U.S. FOOD & DRUG ADMINISTRATION

PQRI Product Quality Research Institute

5TH PQRI/FDA CONFERENCE ON ADVANCING PRODUCT QUALITY

Biographies - Day 2 – December 2, 2021

Development Track: *New Horizons for Pharmaceutical Development*

SESSION 1: Accelerating Development: Fast Tracking Critical Treatments, Antibody Platforms, and Quality Standards for Emerging Modalities

Moderator:

Diane Paskiet, MS
Director of Scientific Affairs
West Pharmaceutical Services
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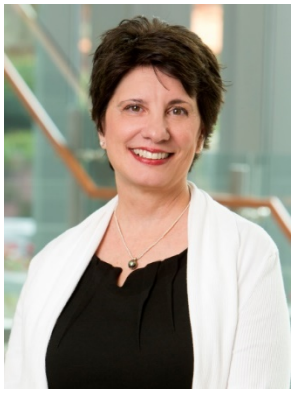

Diane Paskiet has over twenty-five years of experience in the pharmaceutical industry. She is currently Director of Scientific Affairs at West Pharmaceutical Services where she is involved in science and regulatory programs associated with safety and compatibility of pharmaceutical packaging and delivery systems. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories. She is on the Product Quality Research Institute (PQRI) Steering Committee and Chair of the Extractables and Leachables Parenteral Drug Product Working Group. Diane is also on the faculty of the Parenteral Drug Association Training Institute and a Board Member of Xavier Health Innovation Training Center of Excellence (ITCE). She has author/co-author a number of papers and book chapters related to pharmaceutical packaging, delivery systems and combination products.

Speakers:

Michael Lowinger, Ph.D.
Director of Oral Formulation Sciences
Merck & Co., Inc.
michael_lowinger@merck.com

Michael Lowinger joined Merck in 2004, focused on various aspects of drug product design and development. Through the progression of various roles, Mike has overseen the development of over two dozen compounds from early Discovery target validation through late-stage process development and commercialization, including two approved drug products and several in late stage development. Mike previously served as area lead for Merck's oral product HIV development pipeline, covering 8 development compounds and various combination products. He is currently Director of Oral Formulation Sciences, responsible for drug product development of Merck's oral pipeline.

Mike completed his doctoral dissertation in Molecular Pharmaceutics and Drug Delivery from the University of Texas at Austin, where he studied sustained release drug delivery applications of poly(urethanes). He previously obtained his M.S. in Pharmaceutical Science at Temple University and his B.S. in Chemical Engineering at the University of Delaware.

Since 2006, Mike has led global cross-functional technology development teams focused on hot melt extrusion and spray drying processes at Merck, including leadership of an innovation effort dedicated to reducing pill burden of poorly soluble drug compounds. Mike has authored or co-authored 21 publications and is an inventor of two patents.

Maria-Teresa Gutierrez-Lugo, Ph.D.
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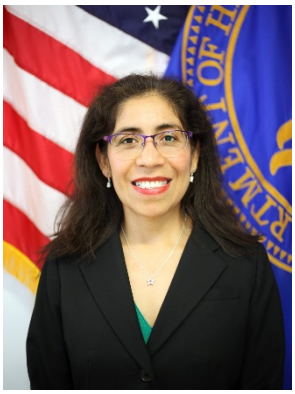

Dr. Gutierrez-Lugo is a Product Quality Review Chief in the Office of Biotechnology Products (OBP), OPQ, CDER, FDA where she oversees the review of monoclonal antibodies and other biotechnology products from development, license applications, and post-approval as well as Emergency Use Authorization of COVID-19 neutralizing antibodies. Prior to joining the FDA in 2008, Dr. Gutierrez-Lugo conducted postdoctoral research at the NIH and at the University of Arizona. She holds a Ph.D. in Chemical Sciences (Pharmacy) from the National Autonomous University of Mexico.

