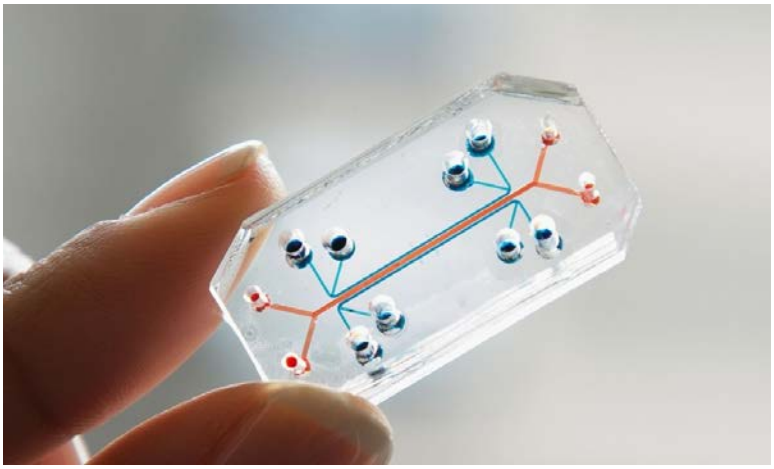
Mid-Atlantic Chapter

Society of Toxicology
(MASOT)

Fall 2018 Scientific Meeting
Sheraton Edison Hotel, Raritan Center, Edison, NJ

The *Mid-Atlantic Chapter of the Society of Toxicology (MASOT)* was formed to: (1) serve as a focal point for toxicological interests within the region; (2) encourage interactions among toxicologists in government, industry, and academia; and, (3) sponsor scientific and educational programs in toxicology. The Chapter and its bylaws were officially approved by the Council of the Society of Toxicology at the March 1982 Annual Meeting.



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MASOT FALL MEETING
October 18, 2018

Organs-on-a-chip and Microphysiological Systems

8:30 – 9:00 **Continental Breakfast/Registration/Networking**

9:00 – 9:15 **Introduction and MASOT Update – Dr. Diane Hardej**
Education and Outreach Committee Update – Dr. Gloria Post

9:15 – 10:00 **Suzanne Fitzpatrick, PhD, DABT, ERT (FDA)**
Title: FDA Perspectives on Organs- and Tissues-on-Chips

10:00 – 10:45 **Kim Boekelheide, MD, PhD (Brown University)**
Title: Human 3D Microtissues for Toxicity Testing via Integrated Imaging, Molecular and Functional Analyses

10:45 – 12:00 **Student Poster Session 1**

12:00 – 1:00 **Lunch and presentation of the Ambassador Award to Dr. Kim Boekelheide, MD, PhD**

1:00 – 2:00 **Student Poster Session 2**

2:00 – 2:45 **Kristin Bircsak, PhD (MIMETAS)**
Title: The OrganoPlate®: Human organ-on-a-chip tissue models for predictive toxicity testing in high throughput

2:45 – 3:30 **Anthony Bahinski, PhD, MBA, FAHA (GlaxoSmithKline)**
Title: Human Organs on Chips: Opportunities and Challenges for Personalized Drug Development

3:30 – 3:45 **Awards and Closing Remarks: Dr. Diane Hardej**

3:45 – 4:30 **Speed Networking Student Event**

FDA Perspectives on Organs- and Tissues-on-Chips

Suzanne Fitzpatrick, PhD, DABT, ERT

Dr. 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 US Food and Drug Administration. Dr. Fitzpatrick is a board certified toxicologist here in the US and in Europe. She is the FDA lead for Tox 21 and is also an FDA Representative to ICCVAM. She is in charge of all toxicology research at CFSAN. Dr. Fitzpatrick represents CFSAN on several FDA Committees and Work Groups including the FDA Biomarkers Group, the NIH FDA Biomarkers Group, the FDA Senior Toxicology Workgroup, the HHS Environmental Justice Committee, and the FDA/NCATS/DARPA Collaboration on Organs/Human on a Chip. She represents FDA at several outside committees, including ILSI HESI Emerging Issues, ILSI North America, NRC Emerging issues Committee, and the OSTP Subcommittee on Toxics and the Environment. Dr Fitzpatrick is the FDA representative to the Federal Children's Environmental Health Task Force. Dr. Fitzpatrick is an FDA representative to several OECD Committees including the Work Group on Non-Genotoxic carcinogens, OECD Validation Management Group-Non-Animal and the OECD Advisory Group on Molecular Screening and Toxicogenomics. She is very active in the Society of Toxicology including serving on the planning committees for Future Tox I, II, III, and IV. She is on the planning committee for the 10th World Congress on Alternatives. Dr. Fitzpatrick is a Past President of the American College of Toxicology. Dr. Fitzpatrick is an Adjunct Professor at Johns Hopkins University. Dr. Fitzpatrick received her BA from the University of California at San Diego and her PhD from Georgetown University.

