SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Jill Furman
Director
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Jill Furman, J.D., serves as the Director of the Office of Compliance in the Center for Drug Evaluation and Research (CDER). The Office of Compliance is charged with protecting the public from poor quality, unsafe, and ineffective drug products through proactive compliance strategies and risk-based enforcement actions.

Ms. Furman joined FDA in 2020 as the Office of Compliance Deputy Director after more than 22 years with the U.S. Department of Justice's (DOJ) Consumer Protection Branch, where she handled a wide range of consumer protection matters, including civil and criminal litigation under the Food, Drug, and Cosmetic Act. In her last eight years at DOJ, Ms. Furman served as the Deputy Director of that office, supervising litigation, and providing leadership and direction to attorneys and staff.

Before joining DOJ, Ms. Furman served as an Assistant District Attorney with the Suffolk County District Attorney's Office in Boston, Massachusetts, where she prosecuted criminal cases in state appellate and trial courts.
Ms. Furman earned her law degree from Boston University School of Law and her bachelor's degree from the University of Pennsylvania.

Regie Samuel
Technical Information Specialist
Helpdesk Operations Team (HOT)
Drug Registration and Listing Branch (DRLB)
Division of Labeling, Registration and Unapproved Drugs (DLRUD)
Office of Unapproved Drugs and Labeling Compliance (OUDLC)
CDER | FDA

Regie Samuel has worked with the FDA, and specifically Drug Registration and Listing, for nearly 11 years. For 3 years, he worked as an FDA contractor supporting the eDRLS and CDER Direct systems on the software development team. Currently, and for the past 8 years, he holds the position of Technical Information Specialist on the DRLS staff. He graduated in 2009 with a B.S. in Finance from the University of Maryland in College Park and obtained an Associate's Certificate in Project Management from George Washington University in 2017.

Soo Jin Park
Lieutenant Commander (LCDR), United States Public Health Service (USPHS)
Regulatory Officer
DRLB | DLRUD | OUDLC | CDER| FDA

LCDR Park is a Regulatory Compliance Officer with the U.S. Food and Drug Administration in the Office Compliance. She received her Doctorate in Pharmacy from University of Sciences in Philadelphia (Philadelphia College of Pharmacy) and Master's in Regulatory Science from University of Maryland College of Pharmacy. She's been with Drug Registration and Listing System (DRLS) Branch since 2008 and is an expert in regulation and operation pertaining to establishment registration and drug listing for both domestic and foreign drug manufacturers. Since 2013, LCDR Park has been heavily involved in writing guidance and policy related to 503B outsourcing facilities. She's the co-lead on outsourcing facilities registration and submission of biannual product reporting.

Laurie Simonds, GWCPM
Technical Information Specialist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Laurie Simonds has over 13 years of experience working for the federal government. She is a Technical Information Specialist with the Drug Registration and Listing Branch (DRLB) in CDER/Office of Compliance at the FDA. Prior to joining the FDA, she worked for over 12 years as a Program Analyst for the U.S. Census Bureau specializing in developing training and knowledge management. She graduated in 2006 from Towson University with a Bachelor of Arts degree in Theatre and earned a Master's Certificate in Project Management from The George Washington University School of Business.

Puii Huber
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER | FDA

Lalnunpuii (Puii) Huber is a Technical Information Specialist with Drug Registration and Listing Branch (DRLB), CDER/Office of Compliance. She has been working on drug registration and listing since 2006, first as a contractor and later as part of the eDRLS Staff. As a contractor, she managed the data entry staff for registration and listing paper forms. Later she was part of the development team that created and implemented the current CDER Direct application. In 2012 she began her federal service and has been working on various projects to further develop and improve FDA's internal and external registration and listing databases and applications. She has a Bachelor of Science degree in Health System Management from the University of Baltimore and obtained a Certificate in Project Management from Duke University.

Troy Cu
Technical Information Specialist
DRLB | DLRUD | OUDLC | CDER | FDA

Troy Cu is a Technical Information Specialist with the Food and Drug Administration's Drug Registration and Listing branch (DRLB). He has worked with the DRLB data and processes, specializing in CDER Direct and SPL issues, for more than 6 years. Previously, he worked for the International Monetary Fund as a System Administrator. He graduated with Associate of Computer Information System and obtained an MCSE and CCNA.

