodefense campus, Achieving Data Quality and Integrity in Maximum Containment Laboratories with the University of Texas Medical Branch Galveston National Laboratories (UTMB GNL), the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID) Integrated Research Facility (IRF) and Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens," recently adding the University of Nebraska Medical Center / National Ebola Training and Education Center as collaborators, offering hands-on, contemporary, virtual-reality training to students and stakeholders in the nation's largest constructed biocontainment unit.

RADM Jones concomitantly serves as the Co-Chair of FDA's newly created Animal Welfare Council under the direction of the Office of the Chief Scientist, while maintaining biosafety level 4 certification as Chairperson for the NIAID IRF Animal Care and Use Committee. She previously worked for the World Health Organization's Institute for Primate Research in Nairobi, Kenya, as well as in industry, the NIH, the HHS Office of the Secretary, FDA's Center for Veterinary Medicine, Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, helping to develop non-cage containment housing for multiple primate species. RADM Jones previously held a dual faculty appointment at Houston's Baylor College of Medicine (BCM) in both Comparative Medicine and Anesthesiology, aiding with the discovery of the p-53 deficient cancer mouse model with Dr. Alan Bradley and her mentor, the late Dr. Charles Montgomery. At BCM, she worked with the famed late heart surgeon, Dr. Michael DeBakey, who pioneered many coronary surgical innovations. She worked with the Department of Defense and the Pentagon on the Military Advisory Panel on joint service parity policies and represented the White House Office of Science and Technology Policy Subcommittee for Disaster Reduction.

RADM Jones graduated from Tuskegee University with a Bachelor of Science in Animal and Poultry Sciences and earned her Doctor of Veterinary Medicine from Louisiana State University in 1989. RADM Jones maintains modern clinical and surgical skills with multiple species by staying active in a large emergency practice with over 70,000 patrons. She was selected as the official on-site veterinarian for the 2019 American Veterinary Medical Association Convention.

RADM Jones represents FDA Executive Leadership on the Federal Level Working Group responsible for Congressional level reporting on behalf of the FDA Commissioner for the HHS Tick-borne Disease Working Group (TBDWG) established under Section 2062 of the 21st Century Cures Act, which is tasked with providing expertise and reviewing HHS efforts related to all tick-borne diseases, to help ensure interagency coordination, minimize overlap, and examine research priorities. She served as the co-Chair of the 2018 TBDWG Subcommittee for Pathogenesis, Transmission and Treatment, followed by a Co-Chair assignment for the 2019 Rickettsial Disease Subcommittee. She also served as the FDA focal point to help implement the NIH led Reform of Animal Research Regulations established under Section 2034(d) of the 21st Century Cures Act.

RADM Jones has deployed for a variety of public health emergencies to include 911, the Anthrax attacks, Katrina and most recently the CoVID19 pandemic. She has received numerous awards and decorations, including a Distinguished Service Medal, a Presidential Citation, the HHS Secretary's Badge, Crisis Response Service Awards, Veterinary Responder of the Year, Commendation Medals and numerous Citations. During her off-duty hours, she can be found

teaching her service dogs to be Good Canine Citizens to visit chronically ill patients and nursing homes. In August 2020, she was awarded with a Diplomate certificate from the American Veterinary Epidemiology Society.

Ekaterina Breous-Nystrom, Ph.D.

Ekaterina Breous-Nystrom is heading the toxicology section of the Department of Investigative Safety at Roche pRED in Basel, Switzerland. Her team's focus is drug safety assessment using human microphysiological systems. She is an immunologist by training with a MS from the University of Otago, New Zealand and a PhD from the University of Ulm, Germany. She did her postdoctoral training at the University of Pennsylvania, USA. Prior to joining Roche, Ekaterina led immuno-oncology drug discovery unit at a Basel-Boston biotech company Agenus.

Christopher P. Austin, M.D.

Christopher P. Austin has served as director of the National Center for Advancing Translational Sciences at the National Institutes of Health since 2012. Prior to this role, he was NCATS' scientific director, focusing on translating basic science discoveries into new treatments and technologies to improve the efficiency of therapeutic/diagnostic development. He founded several initiatives, including the NIH Chemical Genomics Center, the Therapeutics for Rare and Neglected Diseases program, and the Toxicology in the 21st Century program. Before joining NIH in 2002, he led genomic-based target discovery, pharmacogenomic, and neuropsychiatric drug-development programs at Merck. From 2016 to 2018, he served as chair of the International Rare Disease Research Consortium (IRDiRC); Dr. Austin is also a member of National Academy of Medicine. He earned an A.B. from Princeton University, an M.D. from Harvard Medical School, and completed training in internal medicine and neurology at Massachusetts General Hospital.

Russell S. Thomas, Ph.D.

Russell Thomas is the director of the Center for Computational Toxicology and Exposure at the U.S. Environmental Protection Agency (EPA). The Center is performing solutions-driven research to rapidly evaluate the potential human health and environmental risks due to exposures to environmental stressors and ensure the integrity of the freshwater environment and its capacity to support human well-being. Dr. Thomas has a broad, multidisciplinary background and experience. Dr. Thomas' formal academic training includes a B.A. in chemistry from Tabor College, an M.S. in radiation ecology and health physics from Colorado State University, and a Ph.D. in toxicology also at Colorado State. Following his doctoral studies, Dr. Thomas performed postdoctoral research in molecular biology and genomics at the McArdle Cancer Research Laboratory at the University of Wisconsin. Following his academic training, Dr. Thomas performed bioinformatics and genomics research in the biotechnology sector, developed high-throughput *in vitro* screening assays in the biopharma sector, and worked as an investigator and senior manager at a non-profit research institute.