Abstract

The challenge of modern product development and globalization underscores the critical importance of ensuring that regulatory science keeps pace with basic and applied science and technology. Identification and adoption of emerging toxicity tools has the potential to improve preclinical safety predictions. Advances in bioengineering and material sciences and microfluidic technologies have enabled the development of in vitro microphysiological systems that reconstitute tissue-tissue interfaces critical to organ function. However confidence is needed in the performance of any new tools before they are used to demonstrate safety. Traditional validation approaches may not be relevant for in vitro microphysiological systems. FDA's qualification program uses a context of use approach to develop a complete and precise statement that describes the appropriate use of a new tool and how it is applied in regulatory review. Knowing these strengths and limitations allows one to define how these results can be used. In April 2017, FDA announced a multiyear research and development agreement with Emulate, to evaluate the company's organ on a chip technology and to use these chips as models for developing both concordance data and performance standards applicable to all in vitro microphysiological systems.

Ambassador Award Lecture

Human 3D Microtissues for Toxicity Testing via Integrated Imaging, Molecular and Functional Analyses

Kim Boekelheide, MD, PhD

Kim Boekelheide is Professor of Pathology and Laboratory Medicine at the Brown University School of Medicine. He received his B.A. from Harvard University, and M.D. and Ph.D. from Duke University. Current research projects include the development of novel in vitro approaches to safety assessment, the study of fundamental molecular mechanisms by which environmental and occupational toxicants induce cellular injury and male reproductive effects, and the discovery of sperm molecular biomarkers that reflect testicular injury. He is Associate Director of the Brown University Superfund Research Program and Associate Director of the Brown University Center to Advance Predictive Biology. His research has been continuously funded by the National Institute of Environmental Health Sciences since 1985 and he has received several awards including a Burroughs Wellcome Toxicology Scholar Award (1994-1999), and the Lifetime Achievement Award (2015) from the Reproductive and Developmental Toxicology Specialty Section of the Society of Toxicology.

Abstract

Efforts to try and predict the responses of humans to toxic chemicals in our environment and new drug candidates currently require large numbers of animals for regulatory approval. The use of animals is expensive, slow, and often of limited utility because of inter-species differences in response. Traditional 2D *in vitro* cell culture models often fail to reflect the complex biology of organs and tissues. Needed are new, cost effective, and predictive assays that can assess adverse effects of chemicals and drugs in humans.This presentation will describe an integration of biology and engineering to devise simple, high-throughput 3D human microtissues as predictive biology platforms that reflect human physiology and disease, solving fundamental questions of adverse biological response with the goal of modernizing toxicity and drug candidate testing. A key aspect of this approach is the implementation of "*in vitro* pathology," making use of quantitative metrics from reconstructed 3D microtissue images to discern adverse biological effects. This strategy is currently being used to develop 3D microtissues of a variety of human tissues, exploring the utility of single cell lines, co-cultures of cells, and human induced pluripotent stem cells. The goal is to access a wide variety of cellular behavior, characterizing responses across the biologic landscape using simple and rapid tools and techniques.

The OrganoPlate®: Human organ-on-a-chip tissue models for predictive toxicity testing in high throughput

Kristin Bircsak, PhD

Kristin Bircsak is a Senior Scientist with MIMETAS, The Organ-on-a-Chip Company in Gaithersburg, Maryland. In 2016, she received her Ph.D. in Toxicology from Rutgers University following which she completed a postdoctoral fellowship at the University of Pennsylvania. In her training, Kristin utilized various model system to characterize the negative impact of drugs and environmental chemicals on reproduction and development. In her role at MIMETAS, Kristin drives the development of innovative 3D *in vitro* organotypic models and assays. Her research is centered on recapitulating the liver and prostate microenvironment to aid in the accurate prediction of safe and effective candidate compounds. Importantly, her research efforts contribute to the 3Rs effort of reducing, refining, replacing animal use. Kristin has published 11 papers in peer-reviewed journals and was awarded various poster and travel awards to attend international meetings including the 2018 European Society of Toxicology In Vitro. An active member of MASOT and SOT for many years, Kristin has served as a MASOT graduate student representative and Program Committee member and looks forward to participating in this year's meeting as a presenter.

