SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Jacqueline Corrigan-Curay, JD, MD
Principal Deputy Center Director
Office of the Center Director
Center for Drug Evaluation & Research (CDER) | FDA

Jacqueline Corrigan-Curay, J.D., M.D., is the Principal Deputy Center Director in the FDA's Center for Drug Evaluation and Research (CDER) where she provides executive leadership on strategic initiatives that advance CDER's mission to deliver safe, effective and high-quality medications to the American public. Prior to taking on this role, Dr. Corrigan-Curay was the director of CDER's Office of Medical Policy leading the development, coordination, and implementation of medical policy programs and strategic initiatives, including on real-world evidence, use of technology in drug development and prescription drug promotion.

Iilun Murphy, MD
Deputy Director, Clinical and Regulatory Affairs
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Iilun Murphy is the Deputy Director for Clinical and Regulatory Affairs in the Office of Generic Drugs since January 2020. Dr. Murphy began her FDA career in 2007, joining CDER's Office of New Drugs, Division of Gastroenterology and Inborn Errors of Metabolism Products as a medical officer. In 2011, Dr. Murphy transitioned to the newly developed Center for Tobacco Products serving in various leadership roles within the Office of Science until she returned to CDER in 2020.

Dr. Murphy holds a Bachelor of Arts from Cornell University and a Doctor of Medicine from Stanford University School of Medicine. She completed the Harvard University and Boston University Combined Residency Program in Pediatrics. She is board certified in pediatric medicine. Dr. Murphy continues to be involved in clinical teaching as an Assistant Clinical Professor of Pediatrics at George Washington University School of Medicine.

Sau (Larry) Lee, PhD
Deputy Director of Science
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality. He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions (Office of Biotechnology Products (OBP), Office of Lifecycle Products (OLDP), Office of New Drug Products (ONDP), and Office of Pharmaceutical Manufacturing Assessment (OPMA)). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval.

Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. He developed and implemented CDER's Emerging Technology Program to facilitate the adoption of novel technologies for pharmaceutical development and manufacturing. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

Marcia Fields, PharmD
Lieutenant Commander, United States Public Health Service (USPHS)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Marcia Fields is a Controlled Correspondence Coordinator for the Office of Regulatory Operations in the Immediate Office in the FDA's Center for Drug Evaluation and Research (CDER). She received her Doctorate in Pharmacy from the Medical College of Virginia/Virginia Commonwealth University School of Pharmacy in 2012. Prior to joining CDER, she was in FDA's Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Pharmaceutical Quality Operations as a Pharma Investigator. Before joining the FDA, she gained experience in ambulatory care pharmacy and in the pharmaceutical industry.

Shanaz Read, PhD
Program Lead, Controlled Correspondence Team
Division of Internal Policies and Programs (DIPAP)
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation & Research (CDER) | FDA

Shanaz Read is a Policy Lead in the Office of Policy for Pharmaceutical Quality in the Office of Pharmaceutical Quality since 2015 and works on controlled correspondences, MAPPs, and other policy documents. Since 2020, she has been the Controlled Correspondences Coordinator for the Office of Pharmaceutical Quality. She joined FDA/OGD in 2003 as a CMC reviewer, reviewing ANDAs, DMFs and supplements. Before joining FDA she worked as a Formulation scientist in the generic pharmaceutical industry after earning her Ph.D. in Pharmaceutical Sciences from the University of Michigan.

Christine Le, PharmD, PMP
CDR, USPHS
PSG Program Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Commander (CDR) Christine Le joined the Office of Research and Standards (ORS)/OGD in January 2017 as a Regulatory Officer/Program Manager. Throughout her work in the ORS, CDR Le has been instrumental in policy, process development and implementation of the Pre-ANDA program under Generic Drug User Fee Amendments (GDUFA).

As a Program Director since 2021, CDR Le provides leadership, direction, and management in all facets of the FDA Product-Specific Guidance (PSG) program in accordance with strategic plan, mission, and vision of the OGD. Simultaneously, she directs and leads numerous interconnected projects related to the implementation of GDUFA commitments and goals to develop and publish PSGs for generic products. She also serves as the subject matter expert to promote collaboration and engagements of the CDER Offices involved in the PSG program.

CDR Le received her Doctor of Pharmacy (PharmD) from the Bernard J. Dunn School of Pharmacy, Winchester, VA in 2001 and the Project Management Professional (PMP) certification in 2015. She has over 20 years' experience as a clinical pharmacist in Virginia.

Panelist:

Malik Imam
CDR, USPHS, *Deputy Director*
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

CDR Imam has worked in various pharmacy settings including long term care, managed health care, and compounding pharmacy. At the FDA he has been involved with labeling review of generic applications and has represented the Office of Generic Drugs (OGD) on drug nomenclature standards, generic drug user fee implementations, and dispute resolutions. Currently, he is the Deputy Director for the Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD).

Manina Singh, PharmD, RAC, PMP
Deputy Director
Division of Bioequivalence Process Management (DPBM)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Manina Singh is a Deputy Division Director in the Division of Bioequivalence Process Management in Office of Bioequivalence (OB) in Office of Generic Drugs (OGD). In her current role, she leads a division of Regulatory Health Project Managers and collaborates across CDER Offices to optimize, plan, manage, organize, and direct the bioequivalence review processes for the Abbreviated New Drug Applications and other submissions to ensure meeting and exceeding all regulatory commitments. She has over 20 years of experience leading and managing in various health care pharmacy fields including 10 years of project management, supervisory, and regulatory experience. Dr. Singh received her Doctor of Pharmacy degree, with top honors, from University of Maryland at Baltimore and holds Project Management certification and Regulatory Affairs certification.

