Micro-Physiological Systems for Efficacy and Safety Studies: A Workshop on Advances in Organs-On-Chip Technologies for Animals

Committee

Patrick Devine

Co-Chair

Patrick “PJ” Devine is a senior investigator I of discovery and investigative safety in the Department of Preclinical Safety at Novartis Institutes for BioMedical Research Inc. Dr. 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 his post-doctoral work with Patricia Hoyer at the University of Arizona (1999-2003). His focus was on the chemical 4-vinylcyclohexene diepoxide as a model ovotoxicant which depletes dormant ovarian follicles. He continued with the theme of studying ovarian function and reproductive toxicology as a professor at the Institut national de la recherche scientifique in Laval, Quebec, from 2003 to 2010. His major projects included studying the mechanism(s) by which alkylating 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. He 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. His research has involved many in vitro models, but he has performed investigative in vivo research. He 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). Dr. Devine received his B.Sc. in chemistry and biology from the University of Delaware in 1992 and his Ph.D. in toxicology from the University of Maryland, Baltimore in 1999.

Danilo A. Tagle

Co-Chair

Danilo A. Tagle is associate director for special initiatives at the National Center for Advancing Translational Sciences (NCATS). He also recently served as the Center's acting deputy director, as well as the acting director of NCATS' Office of Grants Management and Scientific Review and as executive secretary to the NCATS Advisory Council and Cures Acceleration Network Review Board. Prior to joining NCATS, Tagle was a program director for neurogenetics at the National Institute of Neurological Disorders and Stroke (NINDS), where he was involved in developing programs concerning genomics-based approaches for basic and translational research in inherited brain disorders. Prior to joining NINDS in 2001, Tagle was an investigator and section head of molecular neurogenetics at the National Human Genome Research Institute and has been involved in the highly collaborative effort toward the positional cloning of genes for Huntington’s disease, ataxia-telangiectasia and Niemann-Pick disease type C. He has served on numerous committees and advisory boards including the editorial boards of the journals Gene and the International Journal of Biotechnology. Tagle obtained his Ph.D. in molecular biology and genetics from Wayne State University School of Medicine in 1990. He was an NIH National Research Service Award postdoctoral fellow in human genetics in the laboratory of Francis S. Collins, M.D., Ph.D., at the University of Michigan. Tagle has authored more than 150 scientific publications and has garnered numerous awards and patents.

Ashutosh Agarwal

Member

Ashutosh Agarwal is an associate professor of biomedical engineering and associate director of the Dr. John T. Macdonald Foundation Biomedical Nanotechnology Institute at the University of Miami. The research mission of his Physiomimetic Microsystems Laboratory (http://www.pmlaboratory.com/) is to develop human relevant organ mimic platforms to replace or significantly reduce animal testing for discovery of therapies and drugs. Organs on chips are also being employed for modeling of disease states, for conducting mechanistic studies, and for differentiation, maturation, and evaluation of human stem cells. The lab is supported by multiple consortium grants from the National Institutes of Health, commercialization grants from Wallace H. Coulter Foundation, and sponsored research projects from pharmaceutical companies. Dr. Agarwal was selected as a Kavli Fellow to participate in the National Academy of Sciences Frontiers of Science Symposium in Jerusalem (2019), featured speaker at the National Academy of Engineering-National Academy of Medicine Regional Meeting in Miami (2018), and invited speaker at the World Congress on Alternatives and Animals in the Life Sciences (WC10, 2017). Dr. Agarwal received his Ph.D. in materials science and engineering at the University of Florida in 2009 and completed his postdoctoral research experience at Columbia and Harvard Universities.

Szczepan Baran

Member

Szczepan Baran is Head of Emerging Technologies of Laboratory Animal Science at Novartis Institutes for Biomedical Research. In this position, Dr. Baran leads development and implementation of strategic vision for emerging technologies to optimize non-clinical models of efficacy, mechanism, and safety that improve endpoint prediction, reproducibility, and clinical predictivity. He spearheads digital biomarker and endpoint strategy and alignment with disease areas and clinical franchises, internal groups, and resources for platforms that offer alternatives to traditional pre-clinical modeling, such as microphysiological systems, and builds high performance cross-functional teams that accelerate validation and readiness of emerging technologies that foster a culture of collaboration and high performance innovation. Prior to joining Novartis in 2014, Dr. Baran was COO and founder of the Veterinary Bioscience Institute. While at Fred Hutchinson Cancer Research Center from 2005-2007, he was a member of the team that discovered the first canine embryonic stem cells. He has held faculty positions at Wake Forest School of Medicine, Drexel University College of Medicine, and Delaware Valley University. Dr. Baran is the founder of the largest laboratory animal science and medicine LinkedIn group as well as Labroots Laboratory Animal Virtual Conference, which has the largest participation of any laboratory animal conference in the world. He has served on multiple boards including Academy of Surgical Research and Americans for Medical Progress. Currently, he is serving as chairperson of the North America 3Rs (NA3Rs) Collaborative and is a chair-elect of the 3Rs Working Group International Consortium for Innovation and Quality in Pharmaceutical Development. Dr. Baran earned his B.S. in animal science from the University of Delaware and his VMD from the University of Pennsylvania School of Veterinary Medicine. He completed his residency in laboratory animal medicine and obtained his M.S. degree in comparative physiology and medicine at the University of Washington School of Medicine.