Session 2: MPSs for toxicology testing

Amy M. Avila, Ph.D.

Amy Avila received her Bachelor of Science degree in biochemistry from the University of Delaware and her PhD in pharmacology from Georgetown University, with a focus in neuropharmacology. She conducted post-doctoral research on neurodegenerative disorders at the National Institute of Neurological Disorders and Stroke at the National Institutes of Health. In 2006, she joined the Food and Drug Administration as a pharmacologist/toxicologist reviewer in the Office of New Drugs in the Center for Drug Evaluation and Research (CDER) and is currently is a reviewer in the Division of Pharmacology/Toxicology for Neuroscience. She has been an active member of committees involved in developing and promoting advanced scientific education for reviewers and is currently co-chair of the Emerging Technologies Pharmacology/Toxicology Coordinating Subcommittee within CDER.

Raja Settivari, BVSc AH, Ph.D., DABT

Raja Settivari is the leader for general, genetic and molecular toxicology at Corteva Agriscience. His responsibilities include people leadership, supervision of *in vivo* and *in vitro* GLP and non-GLP mammalian toxicology testing, development and implementation of NAMs-based testing strategies to support mechanistic studies and risk assessment of agrochemicals. He received his doctorate in Toxicology from University of Missouri in 2007 and was a postdoctoral fellow at Harvard Medical School and Indiana University School of Medicine. Raja holds a Veterinary Medicine degree from India and is a diplomate of American Board of Toxicology. Raja has served as grants reviewer for CEFIC Long-range Research Initiative, Alternatives Research & Development Foundation, the Parkinson's Foundation and served as an editorial board member for several toxicology journals. Raja is a member of OECD expert groups for immunotoxicology, dermal sensitization, and is part of ECPA and HESI genotoxicity committees and represents Corteva on Center for Alternatives to Animal Testing advisory board. He is author/co-author of 33 peer-reviewed publications and book chapters.

Gary Gintant, Ph.D.

Dr. Gary Gintant is a Senior Research Fellow at AbbVie involved in multiple drug discovery and safety activities with a focus on translation of in vitro and in-vivo cardiac and cardiovascular models to clinical findings. He joined Abbott/AbbVie in 1998 after teaching/researching in the Pharmacology and Cardiology Depts at Wayne State University School of Medicine in Detroit. His research interests include cardiovascular pharmacology, cellular electrophysiology/ion channels, arrhythmias, human stem-cell derived cardiomyocytes and tissues, and biomarkers-translational medicine. He gained his MA, MPhil and PhD degrees from the College of Physicians & Surgeons of Columbia University in New York City.

David Strauss, M.D. Ph.D.

Dr. Strauss is a physician-scientist with >10 years of FDA regulatory review, translational/clinical research and leadership/management experience spanning the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH). He currently serves as Division Director of FDA/CDER's Division of Applied Regulatory Science, which includes 30 multi-disciplinary government staff scientists and ~45 contractors/postdoctoral fellows conducting laboratory, computational and clinical research to move new science into the FDA review process. The Division also conducts regulatory consults/reviews for challenging premarket (IND/NDA/BLA) or postmarket issues that cannot be addressed by the primary review divisions. Serve on CDER's Drug Development Tool (DDT) Committee, which reviews all DDT submissions to CDER. He previously served as Senior Advisor for Translational & Experimental Medicine in CDER and Medical Officer in CDRH, conducting many premarket medical device reviews.

He is an internationally recognized researcher with >145 peer-reviewed publications and >5,110 citations; published most-read JAMA article of 2019 and serve as Associate Editor of Clinical Pharmacology & Therapeutics. He has a strong track record of translational research having a direct impact on medical product development spanning in vitro and in vivo laboratory models, in silico computational modeling and informatics, and integrated clinical research covering clinical pharmacology, experimental medicine, and real-world data.

Dr Strauss has international regulatory experience as rapporteur (lead) of the International Council for Harmonisation (ICH) Guidelines for nonclinical (ICH S7B) and clinical (ICH E14) assessment of cardiac safety for drugs. He has lead discussions and reconciled divergent views to reach consensus on ~30-person group with representatives from global drug regulators (FDA, United States; EC (EMA), Europe; MHLW/PMDA, Japan; NMPA, China; Health Canada, Canada; Swissmedic, Switzerland; TFDA, Chinese Taipei) and industry (PhRMA; EFPIA; JPMA). He delivered Draft ICH Guideline for public comment in August 2020.

Ivan Rusyn, M.D., Ph.D.

Ivan Rusyn is University Professor in the Department of Veterinary Integrative Biosciences in the College of Veterinary Medicine & Biomedical Sciences at Texas A&M University in College Station. He is also Chair of the Interdisciplinary Faculty of Toxicology, Director of an NIEHS T32 training program in "Regulatory Science in Environmental Health and Toxicology," and Director of the Superfund Research Center. His studies on health effects of chemical agents resulted in over 260 peer-reviewed publications which were cited over 22,000 times (*h*-index=73). He has served on and chaired several US National Academies committees, World Health Organization/International Agency for Research on Cancer monograph working groups. He is serving on the Board of Environmental Studies and Toxicology for the National Academies, Board of the Scientific Councilors of the United States National Institute of Environmental Health Sciences, the advisory board for Texas Department of Public Health, and on the Research Committee of the Health Effects Institute. Dr. Rusyn received a doctor of medicine degree from Ukrainian State Medical University in Kyiv and a Ph.D. in toxicology from the University of North Carolina at Chapel Hill. He conducted postdoctoral research at the Massachusetts Institute of Technology and Heinrich-Heine University in Dusseldorf. Dr. Rusyn's laboratory is funded by

grants and cooperative research agreements from the National Institutes of Health and US Environmental Protection Agency, institutional funding from Texas A&M University, the industry, and other sources.