Peter Capella, PhD
Director
Division of Immediate and Modified Release Products II (DIMRP II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Peter received a Ph.D. in analytical chemistry from the University of Kansas in 1991. He has over 15 years in pharmaceutical development experience from both the NDA and ANDA side, as well as nearly 15 years at the FDA supporting generic drug quality review across a wide range of therapeutic areas. His group directly supported PEPFAR ANDA quality assessments both pre- and post-marketing.

Xiaoming Xu, PhD
Director
Division of Product Quality Research (DPQR)
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | 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 the 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.

Lei K. Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Lei Zhang is the Deputy Director of ORS within OGD. ORS implements the Generic Drug User Fee Amendments (GDUFA) Science and Research commitments to ensure the therapeutic equivalence of generic drug products. Dr. Zhang is an accomplished professional with more than 23 years of combined experience in the areas of drug research, development and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on science-based regulatory decision making. Before joining the FDA in 2002, she worked at Bristol Meyers Squibb as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is the Rapporteur for the ICH M13 Expert Working Group that is developing an M13 guideline to harmonize bioequivalence (BE) study design for immediate-release oral dosage form drugs. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013. She has published more than 120 peer-reviewed papers.

Dave Coppersmith, JD
Regulatory Counsel
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dave Coppersmith is a regulatory counsel in the Division of Policy Development, Office of Generic Drug Policy, Office of Generic Drugs (OGD) in FDA's Center for Drug Evaluation and Research. Before joining OGD in May 2019, he was a supervisory regulatory counsel in the Center for Tobacco Products' Office of Compliance and Enforcement. Mr. Coppersmith received his B.A. in Economics and Political Science from St. Mary's College of Maryland and his J.D. from the University of Baltimore School of Law.

SPEAKERS AFTER THE A.M. BREAK

Savita Nigam, PhD
Senior Project Manager
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Savita Nigam is the Senior Project Manager within the Office of Research and Standards in the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research. Savita provides regulatory, project management and coordination for the review team activities for applications submitted to Abbreviated New Drug Applications (ANDA) through meetings, guidances, and controlled correspondences. She represents ORS on several committees and working groups. She completed PhD. Research work from Jawahar Lal Nehru University, New Delhi and received a PhD. in Microbiology from Barkatullah University, India, and Postdoctoral training in Molecular Endocrinology from University of Laval, Quebec Canada. Prior to her current role, Savita was a Senior Scientist for the Combat Casualty Care Research Program at Fort Detrick Maryland.

Tina T. Nhu, PharmD, Mc. PM, BSPharm
Commander, United States Public Health Service (USPHS)
Team Leader, Regulatory Project Manager
Division of Project Management (DPM)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Commander (CDR) Tina Nhu, Pharm. D, Mc. PM, B.S. Pharm.
is currently assigned to the Food and Drug Administration (FDA) as Regulatory Project Manager (RPM) Team Leader (TL) for the Division of Project Management at the Office of Generic Drugs (OGD) in the FDA's Center for Drug Evaluation and Research.

CDR Nhu graduated with a Bachelor of Pharmacy from the Massachusetts School of Pharmacy and Health Sciences in 2000 and Doctor of Pharmacy from the University of Florida College of Pharmacy in 2010. She began her career with the United States Public Health Service (USPHS) in 2009. As TL, she directs a team of Regulatory Project Managers to manage the review and approval of the Abbreviated New Drug Applications (ANDAs). She also leads and manages all PEPFAR (President's Emergency Plan for AIDS Relief) ANDAs.

April Braddy, PhD, RAC
Director
Division of Bioequivalence III (DBIII)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. April C. Braddy is the Director of the Division of Bioequivalence III in FDA's Office of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research. She has been at the FDA since 2006 and has over 15 years' experience as a regulator. Dr. Braddy began her career as a primary assessor and over the years have served in the roles of Team Leader, Associate Division Director and Deputy Division Director. She has led and co-chaired Center-level scientific committees and initiatives. In addition, Dr. Braddy has represented the Agency on multiple international global initiatives and is currently serving as the FDA's liaison to the International Pharmaceutical Regulators Programme Bioequivalence Working Group for Generics. She is the author and contributor to over 10 publications which includes book chapters and peer-reviewed journal articles on bioequivalence standards, as well as numerous scientific posters

and presentations at conferences during her FDA career. Dr. Braddy is an Excellence in Government Fellow and a member of Rho Chi, an international honor society for pharmaceutical sciences. She earned a Ph.D. in Pharmaceutical Sciences (Pharmacy) from the University of Florida with a concentration in drug discovery - neuropharmacology and a B.Sc. in Microbiology with a minor in Chemistry from Clemson University.

Tao Bai, PhD
Senior Advisor
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Tao Bai is Senior Advisor in Office of Bioequivalence (OB) in Office of Generic Drugs (OGD). In her current role, she provides expert advice and guidance on strategic planning, regulatory policy development, and office operations for OB. She also serves as an expert advisor on ANDA bioequivalence review program, bioequivalence review practice and policy, processes, procedures, and other complex areas that impact OB's functions and activities. Prior to joining FDA in 2010, Dr. Bai was a postdoctoral Research Fellow at University of Maryland School of Pharmacy studying Nasal and Inhalation Drug Products. She received her Ph.D. in Pharmaceutical Sciences from the University of Maryland.

Panelist:

Karen Bengtson
Supervisory Regulatory Health Project Manager
Office of Regulatory Science (ORS)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Parth Soni, PharmD, MBA, PMP
Regulatory Project Manager
Division of Project Management (DPM)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Parth Soni is a Regulatory Project Manager with the Division of Project Management. In addition to the Regulatory Project Management activities, Parth is also co-leading the GDUFA-III's Implementation Workgroup for Mid-Cycle Review Meetings. Parth graduated with a Pharm.D. from Howard University College of Pharmacy in 2011 and with Healthcare MBA from George Washington University in 2021. Prior to joining the FDA, Parth practiced as a clinical/staff pharmacist at The George Washington University Hospital, where he also acted as the co-chair for the continuing education program. Parth has been with the Agency since March 2018 and enjoys his role as the Regulatory Project Manager.

