SPEAKER BIOGRAPHIES

Namandjé N. Bumpus, PhD
Chief Scientist
Office of The Chief Scientist (OCS)
U.S. Food and Drug Administration (FDA)

Dr. Namandjé N. Bumpus serves as the FDA Chief Scientist where she provides strategic leadership and expertise to support scientific excellence, innovation, collaboration, and capacity to achieve FDA's public health mission. Prior to this, Dr. Bumpus was on the faculty at Johns Hopkins University School of Medicine for 12 years, most recently as the E.K. Marshall and Thomas H. Maren Professor and chair of the Department of Pharmacology and Molecular Sciences. She also served previously as associate dean for basic research. Dr. Bumpus' research expertise is in pharmacology with a particular focus on drug metabolism, pharmacogenetics, bioanalytical chemistry, and infectious disease. She earned a BA in biology at Occidental College in 2003, a PhD in pharmacology at the University of Michigan in 2007 and completed a postdoctoral fellowship in molecular and experimental medicine at The Scripps Research Institute in La Jolla, CA in 2010.

Dr. Bumpus currently serves as president of the American Society for Pharmacology and Experimental Therapeutics (ASPET). She previously served as chair of the NIH Xenobiotic and Nutrient Disposition and Action study section. Dr. Bumpus is an elected fellow of the American Association for the Advancement of Science (AAAS) and member of the National Academy of Medicine.

Anil K. Patri, PhD
Director
Nanocore
Office of Scientific Coordination (OSC)
National Center for Toxicological Research (NCTR) | FDA

Dr. Anil Patri leads FDA's Nanotechnology Task Force and oversees collaborative regulatory science research at the Nanocore. His lab developed 7 international standards in nanotechnology through ASTM International in the past 4 years and contributed to many other documentary standards. Dr. Patri serves on the Nanoscale Science, Engineering, and Technology Subcommittee (NSET) on behalf of FDA for inter-agency coordination and leads US-EU Communities of Research on Characterization. Prior to joining FDA in 2014, Dr. Patri served as the Deputy Director of the Nanotechnology Characterization Laboratory at the Frederick National Laboratories for Cancer Research, and as a guest scientist at the National Institute of Standards and Technology (NIST). In a decade long tenure at NCL he oversaw preclinical research towards clinical translation of nanomaterial-based therapeutic agents with proof of principle efficacy for cancer. He conducted applied research at the University of Michigan Center for Biologic Nanotechnology until 2004, after his post-doctoral training, and developed multifunctional targeted nanomaterial intended for cancer therapy and imaging. He is a synthetic chemist by training with graduate research on dendritic nanomaterial from the University of South Florida.

Xiaoming Xu, PhD
Director
Division of Product Quality Research
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Xiaoming Xu is the Director of Division of Product Quality Research in Office of Testing and Research in FDA, where he leads multiple regulatory research areas such as complex formulations, nanomaterials and advanced manufacturing. Xiaoming is a member of FDA Nanotechnology Task Force and is responsible for developing international collaborative programs and standards in areas related to nanotechnology. Xiaoming is also an editorial board member of the International Journal of Pharmaceutics. He received his B.S. and M.S. degrees in Pharmaceutics from China Pharmaceutical University and Ph.D. degree in Pharmaceutical Sciences from University of Connecticut.

Thomas O'Connor, PhD
Deputy Office Director
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. O'Connor is the director of the Division of Product Quality Research in the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post-market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology (such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance). Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA.

Tom originally joined the FDA as chemistry reviewer in the Office Generic Drugs. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering, where he held job functions in both process analytical technology and process control. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Antonio Costa, PhD
Assistant Research Professor
UConn, Department of Pharmaceutical Sciences

Antonio Costa, Ph.D. is an assistant research professor at UConn in the Pharmaceutical Sciences department and the chief executive officer at DIANT Pharma Inc., an early-stage company that provides continuous manufacturing technology. His work focuses on continuous manufacturing approaches, downstream processing of nanoparticle formulations, physicochemical characterization, process analytical technology integration and systems/ fluid flow engineering. He is an author of 15 peer-reviewed publications and inventor on multiple granted patents and patent applications.

Kurt Ristroph, PhD
Assistant Professor, Agricultural and Biological Engineering
Purdue University

Dr. Ristroph is an Assistant Professor in the Department of Agricultural and Biological Engineering at Purdue University. He completed a Ph.D. in Chemical Engineering & Materials Science at Princeton University and has also conducted research at Moderna and at the Monash Institute of Pharmaceutical Sciences in Melbourne, AU. Dr. Ristroph's research focuses on developing scalable nanoformulation processes for pharmaceutical and agricultural applications. His group formulates polymeric and lipid nanocarriers with tunable size and surface chemistries to encapsulate (and co-encapsulate) small molecules and biologic actives for enhanced delivery; optimizes continuous unit operations for downstream nanocarrier processing at scale; and studies the material science fundamentals underpinning self-assembly of nanocarriers and nanoscale liquid crystalline structures to inform future process development. He has authored 25 peer-reviewed papers and raised research funding from the FDA, NIH, NSF, USDA, Gates Foundation, and industrial collaborators.

