



NCAC–SOT FALL 2026 SYMPOSIUM

Advances in Toxicological Science: Regulatory Toxicology, New Approach Methodologies, and Artificial Intelligence

 **Thursday, November 12, 2026** |  **9:00 AM – 4:00 PM EST** |  **Free & Virtual Event**

Introduction

The National Capital Area Chapter of the Society of Toxicology (NCAC–SOT) invites you to our free, virtual Fall 2026 Symposium. This year's program brings together three seminar-style sessions covering regulatory toxicology, new approach methodologies (NAMs), and the expanding role of artificial intelligence (AI) in toxicological science. Early-career scientists will present in our Trainee Speed Talk session, and the day will close with a Career Panel discussion. Excellence in Service recognition will also be presented to NCAC members recognized for their contributions to the regional chapter and to the field of toxicology in Maryland, Virginia, and Washington, D.C.

About the NCAC

The NCAC-SOT was established to provide a regional focus for scientists of all disciplines interested in toxicology. The Chapter acts to:

- ▶ Sponsor and co-sponsor symposia on current issues in toxicology.
- ▶ Provide an annual award to an outstanding student in toxicology to assist in attending the Annual Meeting of the SOT.
- ▶ Maintain communication with the National SOT regarding current toxicology and regulatory concerns.
- ▶ Sponsor Regional Chapter events at the SOT Annual Meetings.

PROGRAM AGENDA

Time	Activity
9:00 – 9:05 AM	Opening Remarks & Symposium Overview <i>Mariana T. Farcas, PhD, DABT (President)</i>
9:05 – 10:25 AM	 Session I: Regulatory Toxicology in Practice: Frameworks, Strategies, and Emerging Considerations <i>Chairs: Nicole Olgun, PhD, DABT (Treasurer)</i> <i>Paola Chrysostomou, MS, DABT (Secretary)</i>
9:05 – 9:10 AM	Introduction by Chairs
9:10 – 9:30 AM	Keeping Up in a Changing Regulatory Environment: Trends, Resources, and Strategies for Toxicologists — Jennifer Ator, PhD, MHS, DABT; <i>ToxServices LLC</i>
9:30 – 9:50 AM	A Comparative Overview of Nonclinical Regulatory Programs for Small Molecules and Biologics — Tony Yang, PhD, DABT; <i>Center for Drug Evaluation and Research, Food and Drug Administration</i>
9:50 – 10:10 AM	Navigating Lifetime Biocompatibility Assessments for Medical Devices — Keith Morris-Schaffer, PhD, DABT, ERT; <i>Exponent</i>
10:10 – 10:25 AM	Q&A Panel Discussion
10:25 – 11:45 AM	 Session II: Evolving Safety Assessment: Applications of New Approach Methodologies (NAMs) <i>Chairs: Argel Islas-Robles, PhD, DABT (Vice President)</i> <i>Frances Belmonte, PhD, DABT (Past President)</i>
10:25 – 10:30 AM	Introduction by Chairs
10:30 – 10:50 AM	Navigating the Regulatory Acceptance Mazes: New Approach Methodologies Based on Human Reconstructed Tissue Models — Gertrude-Emilia Costin, PhD, MBA, ATS, ERT; <i>Institute for In Vitro Sciences, Inc.</i>
10:50 – 11:10 AM	New Approach Methodologies for Botanicals as Complex Mixtures — Connie Mitchell, MS; <i>Health and Environmental Sciences Institute</i>
11:10 – 11:30 AM	Modernizing UV Filter Safety Assessment: The Role of New Approach Methodologies (NAMs) — Kim Norman, PhD, DABT, ERT; <i>Personal Care Products Council</i>
11:30 – 11:45 AM	Q&A Panel Discussion
11:45 AM – 12:10 PM	Break

Time	Activity
12:10 – 1:30 PM	 Session III: From QSAR to AI Agents: Transforming Computational Toxicology and Chemical Risk Assessment <i>Chairs: Mariana T. Farcas, PhD, DABT (President)</i> <i>Ravinder Paul Lall, MS Sc (Website Coordinator)</i>
12:10 – 12:15 PM	Introduction by Chairs
12:15 – 12:35 PM	Beyond the QSAR: Computational Toxicology in The Age of AI — Alexandra Maertens, PhD ; <i>Johns Hopkins Bloomberg School of Public Health</i>
12:35 – 12:55 PM	Using AI Agents for Chemical Risk Assessment — Srijit Seal, PhD ; <i>Human Chemical Company; University of Cambridge and the Broad Institute of MIT and Harvard</i>
12:55 – 1:15 PM	ToxMCP: Connecting AI Agents to Toxicology Tools and Evidence — Ivo Djidrovski, PhD ; <i>in4R.ai</i>
1:15 – 1:30 PM	Q&A Panel Discussion
1:30 – 2:50 PM	 Trainee Speed Talks <i>Chairs: Leah Schneider, PhD (Councilor–Student Liaison)</i> <i>Diana P. Garnica Acevedo, MS (Graduate Student Representative)</i> Group I: Impact of Inorganic Arsenic Exposure on Fetal Heart Development <i>In Vitro</i> — Morgan Steiner, BS ; <i>Johns Hopkins Bloomberg School of Public Health</i> Bisphenol S Induces Mitochondria-Dependent Neurotoxicity in Human Dopaminergic Cells — Brede Gibson, BS ; <i>University of Maryland Eastern Shore</i> Use of the IVIVE Model in the NIH Integrated Chemical Environment (NICE) to Estimate Point of Departure (PoD) Values for Extractable and Leachable Compounds — Huda Alqarni, BS ; <i>Johns Hopkins Bloomberg School of Public Health</i> Evaluation of the Ability of Open-Source Computational Models to Predict the Mutagenic Potential of Extractable and Leachable Compounds — Yihan Miao, BS ; <i>Johns Hopkins Bloomberg School of Public Health</i> Correlation Between Permitted Daily Exposures (PDEs) Calculations for Extractables and Leachables and Molecular Complexity — Alexander Doan, BS Candidate ; <i>University of Maryland</i> Group II: Evaluation of Systemic Inflammatory and Oxidative Stress Biomarkers in Dairy Cows with Podal Pathologies: An Exploratory Pilot Study on Clinical Presence and Progression — Davide Di Paola, PhD ; <i>University of Messina, Italy</i> Profiling of Environmental Mixtures Containing Metals for Their Toxicity Pathways and Mechanism of Action — Masato Ooka, PhD ; <i>National Institutes of Health</i> Mechanistic Characterization of Novel Parkinsonian Toxicants Identified through qHigh-Throughput Screening of MT1G Expression in a Model of Dopaminergic Neurons — María del Rosario García Aguilar, PhD ; <i>National Institutes of Health</i>