Xuan-Mai "Mai" Nguyen, PharmD
Regulatory Project Manager
Division of Project Management (DPM)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Mai Nguyen is a Regulatory Project Manager with the Division of Project Management. In addition to her Regulatory Project Management activities, Mai is also the Co-Project Manager for the GDUFA-III's Implementation Workgroup for Mid-Cycle Review Meetings. Mai graduated with a Pharm.D. from South Carolina College of Pharmacy at the University of South Carolina in 2016. She has been with the Agency since December 2019 and enjoys her role as a Regulatory Project Manager.

SPEAKERS AFTER THE LUNCH BREAK

Edward "Ted" Sherwood
Director
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Ted Sherwood has been the Director of the Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD) since 2014. ORO consists of three divisions: Division of Project Management, Division of Filing Review, and Division of Labeling Review. Previously, he served as the Associate Director of Immediate Office Operations, Office of Pharmaceutical Science [now the Office of Pharmaceutical Quality (OPQ)]. Prior to joining OPQ in 1999, he spent a dozen years in OGD. He held various positions including, reviewing new submissions for determination of fileability, conducting program analyses, and coordinating congressional activities. Ted received his bachelor's degree from the University of Maryland in 1992.

Russell Storms, PhD
Associate Director for Analytics
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Russell Storms is the Associate Director for Analytics in the Office of Regulatory Operations in the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. He received a Ph.D. in Computer Science from the Naval Postgraduate School in Monterey, California in 1998. Russell is responsible for the timely and accurate management of all data calls, reporting, and analysis within the Office of Generic Drugs in support of the Generic Drug User Fee Act (GDUFA).

Jayani Perera, PhD
Senior Chemist
Division of Lifecycle API (DLAPI)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Jayani Perera is a senior chemist in the Division of Lifecycle API (DLAPI) in the office of New Drug Products (ONDP) within the Office of Pharmaceutical Quality (OPQ) in the FDA's Center for Drug Evaluation and Research. She has assisted in the design, optimization, and management of the GDUFA Completeness Assessment (CA) process and the Timely Consult and Early Information Request (TCIR) Process for Drug Master Files. In addition to her role as a primary reviewer in the chemistry, manufacturing, and controls (CMC) of generic API, Jayani also serves as a secondary reviewer for CAs. Recently she served in the GDUFA III DMF implementation working group and assisted in drafting the GDUFA III solicited off-cycle and prior assessment SOPs. Jayani holds a Ph.D. degree in Inorganic/Organometallic Chemistry from Wayne State University in Detroit, Michigan.

Daniel Obrzut, PhD
Branch Chief
Division of Pharmaceutical Manufacturing Assessment I (DPMA I)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | Center for Drug Evaluation & Research (CDER) | FDA

Daniel Obrzut is currently the Branch Chief of Office of Pharmaceutical Manufacturing Assessment (OPMA) / Division of Pharmaceutical Manufacturing I (DPMI) / Branch 2. He was previously a primary and secondary assessor in OPMA with assessments including immediate release solid oral dosage forms, modified release solid oral dosage forms, liquid dosage forms, and lyophilized dosage forms. Prior to joining OPMA, Dan worked in the Office of Lifecycle Drug Product (OLDP) in a branch concentrating on immediate release solid oral dosage forms. Dan represents OPMA to the OPQ Panorama Platform Drivers group, participates on multiple OPMA KASA template working groups, assists with the OPMA SharePoint homepage, represents OPMA on the OPQ IT Task Force, and is participating on the Facility Evaluation Nexus Transition working group. Before joining the FDA, Dan's work involved formulating and characterizing diluents for immunoassays and conducting independent research. He earned a bachelor's degree from Illinois Institute of Technology and an M.S. & Ph.D. from Auburn University in Chemical Engineering. His Ph.D. dissertation is titled "Investigation of the underlying phenomena governing precipitation in supercritical antisolvent processes" which involved imaging and analyzing the spray of solvent and solute into supercritical carbon dioxide and relating this behavior to the resulting microparticles.

Kumara Subramanian, PhD
Senior Pharmaceutical Quality Assessor
Division of Liquid-Based Drug Products I (DLBP I)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Kumara Subramanian serves as Senior Pharmaceutical Quality Assessor in the Office of Lifecycle Drug Products/Office of Pharmaceutical Quality. Kumara joined FDA in 2014 as a chemistry reviewer and served as a primary reviewer, secondary reviewer, and Application Technical Lead (ATL) in the Division of Liquid Based Products I for ANDA applications. Kumara has extensive experience in the review of complex peptide drug products, topical products, and parenteral products. He also serves as the SME for peptide drug products and topical products, and is involved in product-specific guidances, controlled correspondences and pre-ANDA meeting requests. Before joining FDA, Kumara worked as a Senior Research Scientist, Center for Drug Discovery, Northeastern University, Boston for 10 years where he worked extensively on design and synthesis of ligands targeting endocannabinoid system. He received his PhD in Organic Chemistry from Indian Institute of Chemical Technology, Hyderabad.

Jennifer Sarchet, MSHA, BSN, RN, GWCPM
REMS Coordinator
Division of Clinical Safety and Surveillance (DCSS)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Jennifer Sarchet joined the FDA in 2014 and currently serves as one of five REMS Coordinators within OGD. As a REMS Coordinator she serves as a liaison between the Agency and Industry regarding REMS for generic drugs. Prior to her current role, she worked as a Regulatory Project Manager in the Office of New Drugs. She has also held positions as a Clinical Nurse Research Coordinator at the National Institutes of Health. In addition, she served in the Army Nurse Corps prior to joining the PHS. She earned her bachelor's in nursing from Capital University in Columbus, Ohio, and her master's in healthcare administration from the University of Maryland University College.

