Small Business and Industry Assistance
Clinical Investigator
Training Course (CITC)

DECEMBER 6 – 7, 2023
Webcast

FDA

SPEAKER BIOGRAPHIES

DAY ONE: Wednesday, December 6, 2023

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) | CDER |Food and Drug Administration (FDA)

CAPT Brenda Stodart is currently the Director for the Center for Drug Evaluation and Research's (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.

Kimberly Smith, MD, MS
Captain, United States Public Health Service
Real World Evidence Analytics
Office of Medical Policy (OMP) | CDER | 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.

Fortunato Fred Senatore, MD, PhD, FACC
Medical Officer | Team Leader
Division of Cardiology and Nephrology (DCN)
Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)
Office of New Drugs (OND) | CDER | FDA

Dr Fred Senatore has been a medical officer in the Division of Cardiology and Nephrology at the US Food and Drug Administration since 2012 and has served as Lead Physician since January 2020. Prior to his tenure at the FDA, Dr Senatore served in the pharmaceutical industry with increasing responsibility over a span of 17 years.

Dr Senatore received his BA in Biochemistry and MS in Bioengineering from Columbia University, his PhD in Chemical Engineering from Rutgers University, his MD degree from the Texas Tech University Health Sciences Center School of Medicine, his Internal Medicine training at the Mayo Clinic, and his Cardiology training at Harvard Medical School / Massachusetts General Hospital. He was a professor of Chemical Engineering at Texas Tech University, where he was awarded grants and authored papers in areas of artificial organ technology, biocompatibility, hemodynamics, and modeling/simulation of biological processes.

While at the FDA, Dr. Senatore has published in the areas of shock, medication adherence/representative populations, benefit/risk assessment, heart failure and clinical trials during the COVID-19 pandemic. He co-edited a just-released textbook on Basic and Clinical Research, published by SPRINGER. Dr. Senatore teaches a variety of courses on trial design and data analysis. He also provides service to the Heart Failure Collaboratory, National Forum for Heart Disease and Stroke Prevention, Cardiovascular Clinical Trialist (CVCT) Forum, TOPRA (The Organization of Professionals in Regulatory Affairs), ACDRS (American Course on Drug Development and Regulatory Science), ECPM (European Center of Pharmaceutical Medicine), and CCDRS (Chinese Course on Drug Development and Regulatory Science).

Leonard Sacks, MD
Director
Clinical Methodologies | Office of Medical Policy (OMP) | CDER | 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.

John Concato, MD, MS, MPH, BE
Associate Director
Office of Medical Policy (OMP) | Immediate Office | CDER | FDA

John Concato, MD, MS, MPH, is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), U.S. FDA. His responsibilities focus on FDA's Real-World Evidence (RWE) Program, including internal Agency processes, external stakeholder engagement, demonstration projects, guidance development, and serving as Chair of CDER's RWE Subcommittee. Dr. Concato joined FDA in 2019 after a 27-year career at Yale School of Medicine and the U.S. Department of Veterans Affairs (VA), where he was Professor of Medicine, Director of the VA Clinical Epidemiology Research Center, and one of two founding principal investigators of the VA Million Veteran Program mega-biobank.

Scott Winiecki, MD
Lead Physician
Rare Diseases Team (RDT)
Division of Rare Diseases and Medical Genetics (DRDMG)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
OND | CDER | FDA

Dr. Scott K. Winiecki received his MD degree from the University of Maryland and completed his pediatric training at the Children's Hospital of Philadelphia. After 12 years in private pediatric practice, he joined the U.S. Food and Drug Administration in 2011. While working on the safety of blood products and vaccines, he received the FDA's "Outstanding New Reviewer" Award and a Public Health Achievement Award. After 5 ½ years working on biologics, he joined the Center for Drugs in 2016. He spent 6 years managing the Safe Use Initiative, a group whose goal is to reduce preventable harm from medications. In December 2022, he joined the Rare Disease Team where he works collaboratively with external and internal rare disease stakeholders to promote the development of treatments for rare disorders.

Lynne Yao, MD
Director
Division of Pediatric and Maternal Health (DPMH)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
Office of New Drugs (OND) | CDER | 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.

Shabnam Naseer, DO, MMS
Lead Physician
Division of Anti-Infectives (DAI)
Office of Infectious Diseases (OID) | Office of New Drugs (OND) | CDER | 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 worked as an Infectious Disease physician at the University of Maryland, Upper Chesapeake Health for several years while serving on the Infectious Disease Prevention and Pharmacy and Therapeutics Committees. As a Lead Physician in DAI, she oversees a diverse application portfolio of products targeting various bacterial, viral, tick-borne, parasitic, and fungal pathogens and is an active member of many Agency committees.

