SPEAKER BIOGRAPHIES

Day One: Tuesday, December 10, 2024

Brenda Stodart, PharmD, BCGP, RAC-US
Captain, United States Public Health Service | *Director*, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) |Food and Drug Administration (FDA)

CAPT Brenda Stodart is currently the Director for the Center for Drug Evaluation and Research (CDER's) Small Business and Industry Assistance (SBIA) Program. Prior to her current position, CAPT Stodart was a Senior Regulatory Management Officer in the Office of Regulatory Policy (ORP). Before ORP, CAPT Stodart served as a Senior Health Promotion Officer in the Division of Drug Information for nine years. CAPT Stodart received her MS in Regulatory Science from University of Maryland, PharmD from the University of Arkansas Medical Sciences and BS in Pharmacy from Howard University. She is also a Board-Certified Geriatric Pharmacist (BCGP). CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

Leonard Sacks, MBBCh
Associate Director for Clinical Methodologies
Office of Medical policy (OMP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Leonard Sacks received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa, and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. He holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.

Kimberly Smith, MS, MD
Captain, United States Public Health Service
Senior Medical Advisor
Office of Medical policy (OMP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Kimberly Smith is a nephrologist with the Real-World Evidence Analytics team in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). In her current role, she develops and implements programs and policies related to the use of real-world evidence in drug development. Prior to her current role, Dr. Smith served at FDA as team leader for the Division of Clinical Trial Quality in OMP and as the nephrology team leader in the Division of Cardiology and Nephrology in CDER's Office of New Drugs. Before joining the FDA, she was with the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services.

James P. Smith, MD, MS
Director
Office of New Drug Policy (ONDP) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Smith is the Director of the Office of New Drug Policy in the Office of New Drugs (OND), previously having held various leadership positions within the office since its formation in 2018. Prior to his roles in OND Policy, he held positions as a primary reviewer, team leader, and deputy division director of the former Division of Metabolism and Endocrinology Products after joining FDA in 2011. Dr. Smith has overseen development programs targeting diseases ranging from the very rare to the very common, and his specific interests include clinical, scientific, and policy considerations related to generating evidence to demonstrate the safety and effectiveness of new drugs and biological products. Dr. Smith is a graduate of the University of Michigan Medical School and completed an Internal Medicine residency at the same institution before fellowships in both nephrology and clinical pharmacology at Vanderbilt University Medical Center. He also holds a master's degree in Clinical Research Design and Statistical Analysis from the University of Michigan School of Public Health.

Mark Levenson, Ph.D.
Acting Deputy Director
Office of Biostatistics
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Mark Levenson is currently the acting Deputy Director of the Office of Biostatistics in the Center for Drug Evaluation and Research of the US Food and Drug Administration (FDA). At FDA, he has led many major pre-market and post-market drug safety and efficacy reviews. He contributes to statistical policy and guidance development in the areas of real-world evidence, regulatory evidence, and drug safety. He is a member of the CDER Medical Policy Program Review Committee and the FDA Real-World Evidence Committee. Dr. Levenson received a Ph.D. in Statistics from the University of Chicago, a B.A. from Cornell University in Mathematics, and graduated from the Bronx High School of Science. Dr. Levenson is an elected fellow of the American Statistical Association.

Shabnam Naseer, DO, MMS
Lead Physician
Division of Anti-Infectives (DAI)| Office of Infectious Diseases (OID) | Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Shabnam Naseer is a Lead Physician at FDA in the Division of Anti-Infectives (DAI). She received a Master's in Medical Science from Drexel University and her Medical Degree at the Philadelphia College of Osteopathic Medicine in PA. She completed an Internal Medicine Residency at the Albert Einstein College of Medicine in NY and an Infectious Diseases Fellowship at the Georgetown University School of Medicine in Washington, DC. Prior to joining FDA in 2017, she provided Infectious Disease consultative services at University of Maryland for several years and served on the Infectious Disease Prevention and Pharmacy & Therapeutics Committees. As a Lead Physician in DAI, she provides clinical expertise on a multidisciplinary team and oversees a diverse application portfolio of products targeting a variety of infectious diseases. She is also an active member of many Agency committees.