Abstract

Organ-on-a-chip has recently emerged as a new paradigm in enhanced, 3D tissue culture. The field builds on almost 26 years of developments in microfluidic and associated microfabrication techniques and offers more physiologically relevant cell and tissue culture approaches. Application of microengineering techniques in cell culture enables structured co-culture, the use of flow and associated shear stress and application of controlled gradients. MIMETAS develops a commercially available platform based on a microtiter plate format that harbors up to 96 tissue chips and enables perfused 3D co-culture without the use of artificial membranes. The OrganoPlate® is fully compatible with liquid handling equipment and high-content readers and is easily adopted by end-users. Today's presentation will describe three models commonly used with toxicity testing in the OrganoPlate® including human intestine, kidney proximal tubule, and liver. We will review the molecular characterization of each model system following treatment with organ-specific toxicants.

Human Organs on Chips: Opportunities and Challenges for Personalized Drug Development

Anthony Bahinski, PhD, MBA, FAHA

Dr. Anthony Bahinski is Global Head of Safety Pharmacology at GlaxoSmithKline. Prior to joining GlaxoSmithKline, he was a member of the Advanced Technology Team at the Wyss Institute for Biologically Inspired Engineering at Harvard University where he led development of novel Organ-on-a-Chip technologies for more predictive in vitro assays for safety and efficacy of drugs, vaccines and biologics. Dr. Bahinski's career spans academic research and large Pharma, with over 18 years' experience in the pharmaceutical industry (including P&G, Pharmacia, Pfizer). Dr. Bahinski received his PhD in Physiology from Temple University, Philadelphia, PA and his MBA from Xavier University, Cincinnati, OH. He completed post docs at Rockefeller University and the University of Cincinnati. Dr. Bahinski has served on several advisory boards and is a current member of the Science Board of the United States Food and Drug Administration, recently appointed to the EPA's Board of Scientific Counselors (BOSC), member of EU H2020 ORgan-on-Chip In Development (ORCHID) Advisory Board and former member of the Board of Directors of the Safety Pharmacology Society. He is a member of the Editorial Board of the journals, Applied In Vitro Toxicology and Frontiers in Pharmacology of Ion Channels and Channelopathies. He has served on Peer Review Panels at the NIH, EPA and NCI SBIR. He has served the Society of Toxicology as Councilor (Executive Committee) of the Drug Discovery Toxicology Specialty Section and is current Vice President-Elect of the Cardiovascular Toxicology Specialty Section. He is author/co-author of 42 publications including peer-reviewed articles and book chapters.

Abstract

Development of safe and effective drugs is currently hampered by the poor predictive power of existing preclinical animal models that often lead to failure of drug compounds late in their development. Given the tremendous cost of drug development and the long timelines involved, major pharmaceutical companies and government funding agencies are now beginning to recognize a crucial need for new technologies that can quickly and reliably predict drug safety and efficacy in humans in preclinical studies. Advances in bioengineering, material sciences, microfabrication, and microfluidics technologies have enabled the development of microphysiological systems that mimic the functional units of an organ. Organs-on-Chips are microfluidic cell culture devices that contain hollow micrometer-sized chambers inhabited by living cells that recreate the specialized multicellular architectures, tissue-tissue interfaces, physicochemical microenvironments and vascular perfusion necessary to recapitulate organ-level physiology in vitro. Combined with the use of individual patient derived primary, or iPS-derived cells these systems hold promise for the development of more translational disease models and application in precision medicine and personalized health. These microsystems could potentially further our understanding of disease etiology and fill the critical need for improved model systems to predict efficacy, safety, bioavailability, and toxicology outcomes for candidate compounds.

MASOT Student Achievement Award

The MASOT Student Achievement Award is a $1000 award that was developed to recognize significant achievements of MASOT doctoral student members. Criteria that will be considered for this award include academic excellence, outstanding scientific achievement in the field of toxicology, and leadership and service to SOT, MASOT and the applicant's academic institution.