Catherine B. Zander, Ph.D.
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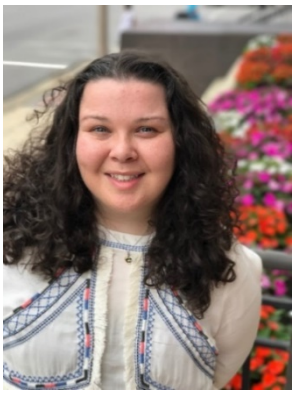

Catherine (Katie) B. Zander is currently a scientific program manager at the Standards Coordinating Body where she works to facilitate conversations and coordinate stakeholders within the regenerative medicine community to accelerate the creation of and the use of standards for cell and gene therapies and tissue engineering.

Prior to her work at SCB, Katie was the American Society of Hematology's first AAAS Science & Technology Policy Fellow, where she worked for the U.S. House of Representatives, Committee on Energy and Commerce (Democrats). There she worked on a variety of issues ranging from drug shortages, the 21st Century Cures Act, and maternal mortality, to nuclear waste cleanup and storage and the regulation of toxic substances. Before that, as a postdoctoral fellow at the University of Alabama at Birmingham, Katie researched the rare blood disease, thrombotic thrombocytopenic purpura (TTP), and established a TTP patient education program in Alabama.

Andrew A. LeBoeuf, JD, MS
Associate Director for Policy (Acting)
Office of New Drug Policy
OND/CDER/FDA
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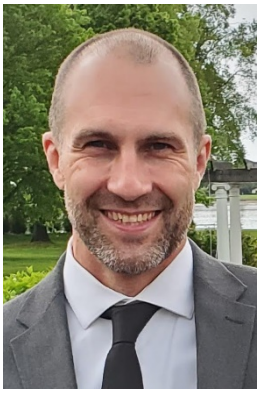
Andrew LeBoeuf is an Associate Director for Policy (Acting) in the Office of New Drug Policy in FDA's Center for Drug Evaluation and Research. In his role, Andrew is responsible for developing new or analyzing current regulatory policies impacting the review and approval of new drug products, including drug-device combination products. Since March, 2020, Andrew has been providing substantial regulatory support to the Office of New Drugs' clinical offices on the review and issuance of Emergency Use Authorizations (EUAs) for CDER-regulated therapeutics for COVID-19. Prior to joining CDER's Office of New Drug Policy, Andrew spent several years working in CDER's Office of Generic Drug Policy as well as FDA's Center for Devices and Radiological Health and the Office of Regulatory Affairs. Andrew received a Juris Doctor from the John Marshall Law School-Chicago, a Masters of Science in Applied Physiology from the Rosalind Franklin University of Medicine and Science, and a Bachelors of Science in Biology from Loyola University of Chicago. He is a member of the Illinois Bar.

SESSION 2: Modeling and Simulations to Enable Rapid Decision Making

Moderator:

Robert Meyer, Ph.D.
Principal Scientist
Merck & Co. Inc.



Robert Meyer received his BS and PhD degrees in Chemical Engineering from the University of Akron and the University of Pennsylvania, respectively. Since joining Merck in 2002, he has worked in many areas of drug product development, with a focus on emerging manufacturing platforms such as hot melt extrusion and continuous manufacturing of oral solid doses, and smaller innovations such as process modeling and PAT. As a principal scientist at Merck, he currently leads innovation and new technology development in the area of small molecule pharmaceutical commercialization.

Speakers:

Rob Smith, Ph.D.
Founder and CEO
Prime Labs, Inc
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Rob Smith is the Founder and CEO of Prime Labs, Inc., a scientific computing company specializing in leveraging advancements in artificial intelligence and cloud capabilities to make faster, easier, and more powerful mass spectrometry analysis software. In over a decade in academic research, Dr. Smith has published dozens of peer-reviewed articles on advancements in computational mass spectrometry. Dr. Smith holds a PhD in computer science (emphasis: applications of artificial intelligence and machine learning to mass spectrometry) and an MS in computer science (emphasis: machine learning and data mining) and is the recipient of the National Science Foundation CAREER award for research in computational mass spectrometry algorithms.