Lynne Yao, MD
Director
Division of Pediatrics and Maternal Health (DPMH)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM)
Office of New Drugs (OND) | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Lynne Yao, M.D., is the Director, Division of Pediatric and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research. Dr. Yao received a B.S. degree in Biology from Yale University, and an M.D. degree from the George Washington University School of Medicine. She is board certified in both Pediatrics and Pediatric Nephrology. Prior to joining FDA, Dr. Yao was the Director of Dialysis and Associate Pediatric Residency Program Director at the Inova Fairfax Hospital for Children in Fairfax, VA. She has been with the FDA since 2008. The Division of Pediatric and Maternal Health oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve collection of data to support the safe use of drugs and biological products in pregnant and lactating individuals. She collaborates with numerous stakeholders both inside and outside of FDA to advance development of safe and effective therapies for children, and pregnant and lactating women.

Day Two: Wednesday, December 11, 2024

Paresma Patel, PhD
Division Director
Division of Product Quality Assessment XIX | Office of Product Quality Assessment III
Office of Pharmaceutical Quality | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Paresma (Pinky) Patel, Ph.D. is a Division Director in CDER's Office of Pharmaceutical Quality, Office of Product Quality Assessment III. In this role, she leads groups responsible for the evaluation of chemistry, manufacturing, and controls (CMC) information with a focus on drug substance quality throughout clinical development to submission of marketing applications. She served as a Branch Chief, supporting the oncology and anti-viral clinical divisions, prior to transitioning to her current role. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health. Dr. Patel completed her Ph.D. in organic chemistry at The Scripps Research Institute and completed a postdoctoral fellowship at the California Institute of Technology.

Nikolett Biel, PhD
Senior Biologist
Division of Hematology Oncology Toxicology (DHOT) | Office of Oncologic Diseases (OOD)
Office of New Drugs (OND) | Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Nikolett Biel is a Senior Biologist and Acting Team Lead in the Division of Hematology Oncology Toxicology supporting the Office of Oncologic Diseases in the Office of New Drugs at the FDA's Center for Drug Evaluation and Research. She received her PhD in Physiology and Pharmacology from the University of Florida College of Medicine in 2013 and joined the FDA in May 2020. Nikolett has experience reviewing pharmacology and toxicology studies in support of oncologic drug applications at the pre-IND, first-in-human IND, and late phase IND stages as well as reviewed several marketing applications and supported drug labeling for both small molecule and biologic drug products.

Shirley K. Seo, PhD
Director
Division of Cardiometabolic and Endocrine Pharmacology (DCEP)
Office of Clinical Pharmacology (OCP) | Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Shirley Seo is the director of the Division of Cardiometabolic and Endocrine Pharmacology in the Office of Clinical Pharmacology at the FDA. Dr. Seo obtained her Ph.D. in pharmaceutics at the University of Texas at Austin in 2004 where her main areas of research focus were drug metabolism, pharmacokinetics, and immunopharmacology. That same year, she began her FDA career in the Office of Generic Drugs, and in 2007, joined the antivirals teams as a reviewer in the Office of Clinical Pharmacology. In 2012, Dr. Seo became the clinical pharmacology team leader for antiviral products, a position she served in for almost 6 years. In her current role as a division director, she is actively engaged in guiding the development of regulatory policy and overseeing regulatory decision-making for drugs in the following disease areas: cardiology, nephrology, non-malignant hematology, diabetes, dyslipidemia, general endocrinology, bone, reproduction, and urology. Her areas of scientific interest and regulatory expertise include: pediatric clinical pharmacology, complex drug interactions, antiviral drug development, and drugs being developed for medical countermeasures. In 2019, she became an associate editor for the journal, Clinical Pharmacology & Therapeutics. Shirley also has a passion for mentoring.

Ann Meeker-O'Connell, MS
Director
Office of Clinical Policy (OCP) | Office of the Chief Medical Officer (OCMO)
Office of the Commissioner (OC) | Food and Drug Administration (FDA)

Ann Meeker-O'Connell is the Director of the Office of Clinical Policy in the Office of the Commissioner at FDA. Ms. Meeker-O'Connell has more than 20 years of experience in biomedical research and development in government, academic, and industry settings, including FDA efforts related to clinical trial modernization and clinical quality by design. She received an M.S. in Pharmacology and was an NIH Integrated Toxicology Fellow at Duke University.