Time	Activity
	Predicting Carcinogens, a Tox21 Pathway-Based Mechanistic Screening Approach — Precious Adedayo Adesina, PhD; <i>National Institutes of Health</i>
2:50 – 2:55 PM	Break
2:55 – 3:00 PM	 Trainee Speed Talk Awards Excellence in Service Honors Closing Remarks <i>Mariana T. Farcas, PhD, DABT (President)</i>
3:00 – 4:00 PM	 Career Panel Discussion <i>Chairs: Xing Chen, PhD (Postdoc Rep)</i> <i>Priscilla Kini, MS (Graduate Student Vice Representative)</i> Panelists: Alexandra Noël, PhD <i>Associate Professor & Director; Inhalation Research Facility, Louisiana State University</i> Terry Leyden, PhD <i>President; The Leyden Group</i> Menghang Xia, PhD <i>Group Leader, Systems Toxicology; National Institutes of Health</i> Elissa Wong, PhD <i>Team Lead, Biologist; Center for Devices and Radiological Health, FDA</i> Vivek Patel, PhD <i>Senior Toxicologist; Institute for In Vitro Sciences, Inc.</i>

2026–2027 NCAC-SOT Executive Board Officers

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Regulatory Toxicology in Practice: Frameworks, Strategies, and Emerging Considerations

**Jennifer Ator, PhD, MHS, DABT***Principal Toxicologist, ToxServices LLC***Keeping Up in a Changing Regulatory Environment: Trends, Resources, and Strategies for Toxicologists****ABSTRACT**

This presentation will provide an overview of recent federal and state regulatory actions pertaining to foods/supplements and consumer products, with particular focus on the continued expansion of state-level PFAS-regulations (along with the current status of analytical methodologies); the U.S. FDA's proposed changes to the GRAS notification process; and the integration of NAMs into regulatory frameworks for these (and other) product types. Of additional interest to NCAC-SOT members involved in laboratory research is a proposed rule, under TSCA, relating to risks posed by uses of certain laboratory chemicals. Fortunately, there are many useful resources available to keep toxicologists informed of the latest developments in these areas, including agency websites and blogs published by law firms.

BIO

Dr. Jennifer Ator is a board-certified Principal Toxicologist, Risk Assessor, and Project Manager who earned her PhD in Toxicology and M.H.S. in Environmental Health Sciences from Johns Hopkins University. Dr. Ator has more than 20 years of experience in the preparation and review of quantitative human health risk assessments, exposure assessments, product and ingredient safety assessments, and regulatory compliance evaluations within a variety of national and international regulatory contexts.

**Tony Yang, PhD, DABT***Senior Toxicologist/Reviewer, Center for Drug Evaluation and Research (CDER), Food and Drug Administration***A Comparative Overview of Nonclinical Regulatory Programs for Small Molecules and Biologics****ABSTRACT**

This presentation provides a comparative overview of the nonclinical regulatory frameworks governing small molecule drugs and biological products, highlighting how differences in molecular size, complexity, and mechanism of action drive distinct safety assessment strategies. Attendees will explore key regulatory expectations across both modalities — including toxicology, pharmacology, and safety pharmacology studies — and examine how these requirements are shaped by guidance from FDA and international bodies such as ICH. By the end of the session, participants will have a clearer understanding of how to navigate and apply the appropriate nonclinical program for their therapeutic modality.

BIO

Dr. Yang is a Senior Toxicologist/Reviewer in the Division of Pharmacology/Toxicology for Infectious Diseases, Office of Infectious Diseases, Office of New Drugs, CDER/FDA. Before moving to CDER, he was a Toxicology Reviewer at CVM, where he performed safety reviews for GRAS notices, Food Additive Petitions, and study protocol reviews. Prior to CVM, Tony was a Toxicologist and Lead Reviewer working on plastic surgery devices and infection control devices at CDRH and also served as a Toxicology reviewer at Center for Tobacco Products. Tony received his PhD from the National University of Singapore.



Keith Morris-Schaffer, PhD, DABT, ERT

Senior Managing Scientist, Exponent

Navigating Lifetime Biocompatibility Assessments for Medical Devices

ABSTRACT

This session offers a concise overview of biocompatibility assessments and challenges that address the entire lifespan of a medical device. Participants will gain insight into key regulatory expectations, different technical approaches, and the critical role of toxicologists in ensuring device safety and compliance.

BIO

Dr. Morris-Schaffer is a board-certified global toxicologist who provides a range of regulatory toxicology and product stewardship services for clients including safety assessments for proactive product applications for chemicals and medical devices as well as for reactive matters such as regulatory data call-ins and product recalls. Dr. Morris-Schaffer specializes in weight-of-evidence evaluations in which in vitro (cell-based testing), in vivo (animal testing), and clinical data are integrated to determine how a chemical or mixture elicits its effects and at what dose. Dr. Morris-Schaffer applies multiple tools to assist with toxicological risk assessments including benchmark dose modeling (BMD), quantitative structural activity relationships (QSAR), read-across, and New Approach Methodologies (NAMs).



SESSION II

Evolving Safety Assessment: Applications of New Approach Methodologies (NAMs)



Gertrude-Emilia Costin, PhD, MBA, ATS, ERT

Vice President, Lab Operations and Study Director, Institute for In Vitro Sciences, Inc.

Navigating the Regulatory Acceptance Mazes: New Approach Methodologies Based on Human Reconstructed Tissue Models

ABSTRACT

The adoption of New Approach Methodologies (NAMs) is transforming safety assessment by providing human-relevant alternatives to animal testing. However, translating innovative methods into regulatory practice remains challenging and application-dependent. This presentation compares two reconstructed human tissue-based approaches: the OECD Test Guideline Skin Irritation Test (SIT) using reconstructed human epidermis models and an emerging in vitro vaginal irritation assessment employing reconstructed human vaginal tissue models for evaluating personal lubricants. Attendees will gain insight into the scientific foundations of these methods, including assay design, performance characteristics, measured endpoints, and interpretation of results. The presentation contrasts the established validation pathway and international acceptance of the SIT with the evolving scientific and regulatory landscape for vaginal irritation assessment. Particular emphasis will be placed on evidentiary requirements, method validation, and demonstrating fitness for purpose. Using case examples and regulatory perspectives, the lecture will illustrate how reconstructed tissue models support safety decision-making, address testing gaps, and advance NAM implementation. Participants will gain practical insight into the opportunities, limitations, and collaborative efforts required to move human tissue-based methods from laboratory innovation to regulatory and industrial application.

BIO

Dr. Gertrude-Emilia Costin joined the Institute for In Vitro Sciences (IIVS) in 2007 and is currently the Vice President, Lab Operations. Her primary area of expertise is in the use of in vitro test methods for the dermal safety assessment of ingredients and final formulations manufactured by cosmetic and personal care industry, or products to be registered under US

Environmental Protection Agency (EPA) or Food and Drug Administration (FDA). Dr. Costin is involved with IIVS educational workshops promoting New Approach Methodologies. Dr. Costin received her PhD (Cum laude) from the Institute of Biochemistry of the Romanian Academy and holds the ERT and ATS toxicology certifications.