Douglas Kiehl
Research Advisor
Eli Lilly and Company
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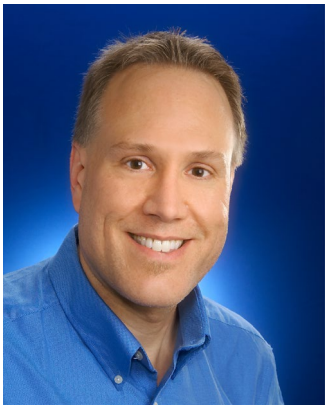

Douglas Kiehl is a Research Advisor at Eli Lilly and Company and leads the Advanced Structural Characterization, Trace Analysis, Extractables/Leachables and Elemental Impurities team. Mr. Kiehl has over 38 years' experience with application of advanced mass spectrometry in characterization of diverse chemical entities, 26 years of which are in the Pharmaceutical Industry. He is a member of the USP Packaging and Distribution Expert Committee, Chair for the PQRI (Product Quality Research Institute) Development Technical Committee, PhRMA Topic Lead for the ICH Q3E Expert Working Group, Board of Directors for the ELSIE (Extractables/Leachables Safety Information Exchange) Consortium, Chair for the SPIE Defense and Commercial Sensing Conference and member of the Biomolecule Reactivity Consortium. His research interests include the development of advanced mass spectrometry-based mapping and visualization techniques to enable the rapid and comprehensive characterization of highly complex mixtures of structurally and compositionally diverse chemical entities. He also leads multidisciplinary efforts (public/private partnerships) to advance threat detection and ultrarapid development, manufacture and deployment of pharmaceutical countermeasures for catastrophic (e.g., pandemic, environmental disaster, chem/biowarfare, etc.) unanticipated medical needs and point-of-use patient therapies.

Suresh Nulu, MS
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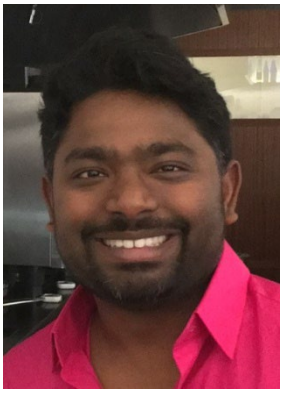

Suresh Nulu is a Director within the Practices Architecture group in the Manufacturing Systems Design and Commercialization (MSDC) wing of Merck Manufacturing Division. He has over 15 years of experience in applying Computational Fluid Dynamics, first principle/hybrid models, and Industry 4.0 philosophies across all stages of the Biopharmaceutical operations.

At Merck, he leads a digital operations architecture team that is responsible for modernizing Merck Manufacturing by integrating industry 4.0 philosophies via codified digital blue prints. He is also a passionate advocate and evangelist for the use of high fidelity, high value, fit-for-purpose models and modern digital/data tools across all dimensions of biopharmaceutical processing, to increase process assurance, enable rapid decision making, enhance workforce productivity and ease resource burdens on organizations.

Drug Device Combination Products Roundtable

Moderator:

Cheryl L.M. Stults, Ph.D.
Principal
C & M Technical Consulting LLC
PQRI Combination Products Focus Group
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Dr. Stults is Principal at C & M Technical Consulting, LLC, working with various local and global companies to advance the development of combination products. Her primary area of focus is on device and packaging materials analysis and characterization for purposes of selection, qualification and control. She holds a Ph.D. in Analytical Chemistry and completed post-doctoral studies in Biochemistry. Prior positions include: Senior Fellow at Novartis Pharmaceuticals Corporation, Assistant Research Professor at San Francisco State University and Quality Associate at a Johnson & Johnson owned company. She has led industry initiatives focused on pharmaceutical packaging and device materials and is a Science Advisor to IPAC-RS and ELSIE. Dr. Stults has been actively involved with the USP Packaging and Distribution Expert Committee contributing to development and revision of materials-related chapters.