Mark Levenson, PhD
Director
Division of Biometrics VII (DBVII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS) | CDER | FDA

Mark Levenson is currently the Director of the Division of Biometrics VII in the Center for Drug Evaluation and Research of the US Food and Drug Administration (FDA). At FDA, he has been the primary reviewer or secondary reviewer on many major pre-market and post-market drug safety problems. He contributes to statistical policy and guidance development in the areas of drug safety, real-world data, and regulatory evidence. 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 and 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.

DAY TWO: Thursday, December 7, 2023

Paresma Patel, PhD
Division Director
Division of New Drug API (DNDAPI)| Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

Paresma Patel, Ph.D. is a Division Director for the Division of New Drug API in CDER's Office of New Drug Products, Office of Pharmaceutical Quality. She started at the FDA in 2015 as a review chemist supporting the oncology divisions. She has worked across multiple clinical divisions as a drug substance and drug product chemistry, manufacturing, and controls (CMC) reviewer and served as a Quality Lead for two years prior to transitioning to a role as Branch Chief in 2021. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health with a focus on target validation and lead optimization of small molecule kinase inhibitors. Dr. Patel completed her Ph.D. in organic chemistry at The Scripps Research Institute in 2010 and completed a postdoctoral fellowship at the California Institute of Technology in 2012.

Matthew Thompson, PhD, MPH
Supervisory Pharmacologist
Division of Hematology Oncology Toxicology (DHOT)
Office of Oncologic Diseases (OOD) | Office of New Drugs (OND) | CDER | FDA

Dr. Thompson is a Supervisory Pharmacologist in the Division of Hematology Oncology Toxicology supporting the Division of Oncology 3 in the Office of Oncologic Diseases at the US Food and Drug Administration. Prior to joining the FDA, Dr. Thompson was a fellow at the National Cancer Institute at the National Institutes of Health. Dr. Thompson received his PhD from the Medical College of Wisconsin and his MPH from the Johns Hopkins Bloomberg School of Public Health.

Shirley K. Seo, PhD
Director
Division of Cardiometabolic and Endocrine Pharmacology
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS) | CDER | 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 Clinical Policy and Programs (OCPP) | Office of the Commissioner | 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.

Stephanie Coquia, MD
Primary Reviewer
Good Clinical Practice Assessment Branch (GCPAB)
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI) | CDER | FDA

Dr. Coquia serves as a primary reviewer in the Good Clinical Practice Assessment Branch within the Office of Scientific Investigations. Her responsibilities include designing and directing inspections of clinical investigators to assess data integrity and the adequacy of human subject protections.

Prior to working at FDA, Dr. Coquia was an academic radiologist at Johns Hopkins Hospital. Dr. Coquia attended Georgetown University School of Medicine and completed her residency at Hershey Medical Center and fellowship training at Johns Hopkins Hospital.

Kassa Ayalew, MD, MPH
Branch Chief
Division of Clinical Compliance Evaluation (DCCE)
Office of Scientific Investigations (OSI) | CDER | FDA

Dr. Ayalew is a Director the Division of Clinical Compliance Evaluation in the Office of Scientific Investigation in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). He oversees verification of the reliability, 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. At his current position, he directs the scientific oversight for CDER-assigned bioresearch monitoring (BIMO) activities including compliance programs of clinical investigators, sponsors and contract research organizations. He also leads the international collaboration with global regulatory counterparts in good clinical practice (GCP) initiatives. Dr. Ayalew has extensive experience in clinical trials including designing and implementing clinical studies and analyzing trial data and publishing study results.

Prior to this position, Dr. Ayalew served as Good Clinical Practice Assessment Branch Chief in the Office of Scientific Investigations. Dr. Ayalew began his tenure at FDA as a Medical Officer in CBER. Prior to joining the Office of Compliance, he served as a Medical Officer and Team Leader both in CBER and CDER. While serving in these positions, he was involved in multi-center, agency level programs dealing with policy and regulatory decisions related to development of biologic, antibacterial, antiviral, oncologic, hematologic, and immunosuppressant products.

Dr. Ayalew obtained his M.D. from Haile Selassie University Medical Faculty in Addis Ababa, Ethiopia (also called Addis Ababa University Medical Faculty). He then worked as an assistant professor in the Department of Pediatrics at the Gondar University of Medical Sciences in Ethiopia and completed post-graduate training in pediatrics and child health at Leipzig University in Germany. He also completed a pediatrics residency at the Long Island College of Hospital (State University of New York) followed by a fellowship program at Children's National Medical Center/George Washington University.

Dr. Ayalew is a Pediatric Infectious Disease physician and holds an active license to practice medicine in Virginia. He continues to provide clinical care in pediatrics and pediatric infectious diseases. He has given numerous didactic lectures and case presentations and has published articles in peer review journals. He holds several awards and credentials from the FDA, where he has over two decades of regulatory medicine and work experience.