Conney W. Berger Jr., PhD, DABT, Memorial Graduate Student Travel Award

As many of you are probably aware, Dr. Conney Berger passed away on October 27th, 2017 after his battle with pancreatic cancer. Conney was very involved with both SOT and MASOT over the years, serving as MASOT President in 2014-2015. He brought his vast knowledge of toxicology to the MASOT membership with his experience from Bristol-Myers Squibb, GlaxoSmithKline, Hoffman-LaRoche and Toxicology Regulatory Services. Conney was a mentor to innumerable MASOT members and served as an inspiration with his dedication to the field of toxicology and service to MASOT and SOT.

We are proud to announce the Conney W. Berger, PhD, DABT Graduate Student Memorial Award in memory of a great man and dedicated scientist. Many thanks to Conney's wife, Aimee Berger, and his son Conne Will Berger III and Sebastian Berger. Graduate students present at the Fall 2018 MASOT meeting in Edison, NJ, will be eligible to enter their name in a drawing for this $500 award with the exclusion of the recipient of the Student Achievement Award. The recipient of this award will be chosen at the conclusion of the meeting.

Student Poster Awards

Most Outstanding

Outstanding

Honorable Mention

Membership Choice

Speed Networking Student Event

All students and post-doctoral trainees are invited to take advantage of a wonderful networking opportunity. Panelists from academia and industry will be available to offer career advice and answer questions in a small group setting.

Panelists:

Lauren Aleksunes, PharmD, PhD: Dr. Aleksunes is an Associate Professor in the Ernest Mario School of Pharmacy at Rutgers University. She runs a multidisciplinary lab that includes PharmD students, PharmD/PhD students, PhD students and MD fellows. Together, they study the metabolism and transport of drugs and toxicants in the placenta, liver, brain, and kidneys.

Milan Prajapati, MS, PhD: Dr. Prajapati received his doctorate degree in pharmaceutical science under the guidance of Dr. Cerreta from St. John's University, NY. He is currently a post-doctoral trainee under the mentorship of Dr. Tom Bartnikas at Brown University, Providence, RI. While his graduate work was focused on studying environmental/occupational exposure of metals, his post-doctoral research is mainly concentrated on mouse models of inherited/acquired metal toxicity. Dr. Prajapati has served on a number of education and outreach initiatives namely 'Dean's hour: careers in toxicology' at St. John's University (2017) and Summer@brown – a pre-college summer program (2018).

John Mitchell, MS, PhD: Dr. John M. Mitchell has been involved in Clinical and Nonclinical Safety Evaluation and Regulatory Affairs for over 43 years. Currently, he is consulting as Executive Director / Senior Scientist, serving as a regulatory and toxicology consultant to pharmaceutical, medical device and OTC companies. Previously, he worked in an academic toxicology laboratory, in consumer products, pharmaceutical and consulting firms, Contract Research Organizations (CROs) and as a Clinical Toxicologist in hospitals. Dr. Mitchell has a BA (Cell and Molecular Biology, UCONN), an MS (Medical Pharmacology, N Y Medical College) and PhDs (Toxicology/Pharmacology, Joint Program, UMDNJ-Rutgers University). He is a

senior adjunct professor at New York Medical College and at NYU Medical School. He has been Secretary/Treasurer and a Councilor for Mid-Atlantic Society of Toxicology (MASOT) and longtime member of the MASOT Program Committee.

C.K. Korgaonkar, MPharm, PhD, DABT: Dr. Korgaonkar is a Senior Toxicologist in the Drug Safety Evaluation Department at Bristol-Myers-Squibb, NJ. As a nonclinical toxicology lead, he is involved in drug development projects for small molecules and biologics in different stages of development in multiple therapeutic areas including oncology and immuno-oncology. He received his doctorate in Pharmacology from the University of Iowa and was a postdoctoral fellow at the Indiana University College of Medicine where he studied molecular mechanisms of cellular toxicity and carcinogenesis.

Deidre Dalmas Wilk, MS, PhD: Dr. Dalmas Wilk is a Scientific Leader within the Investigative Transcriptional and Cellular Safety Group (formerly Safety Assessment) at GlaxoSmithKline. She received her doctorate from the University of the Sciences in Philadelphia and her Master and Bachelor of Science degrees from Thomas Jefferson University and Philadelphia College of Pharmacy and Science, respectively, all in in the Pharmacology and Toxicology. She conducts and oversees bespoke genomic and proteomic investigations to elucidate mechanisms of toxicity observed in nonclinical species and humans. She is also a nonclinical safety representative where she provides global regulatory toxicology support from target validation to registration and approval, with emphasis on oncology and epigenetic therapies.

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