SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Anil K. Patri, Ph.D.
Director
Nanocore
Office of Scientific Coordination (OSC)
National Center for Toxicological Research (NCTR)
U.S. Food and Drug Administration (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.

Douglas Throckmorton, MD
Deputy Center Director for Regulatory Programs
U.S. Food and Drug Administration (FDA)

As Deputy Director for Regulatory Programs, Dr. Throckmorton shares the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks.

Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital. He is a board-certified physician.

Olen Stephens, Ph.D.

Chemist
Office of New Drug Product (ONDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (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.

Wimolnut Manheng, Ph.D.
Toxicologist
Division of Hematology Oncology Toxicology
Office of Oncologic Diseases
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Wimolnut Manheng is a senior toxicologist for Office of Oncologic Diseases, Division of Hematology Oncology Toxicology. Dr. Manheng received her Ph.D. in Environmental Biology in March 2004 from the international education program between Suranaree University of Technology, Thailand and Virginia Commonwealth University, Richmond, VA. Her expertise is in immunotoxicology. She is a board-certified toxicologist with the distinction of Diplomate of the American Board of Toxicology. She reviews and evaluates the results of non-clinical, pharmacological and toxicological studies submitted by the drug sponsor/applicant in support of Investigation New Drugs (INDs), New Drugs Applications (NDAs), Biologicals License Applications (BLAs) amendments, supplements and other related scientific submissions to assess the safety of the drug based on toxicity experiments conducted by the applicant.

Darby Kozak, Ph.D.
Deputy Division Director
Division of Therapeutic Performance One
Office of Research and Standards
Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

Dr. Darby Kozak is a Deputy Division Director in FDA's Office of Generic Drugs where he leads a group of interdisciplinary scientists on the development of new analytical methods and methodologies to evaluate the equivalence of complex generic drug substances and complex generic parenteral, ophthalmic, otic, and inhalation formulations. Prior to joining the FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at the Australian Institute for Bioengineering and Nanotechnology. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Chemistry from the University of Bristol (United Kingdom).

Keith Peden, Ph.D.
Microbiologist
Division of Viral Products Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation & Research (CBER)
U.S. Food and Drug Administration (FDA)

Keith Peden is Chief of the Laboratory of DNA Viruses in the Division of Viral Products, Office of Vaccines Research and Review, CBER, FDA. He is a product reviewer, and his regulatory portfolio encompasses various types of vaccines such as viral-vectored vaccines, DNA vaccines, and mRNA vaccines. His major focus of research is on safety issues associated with cell substrates for vaccine production and in developing micro-neutralization assays to assess the effectiveness of vaccines; the overall aims of both areas of research is to facilitate the introduction of effective and safe vaccines. He obtained his PhD from the MRC Mammalian Genome Unit, Department of Zoology, University of Edinburgh, UK, and carried out research at the Johns Hopkins University School of Medicine, Baltimore, the Pasteur Institute, Paris, and at the NIH before moving to CBER in 1994.

Raymond Briñas, Ph.D.
Review Chemist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition (CFSAN)
U.S. Food and Drug Administration (FDA)

Dr. Raymond Briñas is a Review Chemist in the Office of Food additive Safety (OFAS) in FDA's Center for Food Safety and Applied Nutrition (CFSAN). His regulatory review experience encompasses the safety evaluation of food contact substances, medical devices, and bioengineered foods. In addition, he serves as OFAS's nanotechnology subject matter expert and as OFAS's representative to FDA's Nanotechnology Task Force (NTF). Dr. Briñas is a synthetic organic chemist by training and holds a Ph.D. in Chemistry from the University of Connecticut.

Jiwen Zheng, Ph.D.
Review Chemist
Division of Cardiovascular Devices (DCD)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)

Dr. Jiwen Zheng is a Review Chemist in CDRH/OPEQ/DCD where he serves as a lead reviewer to coordinate cardiovascular devices review. Prior to joining OPEQ, he was the Senior Technical Laboratory Manager in CDRH/Office of Science and Engineering Laboratories (OSEL) who led FDA Advanced Characterization Facility (ACF) to help address cross-center regulatory challenges in nanotechnology in collaboration with FDA researchers and reviewers. Dr. Zheng serves as the FDA liaison for ISO TC 229 Nanotechnology and ISO TC 194 Biological and Clinical Evaluation of Medical Devices/Working Group 14 Material Characterization as well as Co-Chair of FDA Nanotechnology Taskforce (NTF) Standard Sub-Committee. Dr. Zheng received his Ph.D. in Physical Chemistry from Peking University, China.

Xiaoming Xu, Ph.D.
Director
Division of Product Quality Research
Office of Testing and Research
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.