Connie Mitchell, MS

Senior Scientific Program Manager, Health and Environmental Sciences Institute

New Approach Methodologies for Botanicals as Complex Mixtures

ABSTRACT

Botanicals, including products derived from plants, fungi, and algae, are increasingly consumed worldwide. Their complex compositions and variable phytochemical profiles present significant challenges for safety assessment. Traditional toxicology methods are time and resource intensive, and the variability of botanicals makes it difficult to test one lot as representative. The Botanical Safety Consortium (BSC), was established to advance fit-for-purpose toxicity testing strategies for botanicals. The consortium evaluates established new approach methodologies (NAMs), including in vitro assays and in silico models for their applicability to botanical hazard assessment. Case studies of botanicals were selected based on known toxicity profiles to test assay performance and determine whether botanicals behave differently from single chemicals in these systems. The evaluations address toxicological endpoints such as hepatotoxicity, genotoxicity, developmental and reproductive toxicity, neurotoxicity, cardiotoxicity, and dermal toxicity. Early findings have identified fit-for-purpose screening tools that can generally be applied to botanical testing, with some nuances and considerations.

BIO

Connie Mitchell is a Senior Scientific Program Manager at the Health and Environmental Sciences Institute (HESI Global). Prior to joining HESI in early 2020, she was an ORISE Fellow at the US Environmental Protection Agency working on chemical prioritization under the Toxic Substances Control Act. She completed her graduate studies in Environmental Toxicology at the University of California Riverside. There she investigated flame retardant-induced developmental toxicity. As a Senior Scientific Program Manager, she provides scientific, strategic, and management support to collaborative scientific committees involving academic, government, nonprofit, and private sector scientists. She manages the Emerging Systems Toxicology for Assessment of Risk (eSTAR) Committee and the Botanical Safety Consortium (BSC).



Kim Norman, PhD, DABT, ERT

Senior Director, Safety and Regulatory Toxicology, Personal Care Products Council

Modernizing UV Filter Safety Assessment: The Role of New Approach Methodologies (NAMs)

ABSTRACT

Sunscreens are regulated as topical over-the-counter (OTC) drugs in the United States, where safety assessments have traditionally relied on animal toxicology studies and human clinical data. In Europe, where sunscreens are regulated as cosmetic products, there is growing experience incorporating New Approach Methodologies (NAMs) into the safety assessment of sunscreen active ingredients. Recent efforts to bring additional UV filters to the US market have highlighted opportunities to modernize safety assessment approaches while continuing to meet rigorous standards for consumer safety.

This presentation will explore how NAMs can complement traditional sources of evidence in the evaluation of both established and innovative UV filters. The integration of historical toxicology studies, real-world evidence, and NAMs will be discussed as a framework for UV filter safety assessment. Through practical examples, the presentation will discuss how these complementary data streams can support scientifically sound, human-relevant regulatory decision-making while fostering innovation and reducing reliance on animal testing.

BIO

Dr. Kim Norman is a US board-certified toxicologist and European Registered Toxicologist. Kim works at the Personal Care Products Council (PCPC) as Senior Director, Safety and Regulatory Toxicology. In this role, she supports safety related issues for cosmetic ingredients and products, leading technical committees and engaging with domestic and international science organizations. She works collaboratively on the development and implementation of strategies and methods replacing animal use. Kim obtained her PhD from Vanderbilt University studying the increased incidence of non-melanoma skin cancer in organ transplant recipients.

SESSION III



From QSAR to AI Agents: Transforming Computational Toxicology and Chemical Risk Assessment



Alexandra Maertens, PhD

Assistant Professor, Johns Hopkins Bloomberg School of Public Health, Department of Environmental Health and Engineering

Beyond the QSAR: Computational Toxicology in The Age of AI

ABSTRACT

Quantitative structure-activity relationship (QSAR) models have anchored computational toxicology for decades, providing tractable, interpretable links between chemical structure and biological activity. But the field is rapidly moving past classical QSAR toward a broader and more powerful AI toolkit. Deep learning architectures, graph neural networks, and large chemical language models now capture complex structure-activity relationships that traditional descriptor-based approaches miss, while transfer learning and foundation models have the potential to be trained on massive chemical and toxicogenomic datasets, enabling predictions for data-poor endpoints and rare adverse outcomes. Multi-omics integration, automated read-across, and AI-driven adverse outcome pathway (AOP) network construction are extending prediction beyond single endpoints toward mechanistic, systems-level risk assessment. At the same time, these advances raise pressing questions around model interpretability, domain of applicability, uncertainty quantification, and regulatory acceptance—issues that will determine whether next-generation AI models can move from research to regulator.

BIO

Dr Maertens spent the last ten years developing the computational toxicology program at the Center for Alternatives to Animal Testing, where she works in both cheminformatics and bioinformatics to build better models of chemical risk and hazard. She also began the Green Toxicology program, which seeks to work in tandem with Green Chemistry to design safer chemicals.



Srijit Seal, PhD

Principal Scientist at Human Chemical Company; University of Cambridge and the Broad Institute of MIT and Harvard

Using AI Agents for Chemical Risk Assessment

ABSTRACT

Chemical risk assessment is bottlenecked less by predictive models than by everything around them: finding the relevant literature, reconciling conflicting assay data, selecting an applicable model for a given chemical, and documenting why a

conclusion was reached. This session examines what they can and cannot currently do. I will describe agentic architectures that orchestrate established tools — QSAR and machine learning models for ADMET and mutagenicity endpoints, structural alerts, read-across workflows, and structured toxicology databases — under an LLM planner that handles retrieval, tool selection, and evidence synthesis. Worked examples include ICH M7-style mutagenicity assessment and off-target secondary pharmacology triage, where an agent assembles mechanistic context around a numerical prediction rather than replacing it.

The talk gives equal weight to failure modes. Agents inherit every weakness of their underlying models while adding new ones: fabricated citations, unstated applicability-domain violations, and confident narrative reasoning built on a poorly validated prediction. I will cover the evaluation practices that separate genuine capability from benchmark artifacts, including the effect of train-test leakage and class imbalance on reported performance, and confidence intervals on small test sets.

I will close with practical requirements for regulatory use: provenance tracking, auditable reasoning traces, defined human checkpoints, and honest uncertainty communication. The aim is a realistic view of where agents accelerate assessment today and where they should not yet be trusted.

BIO

Srijit Seal works at the intersection of artificial intelligence, cheminformatics, and drug discovery. His research spans ADMET and toxicity prediction, generative modelling, and the design of AI agent systems for computational toxicology. He completed his PhD at the University of Cambridge and subsequently worked at the Broad Institute of MIT and Harvard, where his work focused on integrating cell morphology and other high-content biological data into predictive safety models.