Charles Kerns
REMS Coordinator
Division of Clinical Safety and Surveillance (DCSS)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Charles "Chuck" Kerns is a REMS Coordinator within the Office of Generic Drugs. As a REMS Coordinator he serves as a liaison between the Agency and Industry regarding REMS for generic drug approvals to help mitigate known risks of certain drugs. Chuck has experience as a clinical nurse specializing in Operating Room nursing prior to becoming a nurse officer in the US Public Health Service for more than 20 years. He has prior regulatory experience as an FDA field investigator, and in the Center for Medical Devices and Radiological Health in both pre-market and post-market roles.

Panelist:

Rakhi Shah, PhD
Associate Director for Science and Communications
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Rakhi Shah is working as associate director of science and communications in OPMA. She serves as the principle advisor to the office director and provides staff leadership and direction in the area of assessment of manufacturing and facilities for A/NDAs, supplements including inspections and policy issues to support applications approval. Her prior roles in FDA include branch chief in OPMA, team leader in OGD and sr. research scientist in OTR. She is a recognized subject matter expert in the area of pharmaceutical manufacturing and has served on multiple internal and external committees and working groups. She has a Ph.D. in pharmaceutical sciences, M.S. in Bioprocess technology and B.S. in Pharmaceutical Sciences.

Srinivas Behara, PhD
Chemist
Division of Immediate and Modified Release Products III (DIMRP III)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Srinivas Behara is serving as a Quality Assessor in the Office of Life Cycle Drug Products within the Office of Pharmaceutical Quality. He received M.S (by research) from the University of Sydney, Australia, and Ph.D. from Monash University, Australia, both in the field of orally inhaled drug products. Srinivas Behara has experience reviewing CMC aspects of pre-ANDA, Bio-IND and complex ANDA submissions including nasal sprays and inhalation products.

SPEAKERS AFTER THE A.M. BREAK

Sharon Coleman, JD
Senior Regulatory Counsel
Division of Regulatory Policy II (DRP II)
Office of Regulatory Policy (ORP)
Center for Drug Evaluation & Research (CDER) | FDA

Sharon Coleman is a Senior Regulatory Counsel in FDA's Center for Drug Evaluation and Research's Office of Regulatory Policy. She advises Agency and Center leadership on policy matters relating to the regulation of human drugs under the Federal Food, Drug and Cosmetic Act including new and generic drug approvals, OTC monograph products, and more. She also drafts regulations, guidance documents, and citizen petition responses and provides technical assistance for legislators on draft legislation. Prior to joining the FDA, she worked at a Washington D.C. law firm as a litigator representing clients in complex regulatory litigation at the trial and appellate level before federal and state courts and agencies. She received her J.D. from George Washington University Law School, her M.A. from Columbia University, and her B.A. from Swarthmore College.

Dave Coppersmith, JD
Regulatory Counsel
Division of Policy Development (DPD)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
Center for Drug Evaluation and Research (CDER) | FDA

Dave Coppersmith is a regulatory counsel in the Division of Policy Development, Office of Generic Drug Policy, Office of Generic Drugs (OGD) in FDA's Center for Drug Evaluation and Research. Before joining OGD in May 2019, he was a supervisory regulatory counsel in the Center for Tobacco Products' Office of Compliance and Enforcement. Mr. Coppersmith received his B.A. in Economics and Political Science from St. Mary's College of Maryland and his J.D. from the University of Baltimore School of Law.

Truong Quach, PharmD
Acting Team Lead
Division of Orange Book Publication and Regulatory Assessment (DOBPRA)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Truong Quach is a pharmacist working in the Office of Generic Drugs, Division of Orange Book Publication and Regulatory Assessment and has been with the FDA since 2014. As an Orange Book Pharmacist, he helps the Orange Book publication by identifying drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information.

Sarah Ibrahim, PhD
Associate Director for Stakeholder and Global Engagement
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Sarah Ibrahim is the Associate Director for OGD's Generic Drug Global Affairs. In this role, Dr. Ibrahim develops strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs. Dr. Ibrahim received her PhD in Biopharmaceutics/Pharmaceutics from the School of Pharmacy, University of Cincinnati and a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. Dr. Ibrahim started her career at the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Prior to her FDA career, she had years of experience in the US pharmaceutical industry in pharmaceutical development. She is also a coinventor in several patent applications. As an assistant professor, along with the founding faculty, Dr. Ibrahim established the pharmaceutical sciences department for the second school of pharmacy in the state of New Jersey.

Djamila Harouaka, PhD
Senior Scientific Advisor
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Djamila Harouaka is the Senior Scientific Advisor in the Office of Quality Surveillance (OQS) in the Office of Pharmaceutical Quality (OPQ) in FDA's Center for Drug Evaluation and Research (CDER). In her current role, she provides scientific and technical advice and consultation regarding program matters and complex issues related to pharmaceutical quality surveillance. Djamila also served as a microbiologist in CDER's Office of Compliance (OC) where she assessed the compliance status of compounding facilities and performed high-priority inspections. In addition to her routine work, she also led the development of technical training courses delivered through the Compounding Quality Center of Excellence including the courses on Environmental Monitoring and Aseptic Process Simulations. Djamila began her FDA career in the Office of Regulatory Affairs (ORA), where she worked as a certified Drug Investigator. She earned her PhD in Microbiology from the University of Alabama at Birmingham.