Panelists:

Karthik Balasubramanian, Ph.D.
Director, Generic Combination Products and Semisolds R&D Teva Pharmaceuticals
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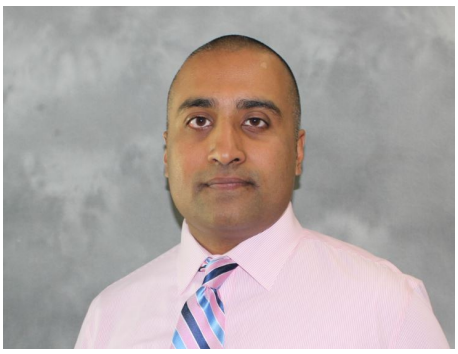

Dr. Karthik Balasubramanian, Ph.D is a director of Generic Combination Product Development at Teva Pharmaceuticals, currently working in biosimilar and semisolid and liquid combination product development. He has over 15 years of experience in all phases of medical device and combination product development, from R&D to Technical Operations. Prior to joining Teva, he has worked in numerous device areas in roles of increasing responsibility, from syringes to large scale diagnostic systems, as well as in sterile injectables and radioactive contrast imaging devices. He has a bachelors in Biomedical Engineering from Columbia University, and a Ph.D in Mechanical Engineering from Drexel University.

Susan Neadle, MS, BS, FAAO
Principal Consultant/Owner
Combination Products Consulting Services, LLC
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Susan Neadle, MS, BS, FAAO is a recognized international Combination Products and Medical Device expert with over 30 years of industry experience. Networked, published, highly active in numerous industry groups with links to a number of teaching institutions, Susan brings deep knowledge and genuine passion for sharing that knowledge with others. Susan's leadership, innovation, and best practices have been recognized with multiple awards, including the Johnson Medal, Johnson & Johnson's highest honor for excellence in Research & Development, and most recently, as a Finalist in TOPRA's 2021 Awards for Regulatory Affairs Excellence. She is Principal Consultant and President of Combination Products Consulting Services LLC, applying her extensive leadership, technical skills and experience to provide hands-on design excellence, international quality & compliance, and regulatory consulting services, to the pharmaceutical, biotech and medical device industries. Among her significant industry affiliations and contributions, she serves as Chair of the ISPE Combination Products CoP, lead author on the ASTM International Combination Products Standard Committee, and teaches a Master's Curriculum on Combination Products at UMBC.

Most recently Susan served as Executive Director and Head of Combination Products, Medical Devices, Digital Health & IVD Regulatory Affairs at Amgen, providing strategic leadership in global combination products/ device regulatory development and portfolio/project management from initial clinical investigation through registration and commercial lifecycle. Susan also served as an advisor for internal regulatory policy priorities, health authority engagement and submissions approaches through strategic engagement and mentoring of colleagues for individual projects and portfolio. She led interactions with multiple global health authorities and served as a catalyst for external consortium deliverables and strategic direction.

Prior to Amgen, Susan retired from Johnson & Johnson, where her distinguished career of more than 25 years included integral leadership roles in R&D, Quality Engineering, Design-to-Value, and Quality Systems Management, spanning pharmaceuticals, medical devices, and consumer health sectors as well as strategic leadership at J&J corporate level. She served as Chair of J&J's Design Council, advancing world-class practices in product and process design and development to drive robust, customer-centric health care solutions across J&J. She also conceived, developed and led J&J's cross-sector Combination Products Community of Practice. Among several achievements, Susan led the team that defined and implemented the globally integrated business model to meet Combination Products health authority regulations for Janssen, J&J's Pharmaceutical sector.

Prasad Peri, Ph.D.
Senior Director, Global Specialty Regulatory Affairs CMC
Teva Branded Pharmaceutical Products R&D Inc.
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Prasad Peri, Ph.D. is currently Senior Director, Global Specialty Regulatory Affairs CMC at Teva Branded Pharmaceutical Products R&D Inc., based in West Chester, PA. He and his team are responsible for the regulatory CMC for Small Molecules, Biologics, Combination Products and Devices. Prior to joining Teva Prasad was employed at Merck and Co. as a Director for Global Regulatory Affairs responsible for Combination products and Devices. Prior to joining Merck, Prasad Peri was Branch Chief at the Office of New Drug Quality Assessment in FDA responsible for the CMC review assessment of products submitted to Divisions of Pulmonary, Allergy, Rheumatology, Anesthesia, Analgesia and Addiction. Prasad Peri holds a Ph.D. in Pharmaceutical Chemistry and a BS in Pharmacy.