Session 3: Going from *in vitro* to *in silico* – data and developmental tools

D. Lansing Taylor, Ph.D.

D. Lansing Taylor began his academic career as an Assistant Professor at Harvard University and remained at Harvard until 1982, developing and using novel fluorescence-based reagents and imaging technologies to investigate fundamental cellular processes such as cell movements and cell division. He then moved to Carnegie Mellon University as a Professor of Biological Sciences and as Director of the Center for Fluorescence Research in the Biomedical Sciences. In 1991, he became the Director of the National Science Foundation-funded Center for Light Microscope Imaging and Biotechnology, and in 1995, was named Vice Dean of CMU's Division of Molecular Sciences. He continued to develop reagent and imaging technologies, while applying the technologies to understand fundamental processes in cells and tissues. He and Alan Waggoner co-founded Biological Detection Systems (BDS) to commercialize the multi-color cyanine dyes and research imaging platforms and it was acquired by Amersham-now GE Life Sciences. He left CMU in 1997 to found Cellomics, Inc., the company that developed High Content Screening (HCS). HCS was the foundation for a shift from focusing primarily on generating images to generating large-scale, quantitative image-based data from cells, tissues and small organisms. He was CEO of this company from 1997 through 2003 when it became part of ThermoFisher. He then founded a third company, Cellumen, that developed a predictive safety assessment platform using primary hepatocytes, multiplexed panels of reagents, reference safety databases and computational biology. He was CEO of Cellumen from 2004 until 2010 when it became part of Cyprotex, a British CRO. He also co-founded Cernostics, Inc., a fluorescence-based, tissue systems pathology company that has created a test for selecting at risk Barrett's esophagus patients and in 2018 he co-founded SpIntellx, a computational and systems pathology company focused on developing therapeutic strategies, diagnostics and prognostics for solid tumor cancers. He holds >25 U.S. patents, including six focused on cell-based imaging. He returned to academia at the end of 2010 to continue his academic interests that now link large-scale cell, tissue and human, biomimetic, tissue-engineered model profiling with computational and systems biology to optimize drug discovery and diagnostics based on quantitative systems pharmacology. Present programs include traumatic brain injury, liver diseases, melanoma and colon cancer. *www.upddi.pitt.edu*

Thomas B. Knudsen, Ph.D.

Dr. Knudsen is a Developmental Systems Biologist at the US EPA Center for Computational Toxicology and Exposure, where he is a lead in the Virtual Tissue Models project. His research on prenatal developmental toxicity and systems biology has led to over 150 scientific papers. Current research is focused on building and testing a 'virtual embryo' framework for predictive

modeling of developmental toxicity. This entails integration of in-vitro data from HTS (high-throughput screening) profiling in ToxCast/Tox21 with biological knowledge of in-vivo embryology and in-silico cell agent-based models for synthetic reconstructing morphogenesis, leading to a quantitative prediction of chemical dysmorphogenesis. Dr. Knudsen is a Past-President of the Teratology Society, Former Editor-in-Chief of Reproductive Toxicology, and currently serves as Editor-in-Chief of Current Research in Toxicology.
Education:

- B.S., Albright College, Reading, PA; Biology, 1976
- Ph.D., Thomas Jefferson University, Philadelphia, PA; Anatomy, 1981

Mark E. Schurdak, Ph.D.

Dr. Schurdak's formal training is in pharmacology and he has practical experience in the innovation of novel screening approaches, complex biological assay development and implementation using QC methods. He has over 20 years of experience in the development and implementation of assays for high-throughput screening (HTS) and hit-to-lead (HtL) campaigns in the biotech and large pharmaceutical companies. As a Group Leader in the high-throughput screening group at Abbott, he instituted the first high-throughput ADME/Tox group at Abbott, and established siRNA and high content screening (HCS) capabilities. Early high-throughput ADME/Tox capabilities were essential for prosecuting hit-to-lead projects and involved structured implementation, QC, and data analysis. This experience grounded him in industrial development including the use of validation statistics and QC methods. Following the successful implementation of multiple HCS and ADME/Tox assays in the HTS group, he moved to the hit-to-lead (HtL) group where he led the biology efforts on projects for oncology and immunology. He directly managed the efforts of two projects and delivered lead series to the respective therapeutic projects for further lead development. Two lead series for one of those projects were advanced to lead optimization and preclinical stages of development under his guidance. Key to the success of these projects were his critical data analysis, creative problem solving approaches, and expertise in assay development for designing selectivity and orthogonal assays to demonstrate the MOA of lead compounds. He was active in other projects within the HtL group, consulting on strategies and implementing assays to identify lead compound series for advancement to lead optimization. In the Early Pain Discovery group within Abbott's department of Neuroscience he was a lead biologist identifying novel therapeutic targets for pain, and developing and implementing HTS and HtL screening campaigns for six projects. Compounds from one of these projects were moved into lead optimization and preclinical animal studies. Upon moving to the University of Pittsburgh Drug Discovery Institute (UPDDI) he took the position of Director of Operations and assumed the role of Scientific Coordinator for the Pittsburgh Special Applications Center, which is part of the NCI NExT Chemical Biology Consortium, and of Director for the University of Pittsburgh Cancer Institute's Chemical Biology Facility. In these positions he coordinated the efforts of multiple groups and managed projects to successful conclusions. At the UPDDI, he has implemented HCS for several projects including STAT3 in head and neck cancer, NR4A1 for ovarian cancer, HSV-1 latency in iPSC derived neurons,