Panelist:
Andrew Fine, PharmD, BCPS
Commander, United States Public Health Service (USPHS)
Senior Advisor
Division of Clinical Review (DCR)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Commander Fine is the Senior Advisor in the Office of Generic Drug 's, Office of Safety and Clinical Evaluation, Division of Clinical Review. As part of the division management team, Commander Fine, provides clinical, regulatory, and process oversight for generic drug activities in the division. Prior to his role as Senior Advisor, Commander Fine served as a team leader in the division for 7 years where he led a team of physicians in their clinical work to support the Generic Drug Program. He earned his PharmD from the University of Illinois College of Pharmacy and completed a pharmacy practice residency at Northwestern Memorial Hospital. Andrew is board certified in pharmacotherapy and earned a certificate in pharmacoepidemiology from the University of Pennsylvania. Prior to joining the Office of Generic Drugs, CDR Fine spent 4.5 years as a safety reviewer in CDER's Office of Surveillance and Epidemiology, Division of Pharmacovigilance where he led post marketing safety efforts for Multiple Sclerosis drug products.

DAY 2 SPEAKERS

Chitra Mahadevan, PharmD, MS
Commander, United States Public Health Service (USPHS)
Director
Division of Bioequivalence Process Management (DBPM)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

CDR Chitra Mahadevan is the Director of the Division of Bioequivalence Process Management in the Office of Bioequivalence, Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research. She received a PharmD from the University of Michigan in 2009 and a MS in Homeland Security from Trident University in 2021. She leads a division of regulatory health project managers who are responsible for managing all processes associated with bioequivalence reviews throughout the drug product lifecycle for Abbreviated New Drug Applications.

Craig Kiester, RPh, MS, RAC
Captain, United States Public Health Service (USPHS)
Division Director
Division of Regulatory & Business Process Management III (DRBPMIII)
Office of Program and Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

CAPT Craig Kiester is a Division Director in the Office of Product Quality in the Center for Drug Evaluation and Research. He manages the project management staff responsible for co-leading the review of the quality portion of original ANDA's. Prior to joining the FDA, he worked in a home infusion pharmacy. In 2001 he started his career with the United States Public Health Service when he came to the FDA's Office of Generic Drugs as a Chemistry Project Manager. Within the Office of Generic Drugs, he has also held positions as a Regulatory Review officer and a Microbiology Project Manager. CDR Kiester received a Bachelor of Science in Pharmacy, in 1998, from Duquesne University and a Master of Science in Health Science from Trident University in 2012.

Hui Zheng, PhD
Pharmacologist
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Hui Zheng is an assessor in the Office of Bioequivalence under the Office of Generic Drugs. She received a Ph.D. in pharmaceutical science from Ohio State University. Hui joined FDA in 2009 and has worked in OGD since 2019. She has experience in bioequivalence assessment for drug products across a wide range of therapeutic areas with different dosage forms. Hui serves as one of division representatives in the topical product specialty focus group.

Archana A. Manerikar PharmD, MS
Pharmacologist
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Archana Manerikar serves as a bioequivalence assessor in the Office of Bioequivalence (OB) within the Office of Generic Drugs (OGD) at FDA. She received a Pharm.D. concurrently with an M.S. in Pharmacometrics from the University of Maryland, Baltimore in 2016. Prior to joining the OGD in 2017, she was an ORISE fellow in the Office of Clinical Pharmacology. In her current role at the OGD/OB, she is responsible for collaborative assessments of abbreviated new drug applications (ANDAs) and controlled correspondences. She is also responsible for providing OB assessments of pre-ANDA submissions including novel bioequivalence approaches for topical products as well as industry outreach aimed at enhancing the quality of ANDA submissions for topical products.

Vipra Kundoor, PhD
Pharmacologist
Division of Bioequivalence I (DBI)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Vipra Kundoor is a Pharmacologist in the Division of Bioequivalence I within Office of Generic Drugs. She is responsible for assessing the bioequivalence of the various dosage forms of generic drugs. She is also involved in addressing controlled correspondences and pre-ANDA meeting packages. She is the focal point expert for nasal and inhalation drug products within the division and conducts secondary reviews for these complex dosage forms. She is also actively involved in the review panel for the Product-Specific Guidances for nasal and inhalation drug products. Prior to joining the FDA in 2010, Dr. Kundoor earned her Ph.D. with specialization in Pharmaceutics at University of Maryland and M.S. with specialization in Pharmacology at South Dakota State University.

Gideon (Scott) Gordon, PhD
Senior Health Informatics Officer
Data Standards Staff (DSS)
Office of Strategic Programs (OSP)
Center for Drug Evaluation & Research (CDER) | FDA

Since 2016, Dr. Gordon has been responsible for a range of activities to standardize data including “real-world data” derived from health information technology for use in clinical research and pharmacovigilance as well as standardization of pharmaceutical quality and manufacturing data for submission to FDA. Previously, Dr. Gordon worked from 2011 with a focus on public health informatics and entered the public health domain in 2005 in public health emergency preparedness. Prior to a post-doctoral position at the Whitehead Institute for Biomedical Sciences, Dr. Gordon received his core scientific training with a Ph.D. in Molecular Microbiology from Tufts University Medical School.

Norman Schmuff, PhD
Associate Director for Science
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Noman Schmuff has a Ph.D. in organic chemistry from the University of Wisconsin-Madison. He has worked in research at the NIH, in digital chemical information at Questel, Inc, and in intellectual property at American Cyanamid, before joining the FDA as a chemistry reviewer in 1990. Subsequently at FDA he has been a Team Leader, Branch Chief, and Associate Director. He has participated in four ICH Expert Working Groups, including what was then the M2 eCTD group. Currently he is the Technical Lead for the PQ/CMC Project. As such he is actively involved in many standards initiatives, including being a delegate to the ISO Identification of Medicinal Products (IDMP) group and participating in the Global IDMP Working Group.