Suzanne Fitzpatrick

Member

Suzanne Fitzpatrick is the senior advisor for toxicology in the Office of the Center Director at Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration (FDA). Dr. Fitzpatrick is a board-certified toxicologist in the U.S. and in Europe. Dr. Fitzpatrick is also an adjunct professor at Johns Hopkins University. Dr. Fitzpatrick is the chair of the FDA's Alternative Methods Work Group that has representation from all parts of the FDA and is currently focusing on in vitro Microphysiological Systems (MPS). Dr. Fitzpatrick is the FDA lead for Tox 21 and is the FDA principal representative to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). She chaired the FDA's Predictive Toxicology RoadMap Committee. Dr. Fitzpatrick was the FDA lead for the FDA/NIH Common Fund award to Wyss Institute to develop a heart lung micromachine. She then helped develop the FDA/DARPA/NCATS program on Organs on a Chip and continues to work and give presentations on this evolving area. She is on the EU Tox Risk Regulator Committee. Dr. Fitzpatrick has received several awards including the 2019 Society of Toxicology (SOT) Enhancement of Animal Welfare Award. Dr. Fitzpatrick served on the planning committees for SOT Future Tox I, II, and III and was the co-chair of Future Tox IV. She is a past president of the American College of Toxicology. Currently, she is the secretary on the Society of Toxicology Council. Dr. Fitzpatrick believes strongly in working together with all stakeholders both nationally and internationally to develop new alternative methods for regulatory testing. Dr. Fitzpatrick received her B.A. from the University of California at San Diego and her Ph.D. from Georgetown University.

Sean Gehen

Member

Sean Gehen leads a global team of human safety (toxicologists and human health risk assessors) experts at Corteva Agriscience. Prior to this role, Sean was a project leader and investigative toxicologist within the Dow AgroSciences Predictive Safety Center working to implement cutting-edge tools for predicting human and environmental safety of early-stage crop protection products. Sean has a passion for bringing forward non-animal methods in the crop protection sector, is currently serving in a leadership capacity in the Society of Toxicology In vitro and Alternative Methods Specialty Section, and is also a member of the National Institute of Environmental Health Sciences' Scientific Advisory Committee on Alternative Toxicological Methods. He received his B.S. in microbiology from Brigham Young University and his Ph.D. in toxicology from The University of Rochester School of Medicine and Dentistry where he studied effects of oxidants on the developing lung.

David M. Kurtz

Member

David Kurtz currently serves as the Head, Quality Assurance Laboratory (QAL) within the Comparative Medicine Branch (CMB) at National Institute of Environmental Health Sciences (NIEHS), one of 27 institutes within the National Institutes of Health. Dr. Kurtz received his DVM from the University of Tennessee in 1989. After 2 years as a small animal private practitioner, Dr. Kurtz completed a residency in laboratory animal medicine at the University of Alabama– Birmingham (UAB) in 1993. He went on to earn a PhD in 1998 from UAB in molecular and cellular pathology in 1998. Dr. Kurtz completed a post-doctoral fellowship in the Division of Cardiology at Washington University School of Medicine in St. Louis (WUSTL) studying metabolic gene expression, as well as serving as a clinical veterinarian for the Division of Comparative Medicine. From 2003 to 2011, he served as the attending veterinarian at the U.S. Environmental Protection Agency National Health and Environmental Effects Research Laboratory in Research Triangle Park, North Carolina under a contract with Experimental Pathology Laboratories, Inc. Dr. Kurtz received diplomate status in the American College of Laboratory Animal Medicine in 2005. During that same period, Dr. Kurtz also served as the attending veterinarian for The Hamner Institutes of Health Sciences and Integrated Laboratory Systems, Inc., both located in Research Triangle Park, NC. Dr. Kurtz joined NIEHS in 2011.