and neuroprotection in Huntington's disease, Alzheimer's Disease, and traumatic brain injury. He has had a leading role in the Neurodegenerative Disease Quantitative Systems Pharmacology (QSP) program integrating clinical, computational and experimental analyses, including development of iPSC derived cell based assays, to gain a comprehensive understanding of disease pathology with which to inform effective therapeutic approaches for disease management. He is also involved in developing and applying informatics software tools for drug discovery and development including development of novel statistics to identify and measure heterogeneity in cell-based assays (PHI – Pittsburgh Heterogeneity Indices). Finally, he is leading the efforts to expand the Microphysiology Systems Database (MPS-Db) as part of a Cooperative Agreement with NCATS, Texas A&M, MIT, and the IQ Consortium. The MPS-Db integrates experimental, reference, and clinical data for multiple microphysiologic organ and disease models, and incorporates tools to assess the reproducibility and predictability of these models, and for computational modeling of MPS data.

Session 4: Panel Discussion on topics of public health importance (COVID)

Simon Funnell, Ph.D.

Dr. Simon Funnell has 34 years of experience as a researcher at Public Health England, Porton Down. Simon's postgraduate and postdoctoral training focused on vaccine research but his career has included translational research to develop vaccines, antibiotics and novel therapies against a wide range of infectious agents including many Select Agents and public health threats.

As a study director and scientific leader, he has overseen the bidding, planning, design, execution and reporting of many complex projects involving the development and utilization of in vivo models using aerosols and other routes of infection with Select Agents and public health pathogens funded by several US government agencies, UK government and more recently CEPI.

The challenges of conducting studies aimed at replacing human clinical Phase III efficacy trials are familiar to him and his colleagues at PHE. PHE's ABSL3 and ABSL4 facilities have been used to conduct a wide range of studies using models of infection usually based on simulating aerosol inhalation. Dr Funnell was deployed to West Africa during the global response to the EBOLA outbreak and has been seconded to the WHO since February 2020 to assist with the global response to SARS-CoV-2.

During this time, he has encouraged techniques to address refinement, reduction and replacement in animal research and his publication on Hyroxychloroquine demonstrates the value of microphysiological systems in SARS-CoV-2 research.

Diane Bimczok, D.V.M., Ph.D.

Dr. Bimczok is a mucosal immunologist with a research interest in the interactions between the gastrointestinal epithelium and immune cells, particularly dendritic cells (DCs). Her overall research focus is to elucidate site-specific mechanisms of immunity and pathogenesis in the gastrointestinal tract. As a D.V.M. Ph.D., she has a broad background in biomedicine and immunology. During her graduate training, she acquired an interest in gastrointestinal DC

function, which led her to a postdoctoral position in the laboratory of Dr. Phillip Smith at the University of Alabama at Birmingham. At UAB, she started investigating the role of DCs in human gastric infection with *H. pylori*. During her time as a postdoc and later a research track faculty member, she established methods to purify DCs from human gastric tissue samples and showed that these DCs induce Th1 responses to *H. pylori* (1). She also showed that epithelial and stromal-derived factors, including retinoic acid, regulate DC function in the stomach (2).

Since joining the Department of Microbiology and Immunology at MSU, she developed an independent research program in mucosal immunobiology, with funding from the NIH, USDA, industry and private foundations. Her laboratory team, which includes a lab manager, four graduate students and three undergraduates, uses a combination of *in vitro* models, *ex vivo* analysis of human cells and tissues, organoids and transgenic mouse models. One of her major research goals is to elucidate how gastric DCs and epithelial cells and their interactions contribute to the immune response to *H. pylori.* To that end, she established human gastric organoids and developed an organoid-DC co-culture system to perform mechanistic investigations on the interactions between *H. pylori*, the gastric epithelium and DCs (3, 4). Based on this work, she and her team have developed a millifluidic tissue chip to investigate antigen sampling mechanisms across the gastrointestinal epithelium in a closely controlled environment. They are currently adapting this chip platform to investigate SARS-CoV-2 infection in human and bat gastrointestinal organoids.

Vivek V. Thacker, **Ph.D.**

Vivek Thacker obtained his PhD in 2014 from the lab of Prof Ulrich Keyser at the Department of Physics, University of Cambridge where he worked on single-molecule sensing using nanopores and plasmonics, DNA self-assembly, and the biophysics of polymers in confined spaces. He was subsequently awarded an EMBO Long Term Fellowship and an HFSP Long Term Fellowship to move to EPFL to the lab of Prof John McKinney in 2015 to develop organ-on-chip approaches to study the early stages of tuberculosis. More recently, he has also applied these approaches to study the pathogenesis of SARS-CoV-2 in the alveolar space, funded by EPFL and the Novartis Institute for Biomedical Research.

Donald E. Ingber, M.D., Ph.D.

Donald Ingber is the Founding Director of the Wyss Institute for Biologically Inspired Engineering at Harvard University, *Judah Folkman Professor of Vascular Biology* at Harvard Medical School and the Vascular Biology Program at Boston Children's Hospital, and Professor of Bioengineering at the Harvard John A. Paulson School of Engineering and Applied Sciences. He received his B.A., M.A., M.Phil., M.D. and Ph.D. from Yale University. Ingber is a pioneer in the field of biologically inspired engineering, and at the Wyss Institute, he currently leads a multifaceted effort to develop breakthrough bioinspired technologies to advance healthcare and to improve sustainability. His work has led to major advances in mechanobiology, tumor angiogenesis, tissue engineering, systems biology, nanobiotechnology and translational medicine, with his most recent pioneering contribution being the development of microfluidic

Organ-on-Chip microphysiological systems. Through his work, Ingber also has helped to break down boundaries between science, art, and design. He has authored more than 500 publications and over 165 issued or pending U.S. patents, founded 5 companies, and has been a guest speaker at more than 550 events internationally. He is a member of the National Academy of Medicine, National Academy of Inventors, American Institute for Medical and Biological Engineering, and the American Academy of Arts and Sciences. Ingber's Human Organ-on-a-Chip technology was named Design of the Year in 2015, acquired by the Museum of Modern Art (MoMA) in New York City for its permanent collection, and honored as one of the Top 10 Emerging Technologies of 2016 by the World Economic Forum.