His current work develops agentic frameworks that wrap contextual, mechanistic reasoning around established QSAR models, alongside tooling for mutagenicity and off-target pharmacology assessment. He writes and speaks regularly on rigorous model evaluation in life sciences, particularly the validation pitfalls that inflate reported performance in published toxicity models.



Ivo Djidrovski, PhD

Founder and Principal AI Systems Architect; in4R.ai

ToxMCP: Connecting AI Agents to Toxicology Tools and Evidence

ABSTRACT

AI agents can coordinate multi-step tasks across scientific databases and computational tools. In toxicology, however, successful tool execution is not enough: scientists must be able to inspect the evidence, understand its limitations and retain control over interpretation and assessment decisions. This presentation introduces ToxMCP, an open-source suite of Model Context Protocol services for computational toxicology. ToxMCP provides structured interfaces through which AI agents can access scientific resources and invoke specialist tools. It is not a new toxicity prediction model; its role is to connect agent-driven workflows to existing scientific capabilities while supporting traceable tool use. A worked example will follow a chemical assessment question through tool selection, execution and review of the resulting evidence. The discussion will distinguish retrieved observations, computational predictions and agent-generated interpretation, and examine how source references, recorded tool inputs and outputs, and explicit human-review points support inspection of the workflow. The O-QT assistant for the OECD QSAR Toolbox will provide complementary context. The presentation will conclude with practical checks for tool execution, missing or conflicting evidence, and the limits of automation. The focus is on making agent-driven toxicology workflows more transparent and reproducible while preserving expert responsibility—not on replacing assessors or implying regulatory acceptance. Project code and documentation: <https://github.com/ToxMCP>.

BIO

Ivo Djidrovski, PhD, is the Founder and Principal AI Systems Architect at in4R.ai, where he develops open, auditable AI infrastructure for chemical safety assessment and other high-stakes scientific workflows. He created ToxMCP, an open-source suite of Model Context Protocol services for computational toxicology, and was the architect and lead author of O-QT, a peer-reviewed multi-agent assistant for the OECD QSAR Toolbox. Previously, he led AI automation work within Utrecht University and the VHP4Safety consortium, translating scientific and assessor workflows into bounded, reproducible software systems. His work spans tool-using agents, scientific retrieval, provenance, structured evaluation and human-review design. He holds a PhD in Stem Cells and Toxicology from Newcastle University and has published across computational toxicology, AI-supported chemical risk assessment and advanced human cell models.



Trainee Speed Talks

**Morgan Steiner, BS**

PhD Candidate; Johns Hopkins Bloomberg School of Public Health

Impact of Inorganic Arsenic Exposure on Fetal Heart Development *In Vitro***SUMMARY**

Arsenic is a naturally occurring metalloid that has been mobilized in the environment via anthropogenic processes. Exposure to inorganic arsenic (iAs) during pregnancy is associated with increased risk for congenital heart defects (CHD). CHD affects 1 in 110 infants and accounts for approximately 40% of all birth defect mortality. Disruption of transcription factors that govern the differentiation of cardiac progenitor cells has been associated with the development of CHD. Prior work from our lab found that dams exposed to iAs during gestation had altered heart structure, which may impact embryonic development. Indeed, mouse embryos from exposed dams had larger hearts and increased left ventricular internal dimensions compared to non-exposed controls. Collectively, these findings suggest that gestational iAs exposure may impair cardiac differentiation and contribute to CHD development, but additional mechanistic studies are warranted. To model cardiogenesis *in vitro*, hiPSCs were differentiated into cardiomyocytes using sequential Wnt activation and inhibition. hiPSCs were exposed to iAs starting at differentiation day (DD) 0. An MTT viability assay was performed on hiPSCs exposed to 0-100 ppb iAs on DD3. Doses of 0, 5, 10, and 50 ppb iAs were selected, as they did not induce excess cell death compared to higher doses. hiPSCs were exposed to the selected doses starting at DD0. Cells were analyzed at DD3, DD5, DD9, DD12, and DD21 by testing the expression of differentiation and oxidative stress genes using qPCR. Calcium signaling and mitochondrial dynamics were also investigated. We found a significant decrease in cell viability, even at low doses of iAs after three days of exposure. Additionally, we found a significant alteration to early and late cardiomyocyte markers with iAs exposure based on qPCR results. Calcium transients and action potential fluorescence were altered even at low doses of arsenic exposure at DD21. Finally, mitochondrial dynamics, including mitochondrial number and respiration, were reduced in exposed hiPSC-derived cardiomyocytes compared to controls. Our findings suggest that iAs exposure may contribute to CHD development by impairing cardiac differentiation and diminishing cardiomyocyte functional dynamics. Due to the high prevalence of CHD in the population and the increased likelihood of iAs exposure in the environment, this study is critical for understanding how iAs exposure during development impacts cardiomyocyte differentiation.

BIO

Morgan Steiner is a fourth-year PhD Candidate at the Johns Hopkins Bloomberg School of Public Health in the Department of Environmental Health and Engineering. She currently works with Dr. Mark Kohr's lab of cardiovascular toxicology. She completed her undergraduate degrees in Biological Sciences and Chemistry at Clemson University in 2023, where she investigated the behavioral and physiological effects of SSRIs on freshwater fish. Her thesis focuses on how heavy metal exposure impacts maternal and fetal heart health using a combination of *in vivo*, *in vitro*, and *in silico* approaches.

**Brede Gibson, BS**

PhD student; University of Maryland Eastern Shore

Bisphenol S Induces Mitochondria-Dependent Neurotoxicity in Human Dopaminergic Cells**SUMMARY**

Bisphenol S (BPS) is widely used as a substitute for bisphenol A (BPA) in polycarbonate plastics, epoxy resins, and thermal paper, yet evidence suggests it is not biologically inert. BPS can cross the blood-brain barrier and may disrupt neurodevelopmental, neurophysiological, and neurodegenerative processes. Because neurons have high energetic demands

and limited regenerative capacity, mitochondrial dysfunction is a central mechanism in neurodegeneration. This study investigated the neurotoxic effects of BPS and the role of mitochondrial dysfunction in human dopaminergic neuronal (SH-SY5Y) cells. SH-SY5Y cells were exposed to varying concentrations of BPS for different time intervals. We assessed cell viability and death, intracellular reactive oxygen species (ROS), mitochondrial membrane potential, cytochrome c release, intracellular ATP levels, and activation of apoptotic pathways. BPS reduced cell viability in a concentration-dependent manner. Low concentrations (0.001-100 μ M) markedly increased ROS production at 3 and 6 hours, an effect attenuated by the antioxidant N-acetyl-L-cysteine (NAC). BPS also increased caspase-3 activity and apoptosis in a time- and concentration-dependent manner, and both were significantly inhibited by NAC or the caspase-3 inhibitor Ac-DEVD-CHO, indicating oxidative stress-mediated, caspase-3-dependent apoptosis. In addition, BPS caused a loss of mitochondrial membrane potential comparable to that induced by the uncoupler carbonyl cyanide m-chlorophenyl hydrazone (CCCP) and significantly reduced intracellular ATP after 24 hours. These findings indicate that BPS induces neurotoxicity through oxidative stress, mitochondrial dysfunction, ATP depletion, and apoptotic cell death. Mitochondrial impairment appears to be a key mechanistic link between BPS exposure and nervous system toxicity, suggesting that BPS may be a risk factor for neurodegenerative disease. Supported by Title III.