Mili Duggal
Health Science Policy Analyst
Office of Medical Policy (OMP)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Mili Duggal is a Health Science Policy Analyst in the Office of Medical Policy, CDER, FDA. As a member of the Clinical Methodology team, Mili's work primarily focuses on leading FDA clinical drug development efforts that promote diversity in trial populations. She is also one of the coordinators of this investigator training course.

Karin Bok, MS, PhD
Deputy Director
Office of Vaccines Research & Review
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Karin Bok is the Deputy Office Director of the Office of Vaccines Research and Review, Food and Drug Administration. She provides Office-level oversight and support of regulatory reviews and actions on vaccines and related biologics, including allergenics, live biotherapeutic products, and bacteriophages. Dr. Bok's expertise covers a wide range of preclinical and clinical development of preparedness and response medical countermeasures, including preventive and therapeutic products against Ebola, Zika, Nipah, Influenza, and Coronavirus. She also had a key role in the development of broadly neutralizing monoclonal antibodies for HIV, as well as universal influenza and RSV vaccines. Karin has extensive experience collaborating with government colleagues and external stakeholders in areas of research and policy, including vaccine safety and maternal immunization. She also held a leading role in H-CORE (HHS Coordination Operations and Response Element, former Operation Warp Speed) contributing to accelerating the development and testing of vaccines against SARS-CoV-2 in the US.

Nicole Verdun, MD
Super Office Director
Office of Therapeutics
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Dr. Verdun (ver-done) received her undergraduate degree from Duke University and her medical degree from the University of Chicago Pritzker School of Medicine. She then completed a Pediatrics Residency at Children's Memorial Hospital-Northwestern University and a Pediatric Hematology-Oncology Fellowship at the Children's Hospital of Philadelphia (CHOP). After practicing as a hematologist with a focus on hemostasis and thrombosis, Dr. Verdun joined FDA in 2012, first in the Office of Hematology Oncology Products as a medical officer and a liaison for sickle cell therapeutics and anticoagulants, and then Therapeutic Biosimilars. She was appointed as the Deputy Director of the Office of Blood Research and Review in the Center for Biologics Evaluation and Research (CBER) in October 2016 and was promoted to Office Director in 2018. In 2023, Dr. Verdun was selected as the Super Office Director of the Office of Therapeutic Products, overseeing 6 Offices dedicated to the regulation and approval of Cell and Gene therapies in the United States. She overseas both a research and regulatory portfolio in CBER.

Day Three: Thursday, December 12, 2024

Cheryl Grandinetti, PharmD
Associate Director for Clinical Policy
Division of Clinical Compliance Evaluation (DCCE) | Office of Scientific Investigations (OSI)
Office of Compliance (OC) | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr Grandinetti is a reviewer in the Good Clinical Practice Assessment Branch (GCAB) of the Division of Clinical Compliance Evaluation /Office of Scientific Investigations in CDER/FDA. She provides regulatory and scientific oversight for CDER-assigned bioresearch monitoring activities and scientific and clinical oversight to FDA field investigators. She serves as a subject matter expert in GCP inspections to evaluate data integrity, quality, and safety of human subjects in clinical trials.

Miah Jung, PharmD, MS
Senior Pharmacologist
Division of Enforcement and Post-marketing Safety (DEPS) | Office of Scientific Investigations (OSI)
Office of Compliance (OC) | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Miah Jung is a senior pharmacologist in the Compliance Enforcement Branch, Office of Scientific Investigations, Center for Drug Evaluation and Research (CDER), FDA. She received a Doctor of Pharmacy from the University of Maryland in 2012. Miah has been with FDA for 10+ years, and serves as a subject matter expert in good clinical practice (GCP) inspections evaluating data integrity, quality, and subject safety in clinical studies for FDA's Bioresearch Monitoring (BIMO) Program.