Session 5: Commercialization/engineering/collaborations

Thomas Neumann, M.D.

Dr. Neumann's fascination with tissue engineering began during his thesis research more than 25 years ago at the University of Halle, Germany. He continued this line of work at the University of Washington, where he was involved in a project focusing on engineering cardiovascular tissues. In 2012, he started Nortis, one of the first companies in the emerging field of organ-on-chip technologies. Nortis is now regarded as one of the leaders in this space. He is the inventor of the proprietary Nortis technology, with over 50 issued patents in the organ-on-chip domain. He is deeply connected with the stakeholders in the organ-on-chip arena, due to numerous collaborative interactions with our customers in academia and pharmaceutical industry, as well as through our company's involvement in important consortia, such as the NIH/NCATS *Microphysiological Systems* and Tissue-Chip-2.0 programs and the Center for Advancement of Science in Space (CASIS). He is a frequent speaker at workshops and conferences in the field of 3D-in vitro models and reviewer on organ-on-chip related grant applications to the NIH. His company has multiple ongoing collaborations with the University of Washington with world-class investigators at the Department of Mechanical Engineering, the Department Bioengineering, the Department Pharmacy, the Institute for Stem Cell & Regenerative Medicine, as well as the Kidney Research Institute.

Clive Roper, BSc PhD CBiol CSci FRSB

Clive graduated with a toxicology PhD in in vitro dermal absorption and metabolism from Newcastle University. He joined Charles River in 1996 as a Research Officer to develop the in vitro skin penetration service. After serving in study director and scientific manager roles, he became Head, In Vitro Sciences in 2010 and Director, In Vitro Toxicology in 2020. His department currently performs in vitro skin absorption, in vitro safety pharmacology, investigational and mechanistic toxicology using advanced tissue models and in vitro respiratory toxicology. He has presented at many meetings and organized small meetings (Skin Metabolism) and large conferences (WC9). Clive has authored and co-authored many posters and abstracts as well as peer review papers. He is a peer reviewer for journals including TIV, Regulatory Pharmacology & Toxicology, Annals of Work Exposures, and Health and Skin

Pharmacology and Physiology. He has been actively involved in advising regulatory agencies including NIH, SCCS, PMRA and EPA as well as industry bodies and has presented a webinar on in vitro toxicology with the FDA. He is also a member of the global Charles River 3Rs Working Group as well as being a founding member of the North American 3Rs Collaborative. In January 2021, Clive became a Member of the Board of the UK NC3Rs.

Michael J. Moore, Ph.D.

Research in Dr. Moore's academic laboratory is dedicated to the development of *in vitro* models of neural growth, physiology, and pathology by using microscale tissue engineering to mimic the morphology and physiology of native neural tissue. The resultant models are designed to enable entirely new approaches for performing studies on axon growth, physiology, and neuropathology, and may be amenable to high-throughput investigation for neurotoxicity screening and drug discovery. He has the necessary background and experience to contribute to this multidisciplinary effort, having a solid education in both bioengineering and neurobiology, a research record primarily focused on biomaterials and tissue engineering for nervous system applications, a strong predilection for multidisciplinary collaborations, and a record of technology commercialization, including licensed patents.

Since joining the faculty at Tulane in 2007, he initiated an entirely new line of investigation, from the ground up, focused on microscale neural tissue engineering for the development of novel, scalable, biomimetic models for *in vitro* studies of neural morphology and physiology. With strong university support, including generous start-up funding and a complete laboratory renovation, they developed a whole new set of techniques and materials for these model systems. These efforts have attracted funding from the State of Louisiana, the NIH, the DoD, an NSF CAREER award, and CASIS, all focused on the development of various tissue-engineered *in vitro* models of the nervous system for numerous applications.

In 2014, he co-founded AxoSim Technologies, a start-up company dedicated to enhancing drug development by offering the industry's most advanced "Nerve-on-a-Chip" for screening pharmaceuticals. In a short time, they received STTR grants from both the NSF (Phase I) and the NIH (Phase I and II), have grown to over 20 full-time employees, and completed contracts with some of the world's largest pharmaceutical companies. His research efforts now entail scholarly publication both from an academic and commercial setting, as well as patents and technology licenses. These pursuits have given me a more complete perspective on the technology pipeline, from academic lab, to technology transfer and licensing, to commercialization.

His laboratory is currently pursuing the development of advanced human microphysiological models of various aspects of the nervous system, including functional components of peripheral nerve, spinal cord, and brain, and functional connections between them.

Session 6: Multi-organ chips and emerging applications for biologics studies

Uwe Marx, M.D.

Dr. Uwe Marx is the scientific founder and the CSO of TissUse, a spin-out from the Technische Universität Berlin dedicated to the development of human organ- and body-on-a-chip systems for drug testing and precision medicine approaches.

With more than 25 years of experience in protein drug development and tissue engineering Uwe Marx has published more than 150 scientific papers and numerous reviews and book chapters. He is an inventor in more than 30 patent families.