BIO

I am a second-year PhD student at the University of Maryland Eastern Shore and a research fellow of the NOAA Living Marine Resources Cooperative Science Center (LMRCSC). My research involves environmental toxicology and analytical chemistry to understand how sea-level rise affects mercury methylation in coastal environments. I also have experience in both two- and three-dimensional cell culture, including Emulate liver chips and immortalized neuronal cell lines (SH-SY5Y). I have used these models to study alterations in oxidative stress, mitochondrial function, and apoptosis following exposure to bisphenol derivatives and heavy metals.



Huda Alqarni, BS

Master of Science Student; Johns Hopkins Bloomberg School of Public Health

Use of the IVIVE Model in the NIH Integrated Chemical Environment (NICE) to Estimate Point of Departure (PoD) Values for Extractable and Leachable Compounds

SUMMARY

In vivo Point of Departure (PoD) toxicity data are not available for many compounds. To address this need, the in vitro-to-in vivo extrapolation (IVIVE) model in the NIH Integrated Chemical Environment may provide a way to estimate in vivo PoD values from in vitro data. In our study, we evaluated whether IVIVE model-derived Equivalent Administered Dose values estimate experimentally derived in vivo PoD values for extractable and leachable compounds associated with medical devices and pharmaceutical packaging.

BIO

Huda Alqarni is a Master of Science student in Toxicology for Human Risk Assessment at the Johns Hopkins Bloomberg School of Public Health. Her research interests include computational toxicology, chemical risk assessment, new approach methodologies, and in vitro-to-in vivo extrapolation. Her current project conducted with the Risk Science Consortium under the mentorship of Ron Brown, evaluates the NIH Integrated Chemical Environment IVIVE model for estimating in vivo Point of Departure values for extractable and leachable compounds relevant to medical devices and pharmaceutical packaging. Huda holds a Bachelor of Science degree in Pharmaceutical Sciences. Her current training focuses on applying toxicological and computational methods to support chemical safety assessment and human health risk evaluation.



Yihan Miao, BS

Master of Science Student; Johns Hopkins Bloomberg School of Public Health

Evaluation of the Ability of Open-Source Computational Models to Predict the Mutagenic Potential of Extractable and Leachable Compounds

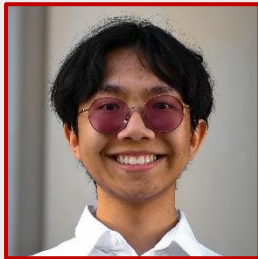
SUMMARY

Extractable and leachable (E/L) compounds released from medical devices and pharmaceutical packaging may possess genotoxic or carcinogenic potential, yet experimental data remain unavailable for many relevant compounds. Computational approaches, such as Quantitative Structure-Activity Relationship (QSAR) models and expert systems, can help address these data gaps by using chemical structures and related information to predict toxicological properties. However, researchers must evaluate these models within their intended context of use before their predictions can support toxicological risk assessment.

In this study, we evaluate computational approaches for predicting mutagenic potential across a broad set of E/L compounds compiled by the Extractables and Leachables Safety Information Exchange (ELSIE). We use the OECD QSAR Toolbox to systematically analyze relevant profiling and experimental endpoints. Because individual compounds may have multiple experimental records with potentially inconsistent outcomes, we curate these data and consolidate the records for each unique compound prior to evaluating model performance. We compare model-derived predictions obtained using the OECD QSAR Toolbox, Toxtree, and VEGA models with available experimental data to evaluate model performance and classify each prediction. Ultimately, we examine concordance and discrepancies across models to develop a consensus weight-of-evidence approach for evaluating the mutagenic potential of E/L compounds that lack experimental data. This approach aims to provide a more robust basis for subsequent toxicological risk assessments.

BIO

Yihan Miao is a master's student in the Toxicology for Human Risk Assessment program at the Johns Hopkins Bloomberg School of Public Health. Her current research focuses on computational toxicology and the evaluation of QSAR models for the genotoxicity and carcinogenicity assessment of extractable and leachable compounds. Before joining Johns Hopkins, she conducted brain tumor research using in vivo mouse models, with experience in AAV-mediated gene delivery, immunohistochemistry, and fluorescence microscopy. Her research interests include toxicology, quantitative data analysis, and biomedical research.



Alexander Doan

BS Candidate; University of Maryland

Correlation Between Permitted Daily Exposures (PDEs) Calculations for Extractables and Leachables and Molecular Complexity

SUMMARY

Parenteral (intravenous) nutrition products frequently contain "leachables", or chemical compounds derived from packaging or from the degradation of the products. Safety assessments for these chemicals are performed using a Permitted Daily Exposure (PDE) calculated from toxicological studies, as recommended by the ICH Q3C(R8). In some cases, compounds don't have toxicologic studies; thus, a read-across methodology is used to define compounds' PDEs as identical to a structurally similar compound. The prevalence of this methodology proves to some extent that minor differences in molecular structures may not lead to large changes in PDE. There might be gradual change in permitted daily exposure based on factors such as structural complexity. This project looked at compounds' characteristics that may relate to molecular complexity to investigate correlation between them and PDE.

PDE values were found in new drug application (NDA) reviews within the U.S. FDA's database, which contained information from animal studies. NDAs were compiled into an excel sheet, and an R-Shiny script retrieved the calculations for each impurity, which was used to analyze structure/toxicity relationships as described below. The structural complexity of a molecule was based on metrics derived from the molecule's Simplified Molecular Input Line Entry System (SMILES) entry. SMILES code length (relating to general size of the molecule), number of rings or double bonds, and number of oxygens present were plotted against the related PDE values in a scatter chart. Linear extrapolation was used to find the coefficient of correlation (R^2) determining the strength of the relationship, from weak (coefficient of at least ~ 0.30) to a strong (coefficient of ~ 0.70 or higher). We used a linear equation to avoid assuming complicated relationships (such as exponential or polynomial), especially without proposing why such a relationship could be the case.

The results showed that correlation ranged from ~ 0.003 to ~ 0.013 . Even excluding outliers, these values only increased to a range of ~ 0.02 to ~ 0.04 , below lowest threshold of 0.3 for a weak correlation. In the future, as the PDE database expands, we may choose to increase the number of compounds to gain a data set that is not as skewed by outliers. In addition, we may investigate relationships that are nonlinear.

BIO

Alexander Doan is an undergraduate bioengineering student at the University of Maryland with a strong interest in pharmaceutical development and production. In collaboration with researchers from the FDA (OND/OII/DHN), he contributed to evaluating potential relationships between molecular complexity and permitted daily exposure (PDE) levels in humans. Alexander plans to pursue doctoral studies in bioengineering and drug development.



