



Speaker Bios

The Health and Environmental Sciences Institute
Immuno-safety Technical Committee (ITC)

Immuno-Safety Career Symposium



**Dr. Marie C. Fortin, Ph.D., DABT, ERT,
Fellow ATS**

Jazz Pharmaceuticals

Adjunct Professor at Rutgers

University

Panelist

Dr. Marie C. Fortin is Director of Toxicology at Jazz Pharmaceuticals and a Fellow of the Academy of Toxicological Sciences, and Boardcertified and European-registered toxicologist. In her role at Jazz, she is responsible for the nonclinical development of new therapeutic agents and designs and oversees in vitro and in vivo studies (non-glp and glp), contributes critical input on multiple aspects of drug development such as pharmacology, pharmacokinetics, immunogenicity, evaluation of the risk-benefit, determination of first-in-human dose, and regulatory filings. In addition, she is Adjunct Professor in the Department of Pharmacology and Toxicology at the Ernest Mario School of Pharmacy at Rutgers University where she mentors graduate students, teaches in the joint program in toxicology, and co-directs the graduate risk assessment course. In her previous industry and consulting roles, she performed human health risk assessment and oversaw an in vitro safety testing laboratory focused on organotypic models.



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Dr. Rashade A. H. Haynes II

**Sr. Principal Scientist at
Bristol Myers Squibb**

**Immuno and Molecular Toxicology and
Investigative Toxicology**

Mentor / Panelist

Dr. Rashade A. H. Haynes II is a Sr. Principal Scientist at Bristol Myers Squibb. Rashade received his B.S. in Animal Science from Rutgers University and obtained his Ph.D. in Veterinary Bioscience (retrovirology/immunology) from The Ohio State University. He focused on regulatory T cell biology and zbtb transcription factors during his postdoctoral work at Memorial Sloan Kettering Cancer Center and Rutgers University. Rashade co-manages Immuno and Molecular Toxicology and manages Investigative Toxicology in the Nonclinical Safety and Veterinary Sciences organization within R & ED. He is responsible for designing and executing strategic-driven solutions for immunological assessments on non-GLP and GLP preclinical studies which support FIH dose projections and regulatory filings. In addition to this work, he oversees the investigative studies conducted by the investigative toxicology group which serve to elucidate the mechanism of toxicities identified in preclinical studies and across the portfolio spanning discovery biology to translational medicine. Outside of his daily responsibilities, he serves as a lead for the BMS Rutgers Alumni Group and many STEM organizations within BMS. He started a mentorship program for middle school to post-graduate students and serves as the lead for a weeklong summer STEM camp for middle school students from underrepresented communities



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Dr. Danice E.C. Wilkins, PhD, MS
Senior Director, Laboratory Sciences at
Charles River-Shrewsbury, MA
ITC Science Outreach lead
Panelist

Dr. Danice Wilkins, Senior Director, Laboratory Sciences at Charles River-Shrewsbury, Massachusetts, is an immunologist with over 20 years of combined academic, CRO (Contract Research Organization), and biopharmaceutical drug development experience. Danice earned her MS and PhD in Cellular and Molecular Biology from the University of Nevada School of Medicine in Reno, Nevada, where her projects focused on the effects of agonist anti-CD40 antibodies on renal cell carcinomas and antigen-independent T cell responses to cancer immunotherapy.

After completing her PhD, Danice joined the Laboratory Sciences group at Charles River-Reno, Nevada where she served as the Program Director for Immunology and the lead scientist for flow cytometry and pharmacodynamic assays. More recently, she has held industry positions at Momenta Pharmaceuticals where she served as the Associate Director of Preclinical and Developmental Sciences, and Elstar (Marengo) Therapeutics where she served as the Director of Immunotoxicology. Danice is currently the head of labs at the Charles River-Shrewsbury, Massachusetts safety assessment site, where she oversees diverse laboratory groups responsible for large and small molecule bioanalysis, immunology, molecular biology, biomarkers, formulations, dose formulation analysis, sample management, and clinical support services.



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Dr. Dr. Shaji Theodore, PhD
Senior Pharmacologist at
Center for Drug Evaluation and Research
(CDER) at FDA
Panelist

Dr. Shaji Theodore is a senior pharmacologist in the Division of Diabetes, Lipid Disorders and Obesity at the Center for Drug Evaluation and Research (CDER) at FDA. Prior to joining CDER he was a toxicologist at the Center for Tobacco Products at FDA. Before joining FDA, Dr. Theodore was an academic researcher investigating the molecular mechanisms of neurodegenerative disorders, especially Parkinson's Disease and HIV associated Dementia and Drug Abuse. Dr. Theodore graduated from the University of Kentucky at Lexington with a doctorate in toxicology. He is a Diplomate of the American Board of Toxicology, and also holds a degree in Veterinary Medicine and a master's degree in pharmacology. At the FDA, Dr. Theodore is responsible for the pharmacology and toxicology review of new drug applications. He also collaborates with leadership within the FDA and with regulatory agencies outside the USA on regulatory issues concerned with drug safety. At the FDA, Dr. Theodore is also involved in review of research grant proposals, serve as co-chair of the immunotoxicology subcommittee, participate in FDA mentoring program, and is part of the novel excipient review program.