He was born in Berlin in 1964. After finishing his medical and biochemistry training, he received his doctorate degree in immunology from the Charité of the Humboldt University in Berlin. Early in his career, research activities were focused on protein drugs, such as immunotoxins and fully human monoclonal antibodies towards blood group antigens, HIV and bacterial toxins. Since 1990, he managed a unit for pilot scale manufacturing of human monoclonal antibodies at the Institute for Medical Immunology at Charité hospital in Berlin. At that time, he broadened his research activities toward 3D bone marrow cultures for patient specific drug testing. In 1995, Dr. Marx joined the University of Leipzig as head of the department of Medical Biotechnology. His research projects focused on various aspects of tissue engineering, e.g. umbilical cord blood stem cell expansion and in vitro blood vessels for drug screening.

Between 2000 and 2010, Uwe Marx joined ProBioGen – a biotech Company he founded in 1994 - as the Chief Scientific Officer. There he has combined novel technologies for development of high producer cell lines and disposable nature fermentation processes with the long track record of the company's CMO activities. Under his supervision, a human lymph node model for in vitro drug testing was developed, patented and introduced into the contract service panel of the Company.

From 2010 until 2019 Dr. Marx was the Program Head of the GO-Bio program “Multi-organ-bioreactors for the predictive substance testing in chip format”, which was supported by the German Federal Ministry of Education and Research (BMBF). This project was started at the Technische Universität Berlin and led to the establishment of a Multi-Organ-Chip technology capable to maintain as of today 16 miniature human organ equivalents, such as liver, brain, skin, intestine and pancreatic islets, at homeostatic steady state over periods of at least four weeks. Marx has been working together with other scientists to reproduce the human organism on a microfluidic chip at a scale of 1:100,000. The aim is to shorten the entire drug development process as well as to reduce animal experiments and drug testing in humans during clinical trials. He received numerous awards for the development of animal-free technologies and served as a reviewer for governmental programmes in the biotechnology segment. He is actively promoting the global microphysiological systems community and is an active member of the working party cell culture technology of the German DECHEMA e.V.. Finally, Dr. Marx has founded numerous German biotech’s including Vita 34 (www.vita34.de) and ProBioGen (www.probiogen.de).

Gordana Vunjak-Novakovic, Ph.D.

Gordana Vunjak-Novakovic is the University Professor, the highest academic rank at Columbia University and the first engineer at Columbia to receive this distinction. She is also the Mikati Foundation Professor of Biomedical Engineering and Medicine, a faculty in the

Department of Medicine and the College of Dental Medicine, and directing the NIH resource center for tissue engineering. The focus of her lab is on engineering functional human tissues for use in regenerative medicine, studies of development and disease, and patient-specific "organs-on-a-chip" platforms. Her studies were reported in Nature, Cell, Nature Biotechnology, Nature Medicine, Nature Biomedical Engineering, Nature Communications, Nature Protocols, PNAS, Cell Stem Cell, Science Advances, and Science Translational Medicine. She mentored over 150 trainees, licensed numerous patents, and launched four start-up companies with the members of her laboratory. Gordana is currently serving on the NIBIB Council and the HHMI Scientific Review Board. Among her many recognitions, she was decorated by the Order of Karadjordje Star - Serbia's highest honor, and elected to the Academia Europaea, Serbian Academy of Arts and Sciences, the National Academy of Engineering, the National Academy of Medicine, the National Academy of Inventors, and the American Academy of Arts and Sciences.

Linda Gay Griffith, Ph.D.

Linda Gay Griffith is the School of Engineering Teaching Innovation Professor of Biological and Mechanical Engineering and MacVicar Fellow at MIT, where she directs the Center for Gynepathology Research. She led development of the MIT Biological Engineering SB degree program, which was approved in 2005 as MIT's first new undergraduate major in 39 years.

Dr. Griffith has pioneered approaches in tissue engineering, including the first tissue-engineered cartilage in the shape of a human ear, commercialization of the 3DP™ printing process for manufacture of FDA-approved scaffolds, commercialization of the 3D perfused LiverChip for drug development, and synthetic matrices for tissue morphogenesis. She recently led one of two major DARPA-supported "body-on-a-chip" programs, resulting in the first platform to culture 10 different human mini-organ systems interacting continuously for a month. She is now establishing the field of *physiomimetics*, integrating these platform technologies with systems biology and systems immunology to humanize drug development for the most challenging chronic inflammatory diseases, including endometriosis and adenomyosis, through collaboration with industry partners in pharma and biotech around the world.

She has over 200 peer-reviewed scientific publications and holds more than a dozen patents. She has chaired numerous scientific meetings, including the Keystone Tissue Organoids Conference (2020), the Signal Transduction by Engineering Extracellular Matrix Gordon Research Conference (2016), and the annual Open Endoscopy Forum (since 2015), which brings together gynecology surgeons, scientists, engineers, annually at MIT for a TED conference–like weekend.

She is a member of the NAE and recipient of a MacArthur Foundation Fellowship, Radcliffe Fellowship, and several awards from professional societies.

Dr. Griffith currently serves on the advisory board of the Society for Women's Health Research and has served on the advisory councils for the National Institute of Dental and Craniofacial Research and National Institute of Arthritis and Musculoskeletal Diseases, and the advisory committee to the director of the National Institutes of Health.

She received her BS from Georgia Tech and PhD from UC Berkeley, both in chemical engineering.

https://lgglab.mit.edu/, *https://cgr.mit.edu/*

Joanna E. Burdette, Ph.D.