Davide Di Paola, PhD

Researcher; University of Messina, Italy

Evaluation of Systemic Inflammatory and Oxidative Stress Biomarkers in Dairy Cows with Podal Pathologies: An Exploratory Pilot Study on Clinical Presence and Progression

SUMMARY

Lameness disorders, encompassing infectious causes such as digital dermatitis (DD) and metabolic etiologies like laminitis, affect 25–50% of dairy cows annually, incurring economic costs exceeding €1,500 per case through reduced milk yield and culling. These conditions trigger systemic inflammation and oxidative stress, reflected in plasma biomarkers. This study quantified plasma interleukin-6 (IL-6), tumor necrosis factor- α (TNF- α), myeloperoxidase (MPO) activity, and malondialdehyde (MDA) levels in cows at diagnosis (T0) and therapeutic trimming (T1), comparing healthy controls (CTR) with digital dermatitis (DD), laminitis, and white line disease (WLD) groups. Plasma biomarkers (IL-6, TNF- α , MPO, MDA) were measured in diseased and healthy cows at two time points: at diagnosis (T0) and at therapeutic trimming (T1). Comparisons were made between control and pathological groups. At T0, all pathological groups exhibited significantly elevated IL-6, TNF- α , MPO and MDA activity versus CTR. By T1, biomarker levels increased markedly in all pathological groups, with the highest elevations observed in cows. These elevations identify IL-6, TNF- α , MPO, and MDA as systemic biomarkers associated with the clinical presence and short-term progression of podal lesions.

BIO

Davide Di Paola is a researcher at the University of Messina, Italy, specializing in environmental toxicology and aquatic ecotoxicology. He holds a PhD in Applied Biology and Experimental Medicine, with research expertise in investigating the toxicological effects and mechanisms of action of emerging environmental contaminants in aquatic organisms, particularly *Mytilus galloprovincialis* and *Danio rerio*. His research focuses on the molecular and biochemical mechanisms underlying contaminant-induced toxicity, including oxidative stress, inflammation, apoptosis and endoplasmic reticulum stress. His work addresses the effects of a wide range of environmental pollutants, including pesticides, PFAS, pharmaceuticals and microplastics, with particular emphasis on contaminant mixtures and the influence of global change drivers, such as temperature and salinity variations, on toxicological responses. He has contributed to national and international research projects, scientific publications and editorial activities. His research interests include the integration of molecular toxicology, experimental ecotoxicology and environmental risk assessment to improve the understanding of contaminant-induced biological effects in aquatic organisms.



Masato Ooka, PhD

Research Fellow; National Institutes of Health

Profiling of Environmental Mixtures Containing Metals for Their Toxicity Pathways and Mechanism of Action

SUMMARY

Superfund sites are where soil, air, and water are polluted with hazardous materials. Individuals residing and working in these areas are often exposed to metals and other hazardous materials, leading to many adverse health outcomes, including cancer. While individuals are often exposed to multiple chemicals simultaneously, the combined effect of such exposures remains largely

unexplored. Here, we investigated the toxicity of metal mixtures in five categories of *in vitro* assays measuring cytotoxicity, oxidative stress, genotoxicity, cytokine release, and angiogenesis. After testing these mixtures in primary cells and cell lines, we discovered that the nickel/arsenic/cadmium and beryllium/arsenic/cadmium combinations exhibited higher cytotoxicity than their individual compounds, suggesting that the mixtures amplified the cytotoxic effect. To investigate the mechanism underlying their toxicity, we evaluated metal-induced oxidative stress, as oxidative stress is a common factor in most metal-related toxicities. Our results showed that cadmium-induced oxidative stress was increased in mixtures. Some mixtures that induced oxidative stress further increased DNA damage, inhibited DNA synthesis, and activated p53. In addition, some mixtures significantly increased interleukin-8 secretion and angiogenesis more than their component compounds. Our findings offer important insights into metal-related toxicity at Superfund sites.

BIO

Masato Ooka is a Research Fellow in the Department of Preclinical Innovation at NCATS, NIH. His work integrates systems biology, high-throughput screening, and translational toxicology, focusing on next-generation platforms for phenotypic profiling and chemical safety assessment. He pioneered 3D Cell Painting in 1536-well format, applying it to large-scale screens across cancer models, environmental mixture toxicology, autophagy, and metabolic activation in HTS. Dr. Ooka earned his PhD in Chemistry at Tokyo Metropolitan University, using gene editing to study DNA repair and genotoxicity. He has authored 31 peer-reviewed publications, including 15 first-author papers, and received three consecutive NIH FARE awards, the Society of Toxicology Best Manuscript Award, and the NCATS Director's Award. He mentors postdocs, postbaccalaureates, and interns, and serves as an *ad hoc* referee for toxicology and chemical biology journals.



María del Rosario García Aguilar, PhD

Postdoctoral fellow; National Institutes of Health

Mechanistic Characterization of Novel Parkinsonian Toxicants Identified through qHigh-Throughput Screening of MT1G Expression in a Model of Dopaminergic Neurons

SUMMARY

The etiology of Parkinson's disease (PD) remains incompletely understood, although environmental chemical exposures are increasingly recognized as contributors to disease susceptibility. To identify potential environmental factors linked to PD, RNA sequencing was performed in differentiated LUHMES (dLUHMES) neurons exposed to seven established Parkinsonian neurotoxins. Comparative transcriptomic analysis identified MT1G as the most consistently induced gene, implicating altered metal homeostasis and oxidative stress in neurotoxicity.

Using CRISPR/Cas9, LUHMES cells were engineered with a luciferase reporter under endogenous MT1G regulatory control, enabling quantitative high-throughput screening of the LOPAC and Tox21 10K libraries. Eighteen MT1G-inducing compounds were selected for mechanistic characterization. Although mitochondrial dysfunction was enhanced by galactose-containing conditions for classical mitotoxins such as rotenone, MT1G-inducing compounds showed no significant increase in toxicity or early mitochondrial depolarization, suggesting alternative mechanisms.

Because MT1G is involved in metal homeostasis, transition-metal involvement was investigated. Cell-impermeable metal chelators rescued viability for several compounds, while ferrozine-based assays demonstrated iron- and copper-chelating activity for multiple candidates. Together, these findings identify novel chemotypes with potential PD-relevant neurotoxicity and suggest that disruption of metal homeostasis and oxidative stress may contribute to their neuronal effects.