Kassa Ayalew, MD, MPH
Division Director
Division of Clinical Compliance Evaluation (DCCE) | Office of Scientific Investigations (OSI)
Office of Compliance (OC) | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Kassa Ayalew is Division Director for the Division of Clinical Compliance Evaluation in the Office of Scientific Investigation at Center for Drug Evaluation and Research (CDER) in FDA. Dr. Ayalew oversees verification of the integrity of efficacy and safety data submitted to the FDA in support of new drug and biologic applications and the protection and assurance of the rights and welfare of human research subjects.

Dr. Ayalew received his M.D. in 1989 from Haile Selassie University Medical Faculty in Addis Ababa, Ethiopia. Following graduation, he worked as an Assistant Professor in the Department of Pediatrics at the Gondar University of Medical Sciences in Ethiopia. After awarded a scholarship, he completed post-graduate training in pediatrics and child health at Leipzig University in Germany. Following successful completion of his post-graduate residency training at Leipzig University, he also completed pediatrics residency at the Long Island College of Hospital followed by a fellowship program at Children's National Medical Center/ George Washington University where he also obtained an MPH in public health. Dr. Ayalew holds an active license to practice medicine in State of Virginia. He is board certified in Pediatrics and Infectious Disease.

Dr. Ayalew works at Patient First Primary and Urgent Care in Virginia where he provides clinical services to both pediatrics and adult patients. He has given numerous didactic lectures, case presentations and published publications in peer review journals. He has decades of clinical and regulatory work experience.

Cara Alfaro, PharmD
Senior Pharmacologist
Good Clinical Practice Assessment Branch (GCPAB) | Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI) | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Alfaro serves as a clinical reviewer in the Good Clinical Practice Assessment Branch in the Office of Scientific Investigations. She works closely with the Office of Inspections and Investigations (OII) to assess data integrity and human subject protections through bioresearch monitoring inspections of selected clinical investigator sites, sponsors, and contract research organizations for NDAs and BLAs submitted to the Division of Neurology.

Prior to joining OSI, Dr. Alfaro was a clinical reviewer in the Division of Psychiatry at FDA. Prior to joining FDA, she was a clinical pharmacy specialist at NIMH and a member of the NIMH IRB. Dr. Alfaro attended Purdue University for her B.S. in Pharmacy and The Ohio State University for her Pharm.D. Dr. Alfaro completed both a residency and fellowship in psychiatric pharmacy at the University of Texas Health Science Center at San Antonio.

Michelle Anantha, MSPAS, PA-C, RAC
Senior Pharmacologist
Division of Clinical Compliance Evaluation (DCCE) | Office of Scientific Investigations (OSI)
Office of Compliance (OC) | Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Michelle Anantha is a senior reviewer with the Good Clinical Practice (GCP) Compliance Oversight Branch in the Office of Scientific Investigations in CDER's Office of Compliance. In her current role, she evaluates GCP-related referrals and complaints, as well as inspectional findings, regarding clinical investigators, sponsor-investigators, sponsors, contract research organizations, institutional review boards, and Radioactive Drug Research Committees. She and her colleagues work collaboratively to ensure subjects' rights, safety, and welfare, and data integrity and reliability, in the conduct of clinical trials for human prescription drugs and therapeutic biologics.
Prior to joining FDA in 2004, Ms. Anantha clinically practiced as a Physician Assistant in oncology and internal medicine and worked in the pharmaceutical industry.

Emily Gebbia, JD
Associate Director for Regulatory Development
Office of Scientific Investigations (OSI) | Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Emily Gebbia is the Associate Director for Regulatory Development in the Office of Scientific Investigations (OSI) in the FDA's Center for Drug Evaluation and Research, Office Compliance. Emily provides strategic leadership and subject matter expertise for OSI's policy efforts, including the development of regulations and guidance related to good clinical practice, human subject protection, and postmarketing safety. Emily prepares and provides technical input on various reports, correspondence, and Congressional inquiries affecting OSI's programs and works on internal business process improvements and internal and external communications. Prior to joining FDA, Emily was an attorney at Hogan Lovells, advising a range of health sector clients, and a law clerk for the Hon. Richard C. Tallman of the Ninth Circuit Court of Appeals. Emily holds a J.D. from Catholic University of America, Columbus School of Law.