Dr. Joanna E. Burdette earned her B.S. from Emory University in Biology and her Ph.D. at the University of Illinois at Chicago. She was a postdoctoral fellow at Northwestern under the direction of Dr. Teresa K. Woodruff. Dr. Burdette is currently a Professor in the Department of Pharmaceutical Sciences at UIC. In 2014, she was promoted to Associate Dean for Research. Her research has helped to develop three-dimensional models of the fallopian tube to define early events responsible for ovarian cancer formation. She is interested in the use of microfluidics as a novel technology to study ovarian and fallopian tube interaction and communication. She is also actively screening natural products for anti-cancer activity with a focus on ovarian cancer. She has been the recipient of the Liz Tilberis Scholar Award from the Ovarian Cancer Research Fund and was named the UIC Rising Star in 2013 and UIC Distinguished Researcher in 2020. She is currently the associate director of the CCTS KL2 mentoring program for junior faculty, director of the K12 IRACDA mentoring program for postdocs, and the co-lead of the Tumor Cell Biology program at the University of Illinois Cancer Center. www.burdettelab.com

Kyung Sung, Ph.D.

Kyung Sung is a Principal Investigator in the Cellular and Tissue Therapies Branch, Division of Cellular and Gene Therapies in the Office of Tissues and Advanced Therapies.

Her research focuses on developing new quantitative assays using microphysiological systems to study the impact of interactions between living cells and biomaterials used in the manufacture and characterization of regenerative medicine cellular products.

She received her Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor and did her postdoctoral training at the University of Wisconsin, Madison. She also worked as a patent examiner in Biotechnology at the US Patent and Trademark Office before she joined the FDA in 2015.
https://www.fda.gov/vaccines-blood-biologics/biologics-research-projects/investigating-effects-cell-materials-interactions-safety-and-effectiveness-cell-based-products

Kevin Kit Parker, Ph.D.

Kit Parker is the Tarr Family Professor of Bioengineering and Applied Physics at the John A. Paulson School of Engineering and Applied Sciences (SEAS) at Harvard University. Here, Kit serves as the director of the SEAS Disease Biophysics Group, a transdisciplinary research group of artists, engineers, and scientists. His lab is involved in projects ranging from cellular biophysics to developing materials for applications in beauty, food, fashion, and regenerative medicine. His team has targeted interests in cardiovascular physiology, *in vitro* disease modeling, and textile material science.

While at Vanderbilt University for his graduate studies, Kit enrolled in US Army ROTC and joined the Tennessee Army National Guard. Kit graduated from Vanderbilt University with his M.S. in Mechanical Engineering in 1993 and Ph.D. in Biological and Applied Physics in 1998. Kit was deployed to Afghanistan in 2002, 2008, and twice in 2011. He has completed active duty mobilizations to US Special Operations Command (2012-2013) and in support of the White

House National Security Staff (2014). He currently holds the rank of Colonel in the US Army Reserve and serves as a Professor at the United States Military Academy at West Point.

Kit earned a B.S. in Biomedical Engineering from Boston University in 1989. He is the founding Editor in Chief of *Biophysics Reviews*, a new journal from the American Institute of Physics. His diverse entrepreneurial and teaching interests also include fashion design, food, cooking technology, leadership, adaptive learning in organizations, and the application of counterinsurgency theory in fighting transnational organized crime.

Thomas Hartung, M.D., Ph.D.

Thomas Hartung, MD PhD, is the Doerenkamp-Zbinden-Chair for Evidence-based Toxicology in the Department of Environmental Health and Engineering at Johns Hopkins Bloomberg School of Public Health, Baltimore, with a joint appointment at the Whiting School of Engineering. He also holds a joint appointment for Molecular Microbiology and Immunology at the Bloomberg School. He is adjunct affiliate professor at Georgetown University, Washington D.C. In addition, he holds a joint appointment as Professor for Pharmacology and Toxicology at University of Konstanz, Germany; he also is Director of Centers for Alternatives to Animal Testing (CAAT, http://caat.jhsph.edu) of both universities.

CAAT hosts the secretariat of the Evidence-based Toxicology Collaboration (http://www.ebtox.org), the Good Read-Across Practice Collaboration, the Good Cell Culture Practice Collaboration, the Green Toxicology Collaboration and the Industry Refinement Working Group. As PI, he headed the Human Toxome project funded as an NIH Transformative Research Grant. He is Chief Editor of Frontiers in Artificial Intelligence. He is the former Head of the European Commission's Center for the Validation of Alternative Methods (ECVAM), Ispra, Italy, and has authored more than 585 scientific publications.

Session 7: Perspectives and strategies on the need for animal cell and chip-banks

Kevin Greenlees, Ph.D., DABT

Dr. Greenlees received a Doctoral degree in cardio-pulmonary physiology from Colorado State University in 1983. Post-doctoral positions at the University of Guelph, Canada, and the Virginia-Maryland Regional College of Veterinary Medicine led to joining the USFDA Center for Veterinary Medicine in 1989. Dr. Greenlees has been a diplomate of the American Board of Toxicology since 1995 and has been a WHO temporary expert and member in meetings of the FAO/WHO Joint Expert Committee on Food Additives for veterinary drugs from 2000 through 2015. He is the current Chair for the Codex Committee on Residues of Veterinary Drugs (CCRVDF) and is currently a Senior Advisor for Science and Policy in the Office of New Animal Drug Evaluation at the Center for Veterinary Medicine in the US Food and Drug Administration.

Bernadette Dunham, D.V.M., Ph.D.