BIO

Pharmaceutical Biologist with a PhD in Sciences and over 10 years of experience in toxicology, experimental research, analytical methods, and quality systems. Currently a Postdoctoral Researcher at the National Center for Advancing Translational Sciences (NCATS), NIH, as part of the Tox21 program, focused on neurotoxicology and Parkinson's disease using human-relevant cellular models, including stem cell-derived differentiated dopaminergic neurons, astrocytes, and microglia. Experienced in the design, optimization, and execution of *in vitro* neurotoxicology assays, with expertise in cell culture and differentiation, flow cytometry, molecular and protein analysis, and mechanistic toxicology. My multidisciplinary background integrates experimental toxicology, neuroscience, cell biology, analytical development, regulatory science, and quality systems across private industry and academia, supporting the development and evaluation of human-relevant approaches for safety assessment and drug discovery.



Precious Adedayo Adesina, PhD

Postdoctoral Fellow; National Institutes of Health

Predicting Carcinogens, a Tox21 Pathway-Based Mechanistic Screening Approach

SUMMARY

Carcinogenicity assessment remains a critical challenge in toxicology due to the mechanistic complexity of cancer development and the inherent limitations of conventional long-term animal bioassays. High-throughput screening platforms such as the Tox21 program offer a powerful alternative by enabling pathway-based mechanistic profiling to flag chemicals with potential carcinogenic activity. Here, we integrated Tox21 multi-pathway activity data with targeted follow-up assays to identify and mechanistically classify candidate genotoxic and non-genotoxic carcinogens. The Tox21 10K compound library containing 8,947 unique compounds was screened using Tox21 assays targeting nine cancer-related pathways and biomarkers: AP-1, CRE, HSE, HRE, NF- κ B, H2AX, SHH, p53, and Wnt. Primary screening data from multiple cancer-related Tox21 pathways were analyzed and visualized as compound–pathway activity heatmaps to identify chemicals with broad pathway perturbation. A total of 102 compounds meeting all three prioritization criteria, activity in ≥ 2 pathways, AC50 values ≤ 10 μ M, and efficacy $>40\%$, were advanced to confirmation and mechanistic follow-up studies. Follow-up assays included a DNA synthesis assay and γ H2AX immunostaining to assess genotoxic and tumor-initiating potential, as well as an angiogenesis assay to assess non-genotoxic tumor-promoting activity. Across three independent experimental runs, 91 of 102 prioritized compounds showed confirmed activity in one or more cancer-related pathways, and 65 compounds exhibited multi-pathway activation profiles. Genotoxic activity was detected in 59 compounds based on DNA synthesis and γ H2AX assay outcomes; 11 compounds demonstrated tumor-promoting activity in the angiogenesis assay; and 6 compounds exhibited both genotoxic and non-genotoxic characteristics, suggesting potential dual mechanisms of carcinogenicity. Among all pathways evaluated, p53 and γ H2AX demonstrated the highest confirmation rates and strongest associations with mechanistic carcinogenic signatures. These findings demonstrate that integrating Tox21 multi-pathway screening data with targeted mechanistic assays substantially improves the identification and mechanistic classification of candidate carcinogens. This approach provides a mechanistically informed, resource-efficient framework for prioritizing environmental chemicals in carcinogenicity hazard evaluation, advancing the broader goals of predictive toxicology.

BIO

Precious Adesina is a Postdoctoral Fellow in the Division of Preclinical Innovation at NCATS, NIH, where he studies how chemicals disrupt cardiovascular, endocrine, and cancer-related signaling at the cellular level. Using the Tox21 10,000-compound library, he applies high-throughput screening to flag compounds of concern, informing chemical safety and toxicology research. He earned his PhD in Biochemistry from Hiroshima University, where his research identified gut microbial metabolites, particularly short-chain fatty acids, as activators of cellular stress-response pathways that maintain intestinal barrier integrity. He maintains interest in intestinal models and has authored multiple first-author publications, including in *Chemical Research in Toxicology* and the *American Journal of Physiology-Gastrointestinal and Liver Physiology*.

Excellence in Scientific Contribution



Menghang Xia, PhD

*Group Leader; National Center for Advancing Translational Sciences,
National Institutes of Health*

BIO

Dr. Menghang Xia is Group Leader of Systems Toxicology in the Division of Pre-Clinical Innovation at the National Center for Advancing Translational Sciences (NCATS), NIH, and recipient of the 2026 NCAC Excellence in Scientific Contribution Award. For more than a decade, she has played a central leadership role in the Tox21 program, a multiagency collaboration among NCATS, NTP/NIEHS, EPA, and FDA, leading the development and validation of a high-throughput assay battery spanning nuclear receptors, stress response pathways, GPCRs, and developmental signaling. Under her leadership, the Tox21 10K compound library has been profiled across more than 120 assays, generating over 120 million publicly available data points now used worldwide in predictive toxicology and chemical risk assessment. Her team's discovery that certain environmental chemicals activate human GnRH and kisspeptin receptor pathways provided key mechanistic evidence linking environmental exposures to earlier puberty in girls. Dr. Xia earned her PhD in pharmacology from SUNY Buffalo and completed postdoctoral training at UCSF. She has authored over 270 peer-reviewed publications and book chapters, and her mentorship has been recognized with the NIH and NCATS Director's Mentorship Awards and the SOT Women in Toxicology Mentoring Award.

Excellence in Community Impact



Colleen McLoughlin, PhD, DABT, ERT

Toxicology and Interdisciplinary Sciences Director, Enhesa

BIO

Dr. Colleen McLoughlin is the Toxicology and Interdisciplinary Sciences Director at Enhesa, where she leads a team of toxicologists and scientists working at the intersection of toxicology research and regulatory science, advising companies on their product stewardship and compliance programs. Her work spans chemical hazard and risk assessment, regulatory and scientific research, and building data-driven tools that help organizations understand chemical hazards, navigate evolving global regulations, and move toward safer chemistry. She holds a Ph.D. in Biomedical Engineering from Virginia Commonwealth University, completed a postdoctoral fellowship at NIOSH, and is a Diplomate of the American Board of Toxicology and a European Registered Toxicologist. Colleen has been part of NCAC-SOT since serving as its student representative in 2010-2012, and later served in the chapter's presidential chain as Vice President/President-Elect (2021-2022), President (2022-2023), and Past President (2023-2024). She currently chairs the Advancement and Application of Alternatives Assessment (A4) Interest Group within SETAC, having previously served as Vice Chair and as Program Committee co-chair. A committed mentor, she was a multi-year mentor in SOT's Toxicology Mentoring Skills Development Program and now mentors through UC Davis's MSDT-One Health program. She also serves as Vice President of Health Equity and Access in Rural Regions (HEARR), where she helped the organization secure its 501(c)(3) nonprofit status.

Excellence in Mentorship



Gertrude-Emilia Costin, PhD, MBA, ATS, ERT

Vice President, Lab Operations and Study Director; Institute for In Vitro Sciences, Inc.