Nimmy Mathews, PharmD, MS, BCSPC, CPGP
Lieutenant Commander, United States Public Health Service (USPHS)
Regulatory Project Manager
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

LCDR Nimmy Mathews is a Regulatory Project Manager with the Division of Project Management, Office of Regulatory Operations (ORO), within the Office of Generic Drugs (OGD). She received her Doctor of Pharmacy from the University of Sciences in Philadelphia and her Master of Science in Regulatory Affairs from George Washington University. Additionally, she has a Board Certification in Sterile Compounding and is a Certified Pharmaceutical GMP Professional.

She began her career as a pharmacist in 2008 and joined the FDA in 2014. While at FDA, LCDR Mathews has held positions with OGD as well as the Office of Regulatory Affairs (ORA). In addition to her current Regulatory Project Management activities, Nimmy also serves as a co-lead for the GDUFA-III's Implementation Workgroup for Facility Not Ready pathway.

Panelist:

LCDR Malik Imam
Deputy Director
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

LCDR Imam has worked in various pharmacy settings including long term care, managed health care, and compounding pharmacy. At the FDA he has been involved with labeling review of generic applications and has represented the Office of Generic Drugs (OGD) on drug nomenclature standards, generic drug user fee implementations, and dispute resolutions. Currently, he is the Deputy Director for the Office of Regulatory Operations (ORO) within the Office of Generic Drugs (OGD).

Andrew Fine, PharmD, BCPS
Commander, United States Public Health Service (USPHS)
Senior Advisor
Division of Clinical Review (DCR)
Office of Safety and Clinical Evaluation (OSCE)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Commander Fine is the Senior Advisor in the Office of Generic Drug 's, Office of Safety and Clinical Evaluation, Division of Clinical Review. As part of the division management team, Commander Fine, provides clinical, regulatory, and process oversight for generic drug activities in the division. Prior to his role as Senior Advisor, Commander Fine served as a team leader in the division for 7 years where he led a team of physicians in their clinical work to support the Generic Drug Program. He earned his PharmD from the University of Illinois College of Pharmacy and completed a pharmacy practice residency at Northwestern Memorial Hospital. Andrew is board certified in pharmacotherapy and earned a certificate in pharmacoepidemiology from the University of Pennsylvania. Prior to joining the Office of Generic Drugs, CDR Fine spent 4.5 years as a safety reviewer in CDER's Office of Surveillance and Epidemiology, Division of Pharmacovigilance where he led post marketing safety efforts for Multiple Sclerosis drug products.

SPEAKERS AFTER THE A.M. BREAK

Julie Neshiewat, PharmD, BCPS, CPH
Supervisor
Division of Labeling Review (DLR)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

CDR Julie Neshiewat is a Supervisor in the Division of Labeling Review in the Office of Regulatory Operations within FDA's Center for Drug Evaluation and Research/Office of Generic Drugs. She received her Doctor of Pharmacy from Virginia Commonwealth University in 2010. She became a Board-Certified Pharmacotherapy Specialist in 2013 and obtained her Certified in Public Health credential in 2017. Prior to joining the FDA, CDR Neshiewat completed a Postgraduate Year One Pharmacy Residency at the University of Virginia Health System.

Oluwakemi O. Odesina, PharmD, BCPS, CPH
Labeling Reviewer
Division of Labeling Review (DLR)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Oluwakemi "Kemi" Odesina is a senior Labeling Reviewer in the Division of Labeling Review (DLR), Office of Regulatory Operations (ORO), within the Office of Generic Drugs (OGD).

She began her federal career in 2011 as an inpatient clinical pharmacist at the Walter Reed National Military Medical Center. She joined the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in 2014.

Dr. Odesina completed her undergraduate studies at the University of Maryland, College Park and earned her Doctor of Pharmacy degree (PharmD) at the University of Charleston School of Pharmacy. She is a Board-Certified Pharmacotherapy Specialist (BCPS). She is also Certified in Public Health (CPH).

Kodilichi (Kodi) Echeozo, PharmD, BCPS, CPH
Labeling Reviewer
Division of Labeling Review (DLR)
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

LCDR Kodilichi (Kodi) Echeozo is serves as Labeling Reviewer with the Office of Generic Drugs at the U.S. Food and Drug Administration (FDA). She plays a critical role in advancing FDA's public health mission by mitigating errors on medication labeling to promote the safe and effective use of generic drugs. She graduated Summa Cum Laude at Trinity University with a B.S. degree in Biology and received her PharmD and MBA degree from Roseman University of Health Sciences. LCDR Echeozo is a Board-Certified Pharmacotherapy Specialist (BCPS) and Ambulatory Care Pharmacist (BCACP).

Karen Ireland, MS, PMP, RAC-Drugs
Senior Regulatory Health Project Manager
Division of Regulatory Business Process Manager II (DRBPMII)
Office of Programs and Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Karen Ireland serves as a Senior Regulatory Business Process Manager in OPQ's Office of Programs and Regulatory Operations (OPRO). She has been in FDA with OPRO since 2017. She has a Bachelor of Science in Microbiology from University of California, San Diego and a Master of Science in Biotechnology (concentration in biodefense) from Johns Hopkins University. She also is certified in project management and regulatory affairs (drugs). She has experience supporting the quality review of pre-market abbreviated new drug applications and has represented OPRO in working groups for guidance and changes in the GDUFA III program.