Hailing Zhang, PhD
Branch Chief
Division of Liquid-Based Products II (DLBP II), Branch 6
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. Hailing Zhang is a supervisory chemist and the branch chief of Branch 6 in Division of Liquid-based Drug Product II, Office of Lifecycle Drug Product. Hailing obtained her Ph.D. in Organic Chemistry and Physical organic chemistry from Emory University (Atlanta, GA). She was an associate professor of Pharmaceutical Science in College of Pharmacy at Mercer University (Atlanta, GA) before joined in FDA in 2014. In her current role as the Branch Chief, Hailing is overseeing a team of talented drug product quality accessors to conduct IQA for ANDAs, as well as mentoring and managing review of Bio-INDs, controlled correspondences and Pre-ANDA meeting packages. She is recognized as a subject matter expert for liposome drug products, closely involved with the quality assessment, regulatory research, and development of guidance for liposome drug products. Hailing contributed to the approval of several ANDAs for liposome drug as well as the development of FDA Guidance for Industry such as "Liposome Drug Products: Chemistry, Manufacturing, and Controls", "Human Pharmacokinetics and Bioavailability; and Labeling documentation; Drug Products, Including Biological Products, that Contain Nanomaterials", and several product specific guidance for liposome drug products.

William Smith, PhD
Research Scientist
Division of Product Quality Research (DPQR)
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. William C. Smith (Billy), is a Research Scientist in the Division of Product Quality Research working on complex drug formulations from topicals to injectables and implantable polymeric devices. Billy runs the DPQR Micromeritics "Particle Size" Lab focusing on the physicochemical characterization of nano- and micro-scale materials to support regulatory assessment and review, and evaluation of drug product quality. Billy received his B.S. degree in Chemistry from the Evergreen State College before finishing his Ph.D. in 2019 from the Colorado School of Mines under Dr. Kim R. Williams, in analytical chemistry, focusing on the development of advanced separations techniques for the characterization of complex polymers and colloidal nanomaterials.

Tina Morrison, PhD
Director
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist (OCS) | FDA

Tina Morrison is the Director of the Office of Regulatory Science and Innovation (ORSI) in FDA's Office of the Chief Scientist.

She joined the FDA in 2008 through the Medical Device Fellowship Program. For the first seven years, Tina was a regulatory reviewer of cardiovascular devices, during which time she participated in several initiatives as part of CDRH's Innovation Pathway: early feasibility studies program, streamlining clinical trials, the medical device development tools program, and the Medical Device Innovation Consortium. Alongside the regulatory review work, she also advanced the role of computer modeling and simulation in medical device design and product evaluation. Tina joined the Office of Science and Engineering Laboratories as a Deputy Division Director in 2015, where she founded and chaired two working groups: CDRH's Regulatory Review of Computational Modeling working group, and FDA's Modeling and Simulation working group. Additionally, Tina led the development of guidance and standards for enhancing modeling credibility and acceptance. For instance, she led the development of a verification and validation standard for ASME, which culminated in 2018 with the first-ever set of evaluating procedures for computational modeling of medical devices, the ASME V&V 40 standard. This framework is currently being adapted for the review of computational modeling for drug development in CDER. For these achievements, Tina was selected as the 2019 Federal Engineer of the Year for the FDA, and in 2020, she was inducted into the University of Connecticut's Academy of Distinguished Engineers.

Tina holds an MS and a BS in Mechanical Engineering from the University of Connecticut. She completed a postdoctoral fellowship at Stanford University in Cardiovascular Biomechanics and earned a PhD in Theoretical & Applied Mechanics from Cornell University.

Olen Stephens, PhD
Chemist
Office of New Drug Product (ONDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | FDA

Olen Stephens is a chemistry reviewer for the CMC branch that supports the Oncology Center for Excellence. Over the past 14 years, he has served as a reviewer, CMC lead, and acting branch chief to support over half the clinical division in the Office of New Drugs at CDER. His formal training began as a bioorganic chemist at the University of Utah for his Ph.D., where he studied double stranded RNA protein interactions and continued as a post-doc at Yale in biophysical chemistry, designing de novo secondary structures using peptides. Olen currently serves as the CDER Nanotechnology Working Group Coordinator and on the FDA Nanotechnology Taskforce.

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