Milica Radisic

Member

Milica Radisic is a professor at the University of Toronto and the Canada Research Chair in Functional Cardiovascular Tissue Engineering and senior scientist at the Toronto General Research Institute. She is also the associate chair-research for the Department of Chemical Engineering and Applied Chemistry at the University of Toronto, director of the Natural Sciences and Engineering Research Council's Collaborative Research and Training Experience Program (NSERC CREATE) in Organ-on-a-Chip Engineering and Entrepreneurship, and director of Ontario-Quebec Center for Organ-on-a-Chip Engineering. She is a fellow of the Royal Society of Canada-Academy of Science, Canadian Academy of Engineering, the American Institute for Medical and Biological Engineering, and the Tissue Engineering and Regenerative Medicine Society (TERMIS). She has received numerous awards and fellowships including MIT Technology Review's Top 35 Innovators Under 35. She was a recipient of the Professional Engineers Ontario-Young Engineer Medal in 2011, Engineers Canada Young Engineer Achievement Award in 2012, Queen Elizabeth II Diamond Jubilee Medal in 2013, NSERC E.W.R Steacie Fellowship in 2014, YWCA Toronto Woman of Distinction Award in 2018, and Ontario Professional Engineers Awards' Research and Development Medal in 2019, to name a few. Her research focuses on organ-on-a-chip engineering and development of new biomaterials that promote healing and attenuate scarring. She developed new methods to mature induced pluripotent stem cells (iPSC) derived cardiac tissues using electrical stimulation. Currently, she holds research funding f rom the Canadian Institutes of Health Research (CIHR), NSERC, Canada Foundation for Innovation, Ontario Research Fund, National Institutes of Health (NIH), and the Heart and Stroke Foundation. She is an associate editor for ACS Biomaterials Science and Engineering, a member of the editorial board of Tissue Engineering, Advanced Drug Delivery Reviews, Regenerative Biomaterials, Advanced Biosystems, Journal of Molecular and Cellular Cardiology, and eLife. She serves on review panels for CIHR and the NIH. She is actively involved with the Biomedical Engineering Society (Cardiovascular Track Chair in 2013 and 2104) and TERMIS-AM (council member, chair of the membership committee). She was a co-organizer of a 2017 Keystone Symposium, "Engineered Cells and Tissues as Platforms for Discovery and Therapy." She served on the board of directors f or the Ontario Society of Professional Engineers and currently serves on the board of directors of the Canadian Biomaterials Society. Her research findings have been presented in over 200 research papers, reviews, and book chapters. Her publications appear in prestigious journals such as: Cell, Nature Materials, Nature Methods, Nature Protocols, Nature Communications, PNAS, etc. In 2014, she co-founded an award winning company, TARA Biosystems, that uses matured human engineered heart tissues in drug development. TARA currently tests drugs for major pharmaceutical companies. In 2017, she founded Quthero Inc., a company focused on disrupting the skin regeneration and wound healing market through the use of proprietary Q-gel to promote scar-free wound healing. She obtained her B.Eng. from McMaster University and Ph.D. from the Massachusetts Institute of Technology, both in chemical engineering.

John Rogers

Member

John Rogers is the associate director of the Public Health and Integrated Toxicology Division, Center for Public Health and Environmental Assessment, U.S. Environmental Protection Agency (EPA). Prior to that, he served as chief of the Developmental Biology Branch, and he has been with EPA for 32 years. Dr. Rogers is also a graduate faculty affiliate in the Curriculum in Toxicology, University of North Carolina-Chapel Hill, and adjunct professor at North Carolina State University College of Veterinary Medicine. Dr. Rogers's research addresses mechanisms of abnormal development including maternally-mediated developmental toxicity, maternal nutrition, and the developmental origins of health and disease. Dr. Rogers is a past president of the Teratology Society, a member of the Society of Toxicology (SOT), past president of the Reproductive and Developmental Toxicity Specialty Section of SOT, and a member of the International Society for Developmental Origins of Health and Disease (DOHaD). Dr. Rogers has published over 125 peer-reviewed papers, invited reviews, and book chapter and has edited two books. Dr. Rogers has received 13 EPA Scientific and Technical Achievement Awards for his published works and three Bronze Medals for service to the U.S. EPA. He received his Ph.D. in biology from the University of Miami and was a National Eye Institute postdoctoral fellow at the University of California, Davis.