Kai Kwok, PhD
Senior Pharmaceutical Quality Assessor
Division of Liquid-Based Drug Products II (DLBP II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Kai Kwok is a Senior Pharmaceutical Quality Assessor in the Division of Liquid-based Drug Products. In this role, he acts as the application technical lead for integrated quality assessment of generic parenteral, ophthalmic, topical, oral and inhalation solution drug products. For the past 7 years, he has been reviewing ANDA, Bio-IND, and Pre-ANDA meeting packages involving complex drug products. Also, he served as a FDA liaison in the USP Packaging and Distribution Expert Committee for developing USP packaging chapters and standards and as a member for development of FDA guidance for drug delivery performance of drug-device combination products. Prior to FDA, he spent over 10 years as a formulation scientist for drug product and manufacturing process development in pharmaceutical companies. He received his B.S. in Pharmacy from Temple University and Ph.D. in Pharmaceutical Sciences from University of Michigan.

SPEAKERS AFTER THE LUNCH BREAK

Keduo Qian, PhD
Chemist
Division of Lifecycle API (DLAPI)
Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Keduo is a senior reviewer in the Division of Lifecycle API (DLAPI), Office of New Drug Products (ONDP). She has received her Ph.D. in Pharmaceutical Sciences from the University of North Carolina at Chapel Hill. Keduo has experience reviewing drug substances in support of various types of FDA applications. She is a relied-upon leader in the review of complex APIs, particularly oligosaccharides and iron-containing macromolecular complexes. She has participated in numerous inter-office complex review-related activities across CDER including OGD/ORS, OPQ/OTR, OPQ/OPMA, as well as with CDRH/OSEL.

Rajib Paul, PhD
Senior Pharmaceutical Quality Assessor
Division of Post marketing Assessment II (DPMA II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Rajib Paul is a Senior Pharmaceutical Quality Assessor for Division of Post-Marketing Activities II (DPMA II) which is responsible for post-marketing activities for generic drugs, including the assessment of ANDA supplements in the FDA's Center for Drug Evaluation and Research. Dr. Paul has been at the FDA since 2014, starting as a CMC assessor for ANDAs and ANDA supplements. He also serves on multiple working groups to facilitate the drug product review process. Prior to joining the FDA Dr. Paul held several positions in pharmaceutical industry, academia, and National Institutions of Health (NIH) relating to CMC activities including drug product manufacturing, drug development and revealing molecular mechanisms. During his scientific career, he has co-authored over 25 peer-reviewed scientific publications. Dr. Paul received a PhD in Pharmaceutical Sciences from the University of Tokyo, Japan.

Bo Jiang, PhD
Senior Pharmaceutical Quality Assessor
Division of Pharmaceutical Manufacturing Assessment I (DPMA I)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Bo Jiang joined the FDA in 2013 as a Chemist reviewer in OGD reviewing CMC sections of ANDA applications for various dosage forms. In 2015, Bo transitioned to OPF within OPQ as a process reviewer focus on assessment of manufacturing process and facilities. In June 2016, Bo started as Acting QAL in Branch I of DPMA I, and has worked as SPQA since November 2021. Bo has been involved in multiple work groups among which related to data integrity are OPMA Data Integrity WG, OPQ Facility Withdrawal WG, OPQ AIP MAPP WG, and OPQ DI MAPP WG. Prior to joining the Agency, Bo had worked in the pharmaceutical industry for about eight years on formulation development and process development and on drug product manufacturing for clinical trials and commercialization. Bo obtained his bachelor`s degree in Pharmacy and Master`s degree in Pharmaceutical Sciences both from Sichuan University, China, and his Ph.D. in Pharmaceutical Sciences from University of Tennessee Health Science Center.

Paul Schwartz, PhD
Director
Division of Post marketing Assessment II (DPMA II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Paul Schwartz is the Director of the division of pharmaceutical scientists in the Office of Pharmaceutical Quality responsible for evaluating manufacturing changes for approved generic drugs. In this capacity, he also works closely with the Drug Shortage Staff in CDER in helping to alleviate or prevent drug shortages for critical medically necessary drugs.

Previously, Dr. Schwartz was a CMC reviewer, team leader, deputy director and division director in the Office of Generic Drugs. Prior to joining FDA, Dr. Schwartz was a research chemist working in the pharmacology labs at the VA Medical Center in Charleston, SC working in antitumor drug development.

Olugbenga (Gbenga) Okubadejo, PharmD
Director
Division of Regulatory & Business Process Management III (DRBPMIII)
Office of Program and Regulatory Operations (OPRO)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Gbenga is currently the Division Director for Post-Marketing Activities in the Office of Program and Regulatory Operations (OPRO), Office of Pharmaceutical Quality (OPQ). He joined the FDA in 2013 as a Regulatory Business Process Manager in OPRO and subsequently held the positions of Acting Quality Assessment Lead and Branch Chief. He earned the BSPharm from the Arnold and Marie Schwarz College of Pharmacy, located in Brooklyn, New York and his Doctorate of Pharmacy from the Bernard J. Dunn School of Pharmacy - Shenandoah University, located in Winchester, VA.

Lane Cristensen, PhD
Branch Chief
Division of Pharmaceutical Manufacturing Assessment IV (DPMA IV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Lane is currently a Branch Chief in CDER's OPQ Office of Pharmaceutical Manufacturing Assessment. He joined the FDA in 2009 and has also had positions with CDRH Office of Compliance, CDER Office of Generic Drugs and OC Office of Global Policy and Strategy completing international assignments in positions with FDA's India and China offices. He received his PhD in Pharmaceutics and Pharmaceutical Chemistry from the University of Utah followed by a post-doctoral fellowship within the pharmaceutical industry.