BIO

Dr. Gertrude-Emilia Costin joined the Institute for In Vitro Sciences (IIVS) in 2007 as a Study Director and currently serves as Vice President of Laboratory Operations. Her primary area of expertise is the application of New Approach Methodologies (NAMs) for hazard identification and risk assessment of ingredients and finished products manufactured by the cosmetic and personal care industries, as well as products subject to regulatory review by the U.S. Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA). As Vice President of Laboratory Operations, Dr. Costin oversees critical laboratory functions, leads IIVS's operational strategy, and serves as Good Laboratory Practice (GLP) Test Facility Management, providing the management oversight necessary to ensure continued GLP compliance across laboratory operations. In support of IIVS's educational mission, Dr. Costin plays an active role in developing and delivering educational and training workshops that promote the adoption of non-animal testing methods among industry and academic scientists, regulators, and other stakeholders. She is also responsible for staff development, coaching, and mentoring within IIVS. Beyond her institutional responsibilities, Dr. Costin has made significant contributions to professional mentoring and workforce development. Over the years, she has mentored scientists through the National Capital Area Chapter of the Society of Toxicology (NCAC-SOT), the PanAmerican Society for Pigment Cell Research (PASPCR), and the American Society for Cellular and Computational Toxicology (ASCCCT). Dr. Costin earned her PhD, cum laude, from the Institute of Biochemistry of the Romanian Academy and holds both the European Registered Toxicologist (ERT) and Academy of Toxicological Sciences (ATS) certifications.



MENTORING EVENT

Career Panel Discussion



Alexandra Noël, PhD

*Associate Professor and Director of the Inhalation Research Facility;
Department of Comparative Biomedical Sciences, School of Veterinary Medicine,
Louisiana State University*

BIO

Dr. Alexandra Noël received her bachelor's degree in Biomedical Sciences, her master's in Occupational and Environmental Health, as well as her PhD in Public Health, with a specialization in Toxicology and Risk Assessment, all from the Faculty of Medicine of the University of Montreal (Quebec, Canada). She is an Associate Professor in the Department of Comparative Biomedical Sciences at Louisiana State University (LSU) and Director of the Inhalation Research Facility. She conducts in vitro and in vivo inhalation toxicology studies on cardio-pulmonary effects resulting from in utero and adult exposures to inhaled pollutants. Since 2018, her laboratory has been continuously funded by the National Institutes of Health (NIH), including NIEHS, NHLBI and NIGMS. She has led several extramurally funded research projects as a Principal Investigator or Core Leader cumulating more than \$6 million dollars. Her publication record includes over 50 peer-reviewed scientific articles, which generated over 1,800 citations. Additionally, Dr. Noël is the leader of the Inhalation Toxicology Core of the LSU Superfund Research Program. She is the Director of the Inhalation & Infection Core of the LSU Lung COBRE. Moreover, her leadership skills are recognized beyond LSU, since she is a counselor for the Inhalation and Respiratory Specialty Section (IRSS) (2024-2026) of the Society of Toxicology (SOT). She is also the Chair of the Membership Committee (2025-2027) of the American Thoracic Society (ATS). Furthermore, Dr. Noël is a member of the NIH Advisory Committee on

Research on Women's Health (ACRWH) (2022-2026) and she is an Associate Editor for the American Journal of Respiratory Cell and Molecular Biology (2023-2028).



Terry Leyden, PhD
President; The Leyden Group

 BIO

Terry Leyden founded The Leyden Group, a Colorado-based recruiting firm, in 2003. During that time and prior, Terry has led a recruiting practice which focuses exclusively on the product safety sciences. Companies in the pharmaceutical, chemical, consumer product, contract research and consulting businesses engage Terry and his team to identify toxicologists, veterinary pathologists, risk/exposure assessors and related scientists for roles from early career to executive level.



Menghang Xia, PhD
*Group Leader of Systems Toxicology; Division of Pre-Clinical Innovation,
National Center for Advancing Translational Sciences, National Institutes of Health*

 BIO

Dr. Menghang Xia is a Group Leader of Systems Toxicology at the National Center for Advancing Translational Sciences, NIH. Serving as a co-chair of Assay Evaluation and Screening working group at the US Tox21 program, Dr. Xia led the major effort to develop and validate a battery of in vitro assays in a qHTS platform. Dr. Xia and her team have developed and screened more than 120 assays using advanced technology and robotic systems, and profiled compounds on various pathways and targets, such as stress response signaling, developmental pathways, and nuclear receptors. Dr. Xia is an author of over 270 peer-reviewed research articles and book chapters. She has given numerous scientific presentations at national and international conferences. She also has served as an editorial board member for several scientific journals. She received numerous awards including NIH and NCATS Director's Mentorship Awards, NIH and NCATS Director's Awards for Scientific and Medical Achievement, the 2024 SOT Enhancement of Animal Welfare Award, and the 2025 UB Distinguished Biomedical Alumna Award. She received her Bachelor of Medicine from Shanghai Medical University, followed by her PhD in Pharmacology from SUNY at Buffalo. Dr. Xia did her postdoctoral training at the UCSF.



Elissa Wong, PhD
Team Lead, Biologist; Center for Devices and Radiological Health, Food and Drug Administration

 BIO

Dr. Elissa Wong is currently a Team Lead Biologist at the Center for Devices and Radiological Health (CDRH) in the Division of Ophthalmic Devices (DHT1A) at the US Food and Drug Administration (US FDA) where she is involved in Total Product Lifecycle

(TPLC) review of medical devices. She received a BA in biology from Swarthmore College and MS and PhD in Toxicology from the University of Rochester (Rochester NY). During graduate school she worked in the neurotoxicology laboratory of Dr. Ania Majewska and mentored multiple undergraduate students on various research projects. All undergraduates achieved authorship on peer reviewed publications. While in graduate school, Dr. Wong was also active on the Graduate Student Leadership Committee of SOT and was the graduate student representative for the Northeast Regional Chapter of SOT (NESOT). In 2018, Dr. Wong began an ORISE fellowship at CDRH in the Department of Biomedical Physics and was the postdoctoral representative for the Medical Device Combination Product Specialty Section of SOT (MDCPSS). In 2019, she transitioned into a scientific reviewer role, joining the Contact Lens and Dry Eye Devices Team (THT1A2) as a Biologist, primarily as a subject matter expert in biocompatibility. In August 2023, she became Acting Team Lead Biologist of the THT1A2 team and transitioned to Team Lead Biologist in April 2024.



Vivek Patel, PhD

Senior Toxicologist; Institute for In Vitro Sciences, Inc.

BIO

Dr. Vivek Patel is a Senior Toxicologist at the Institute for In Vitro Sciences (IIVS), where he leads the Respiratory and Genetic Toxicology programs. He works with industry partners to design toxicity and efficacy testing strategies using advanced human-relevant models to support safety assessment and regulatory decision-making. His research focuses on the development and optimization of in vitro respiratory testing methods. Dr. Patel completed postdoctoral training at the University of Tennessee and Louisiana State University and earned his MS and PhD in Toxicology from St. John's University. He has authored numerous peer-reviewed publications and is an active contributor to the advancement of New Approach Methodologies in toxicology.

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