Dr. Bernadette Dunham is with the Milken Institute School of Public Health at George Washington University (2016 to present) where her focus is on One Health issues. In October

2019, Dr. Dunham was appointed as a member of the National Academies of Sciences, Engineering and Medicine's Board on Agriculture and Natural Resources for a three-year term thru December 2022. Dr. Dunham returned to FDA in August 2019 to serve as an Advisor to the FDA One Health Initiative. Dr. Dunham has served the FDA as Director of the Center for Veterinary Medicine (CVM), Deputy Director of CVM, Director of the Office of Minor Use and Minor Species, and Deputy Director of the Office of New Animal Drug Evaluation. Before beginning her government career in 2002, she was an Assistant Director with American Veterinary Medical Association's Governmental Relations Division in Washington, D.C. from 1995-2002. Dr. Dunham served as Director of Laboratory Medicine and Adjunct Professor of Pharmacology at the State University of New York Health Science Center, Syracuse, N.Y. from 1987-1995. Before returning to academy in 1979, Dr. Dunham was in private veterinary practice for four years in Oshawa, Ontario, Canada. Dr. Dunham received her DVM degree from the Ontario College of Veterinary Medicine, University of Guelph, Canada and her Ph.D. from Boston University, MA.

Dr. Dunham is a member of the American Veterinary Medical Association, the American Academy of Veterinary Pharmacology and Therapeutics, the National Academies of Practice, the American Public Health Association, and an Honorary member of the American Association of Food Safety and Public Health. She is an Honorary Diplomate and an awardee of the K.F. Meyer - James H. Steele Gold-Headed Cane Award from the American Veterinary Epidemiology Society. She has served on peer review panels for the National Academies of Science, the American Heart Association - New York State Affiliate, United States Department of Agriculture-Cooperative State Research, Education and Extension Service, Competitive Programs, and the National Institutes of Health. Dr. Dunham served as the Chairperson for the 18th Session of the Codex Alimentarius Committee on Residues of Veterinary Drugs in Foods.

PJ Devine, Ph.D.

PJ Devine studied mechanisms of developmental toxicity of methylmercury in graduate school (1992-1999), then investigated mechanisms by which chemicals affected small ovarian follicles and female fertility during a post-doctoral fellowship with Patricia Hoyer at the University of Arizona (1999-2003). PJ continued with the theme of studying ovarian function and reproductive toxicology as a professor at the Institut national de la recherche scientifique in Laval, QC, from 2003 to 2010. Major projects included studying the mechanism(s) by which chemotherapeutic agents caused depletion of small ovarian follicles, identifying biomarkers of fertility for toxicology studies, and examining the role of pollution on frog reproduction and development. PJ joined the Novartis Institutes for BioMedical Research in 2010 to examine issues related to endocrine and reproductive toxicology. His current position involves advising project teams on safety aspects of drug development and studying mechanisms by which drugs cause adverse effects. His focus is on metabolic disorders, advanced therapies, biomarkers of safety, and investigative toxicology. Research has involved many *in vitro* models, but also investigative *in vivo* research. PJ is also involved in cross-industry consortia involving biomarkers (Preclinical

Safety Testing consortium, PSTC) and evaluating complex *in vitro* models (Innovation and Quality microphysiological systems, IQ MPS).

Education: B.Sc. in Chemistry and Biology, University of Delaware (1992). Ph.D. in Toxicology, University of Maryland, Baltimore (1999).

E. Sidney Hunter, III, Ph.D.

Dr. Hunter is a Developmental Toxicologist at the US EPA Center for Computational Toxicology and Exposure. He is the Branch Chief of the Advanced Experimental Toxicology Models Branch, Biomolecular and Computational Toxicology Division in CCTE. He is a lead in the Virtual Tissues Model Project. His research has focused on understanding the mechanisms responsible for chemically-induced developmental toxicity. He used the whole embryo culture technique to study the morphological, metabolic, transcriptional and proteomic effects of chemicals during neural tube closure and early craniofacial development. The Hunter lab used an adherent mouse embryonic stem cell culture model to evaluate the effects of ToxCast compounds and selected chemical libraries on stem cell differentiation and proliferation. These data are being used to determine signaling pathways sensitive to chemical perturbation in stem cells and apply that knowledge to predicting embryonic effects. As part of the EPA's Virtual Tissues Models project, the Hunter lab works to establish organotypic and microphysiological system culture models of early human heart, neurovascular development and placenta to evaluate chemical effects on developmentally critical targets and contribute to the creation of computer and predictive models of chemical effects on human development.

Education:

- B.S., Hampden-Sydney College, Hampden-Sydney, VA; Chemistry, 1980
- M.S., Old Dominion University, Norfolk, VA; Toxicology, 1983
- Ph.D., University of North Carolina Chapel Hill, Chapel Hill, NC; Anatomy, 1986

Lorna Ewart, Ph.D.

Lorna Ewart is Emulate's Executive Vice President in Europe where she leads the European activities. In addition, Lorna also heads the internal R&D organization and the fee-for-service organization. She has over 20 years' experience in the pharmaceutical industry, spanning BioScience and Drug Safety. Within the pharmaceutical industry, Lorna rapidly developed a reputation as a valued partner with academic institutions, regulatory bodies, and technology developers and successfully established the Microphysiological Systems Centre of Excellence within AstraZeneca's R&D Biopharmaceuticals Unit in Cambridge, UK. Earlier in her career, Lorna was the therapy area lead toxicologist for Respiratory and Inflammation in AstraZeneca's Gothenburg R&D site, Sweden. Following her Ph.D., she joined the Respiratory and Inflammation research area within AstraZeneca, optimizing efficacy in small molecules before moving into preclinical Drug Safety where she led a Safety Pharmacology team delivering GLP data across multiple therapeutic areas.

Lorna is a classically trained pharmacologist and obtained her honors degree at the University of Aberdeen and her Ph.D. at the William Harvey Research Institute in London. She is a fellow of the Royal Society of Biology and British Pharmacological Society.