Michael Chasey, MS
Supervisory Consumer Safety Officer
Division of Pharmaceutical Quality Programs (DPQP)
Office of Pharmaceutical Quality Operations (OPQO)
Office of Medical Products and Tobacco Operations (OMPTO)
Office of Regulatory Affairs (ORA) | FDA

Mr. Chasey is the Director of the Division of Pharmaceutical Quality Programs (DPQP) within OPQO/OMPTO/ORA/FDA. He provides leadership and oversight for the coordination of domestic and international inspectional activities related to pharmaceutical products, including Mutual Reliance Agreement (MRA) activities. Prior to this role, he served as a Branch Chief overseeing the foreign inspection program and the foreign dedicated drug cadre. He has played an instrumental role in the development of various alternative tool policies used to supplement onsite inspections during public health emergency. He holds an M.S. specializing in Analytical Chemistry from the College of William and Mary.

Panelist:

Derek Smith, PhD
Deputy Director
Division of Pharmaceutical Manufacturing Assessment IV (DPMA IV)
Office of Pharmaceutical Manufacturing Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Derek Smith joined FDA in 2010 and has served as compliance officer, CMC assessor, Quality assessment lead, Branch Chief, and Division Director prior to his current role. Derek is the Associate Director of Regulatory Affairs (Acting) for the Office of Pharmaceutical Manufacturing Assessment within OPQ. He provides leadership and oversight for the assessment of the manufacturing process and facilities for biologics and small molecule drug applications with a focus on the integration of application assessment and inspection findings and data reliability assessments. He also serves as the co-chair for the New Inspection Protocol Project (NIPP) initiative for pre-approval inspections and is a member of the Knowledge-aided Assessment and Structured Application (KASA) initiative steering committee. He holds a Ph. D in Chemical and Biochemical Engineering from the University of Maryland, Baltimore County.

SPEAKERS AFTER THE LUNCH BREAK

Jonathan Resnick
Project Management Officer
Office of Business Informatics (OBI)
Center for Drug Evaluation & Research (CDER) | FDA

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions. His focus is on electronic submissions and has been with the FDA since 2011. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Seyoum Senay
Supervisory Operations Research
Office of Business Informatics (OBI)
Center for Drug Evaluation & Research (CDER) | FDA

Mr. Senay is leading the FDA CDER mission-critical Informatics initiatives in support of human drug regulatory review process with a customer focus through analysis and pragmatic solutions that work to advance CDER's public health mission. He represents CDER in the FDA cloud strategy working group for decision making, collaboration, coordination, and execution of programs. Mr. Senay earned a reputation among many clients for ensuring customer satisfaction and delivering desired outcomes. Currently, Mr. Senay is leading innovative cloud transformation efforts to enable collaboration and improve operational efficiency. This capability continues to reduce regulatory overhead for sponsors, research institutes, academia, and small businesses.
In addition, Mr. Senay successfully completed the U.S Excellence in Government Leadership Fellow (EIG) program to solve national problems by driving innovation, inspiring employees, and delivering results. Mr. Senay holds a master's degree in Information Systems from The Johns Hopkins University and a Certified Program Manager by the Federal Acquisition Institute.

Nilufer Tampal, PhD
Associate Director for Scientific Quality
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in OB within OGD. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides leadership and expertise in utilization of advanced analytic data tools in the assessment of bioequivalence studies submitted in ANDAs. Dr. Tampal serves as the FDA Topic Lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky and an M.S. in Chemistry from Bombay University, India. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance and has held various leadership positions in OB for the last 12 years. Prior to her FDA career, she gained years of experience in synthesis and analysis of small molecules working as chemist at a multinational pharmaceutical company in India.

Pallavi Nithyanandan
Director
Compendial Operations and Standards Staff (COSS)
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Pallavi Nithyanandan is the Director for the Compendial Operations and Standards Staff, Office of Policy for Pharmaceutical Quality, Center for Drug Evaluation and Research (CDER). She has been with US FDA since 2010. She received her PhD in Pharmaceutical Sciences from the University of Maryland Baltimore in 2005, and a Bachelors in Pharmaceutical Sciences from Mumbai University in 2000. Her dissertation research was in Pharmaceutics and Inhalation Drug Delivery. Prior to joining FDA, she worked as a research scientist at the United States Pharmacopeial Convention from 2005-2010. In her current role, she leads the group that manages CDER's interactions with compendial and voluntary consensus standard development organizations. She serves as one of CDER's experts on Compendial issues and is the CDER Delegate to the United States Pharmacopeial Convention. She is also involved in policy development activities relevant to standards and pharmaceutical quality.

David Keire, PhD
Director
Office of Testing and Research (OTR)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Keire received a Ph.D. in Analytical Chemistry at the University of California, Riverside in 1990. In 2008, Dr. Keire joined CDER/OPQ/Office of Testing and Research (OTR) and his since then analytical chemistry skills have been applied to issues that arise with complex drugs (e.g., heparin, glatiramer acetate, transdermal systems, inhalers, modified release dosage forms and protein-based therapeutics). In 2019, David won the prestigious St. Louis American Chemical Society Award for his contributions to the chemical profession. Currently, he is the office director of OTR that has about 130 staff across St Louis, Missouri and White Oak, Maryland sites. He has over 120 peer reviewed research articles and book chapters describing his work.

Panelist:
Likan Liang, PhD
Branch Chief
Division of Liquid-Based Drug Products II (DLBP II)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation & Research (CDER) | FDA

Dr. Liang is a Branch Chief in the Division of Liquid-Based Products II, Office of Lifecycle Drug Products. Dr. Liang joined the FDA as a Chemist in 2013 and has reviewed generic applications of both solid and liquid dosage forms and served as OPQ chair in reviews of multiple complex product development meeting requests. Before joining the FDA, Dr. Liang has worked in the pharmaceutical industry for about 16 years in various capacities, in areas including API synthesis and manufacturing, formulation development for multiple dosage forms and complex drug formulations, and drug product manufacturing process development, scale up, technology transfer, and commercial scale manufacturing.