Leyla Rahjou-Esfandiary
Branch Chief
DRLB | DLRUD | OUDLC | CDER | FDA

Leyla Rahjou-Esfandiary is the Branch Chief for Drug Registration and Listing Branch in Office of Unapproved Drugs and Labeling Compliance. She started her FDA carrier with DRLS in 2008 and later helped create the DRLS compliance program in 2015. She earned her Pharm. D. degree from Tehran University School of Medical Science in Iran in 1996 and has a certificate degree in American Course on Drug Development and Regulatory Sciences from University of California San Francisco. She has worked in retail pharmacy and hospital settings prior to joining the federal government. She's a subject matter expert in data integrity, compliance and NDC.

Yogesh Paruthi
Consumer Safety Officer
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Yogesh Paruthi is a Consumer Safety Officer with the Drug Registration and Listing Branch in CDER's Office of Compliance. Prior to his current position, he served in clinical research, supervisory, and ambulatory care roles for John Hopkins Suburban Hospital, Giant Pharmacy and Kaiser Permanente. Yogesh received his Doctor of Pharmacy degree from Touro College of Pharmacy and his Bachelor of Pharmacy degree from Guru Jambheswar University in India. He holds ASHP certification in Investigational Drugs and Informatics.

Vikas Arora
Pharmacist
Office of Program and Regulatory Operations (OPRO)
OC | CDER | FDA

Vikas Arora is a pharmacist and has been working at the U.S. Food and Drug Administration for 8 years. He currently serves as a Health Science Project Manager in the Office of Program and Regulatory Operations in the Office of Compliance. Prior to his current position, he served as a Senior Regulatory Project Manager with the Office of Generic Drugs managing the lifecycle of ANDAs. Before joining the FDA, he worked as a practicing pharmacist in hospital and community settings. Vikas received his Doctorate of Pharmacy from the Virginia Commonwealth University and his Bachelor of Science degree from The George Washington University.

Yajun Jason Tu, PharmD, PhD
Lieutenant Commander (LCDR), United States Public Health Service (USPHS)
Program Management Officer
Policy and Operations Branch (POB)
Division of User Fee Management (DUFM)
Office of Management (OM) | CDER | FDA

LCDR Yajun Jason Tu is the Program Manager for CDER's Office of Management, Division of User Fee Management (DUFM), Policy and Operations Branch. He has experience leading and managing all processes associated with drug quality reviews, facility inspections, multiple user fee programs, and supporting the regulatory and business operations of the drug approval process. He received his Ph.D. in Biochemistry and Molecular Biology in 2000 and Doctorate of Pharmacy from University of Maryland School of Pharmacy in 2012.

Huascar Batista
Senior Advisor
Office of Compounding Quality and Compliance (OCQO)
Office of Compliance (OC) | CDER | FDA

Huascar Batista is a Senior Advisor in the Office of Compounding Quality and Compliance (OCQC). The OCQC aims to protect patients from unsafe ineffective and poor quality drugs. In OCQC his work includes supply chain policy and compliance to preserve access to lawfully marketed compounded drugs. His experience includes work in the Imports Exports Compliance Branch in the Office of Drug Security Integrity and Response. Prior to his work at the CDER Office of Compliance Mr. Batista worked in the FDA Office of Regional Affairs New York District Imports Branches.

David Mazyck
Consumer Safety Officer
DRLB | DLRUD | OUDLC | CDER | FDA

David Mazyck has over 20 years of government regulatory experience. He is a Consumer Safety Officer with the Food and Drug Administration's Office of Compliance, having worked for the FDA for over 15 years in the registration and listing compliance program. Prior to joining the FDA, he served as the Senior Task Leader for Zimmerman Associates on the Drug Registration Listing System government contract, and as the Insurance Billing Manager for Midlands Oncology Associates. Mr. Mazyck is a graduate of the University of South Carolina, where he earned a Bachelor of Science degree in Biology.

Julian Chun
Pharmacist
DQCT | DRLB | DLRUD | OUDLC | CDER | FDA

Julian Chun is a pharmacist with the Drug Registration and Listing Staff in CDER's Office of Compliance. Prior to his current position, Julian served in managerial and clinical roles for Johns Hopkins Outpatient Pharmacy and Giant Pharmacy. Julian received his Doctor of Pharmacy degree from University of Maryland and a Master of Business Administration degree from Johns Hopkins University. He holds a specialty board certification in ambulatory care pharmacy and regulatory affairs certification for drugs.

Tasneem Hussain
Pharmacist
DRLB | DLRUD | OUDLC | CDER | FDA

Tasneem Hussain is a pharmacist with the Drug Registration and Listing Branch in CDER's Office of Compliance. Since joining the FDA in 2016, she has worked extensively to enhance the work of the compliance program, where she reviews registration and listing data and sends enforcement letters to non-compliant firms. Previously she has worked as a Staff Pharmacist, Immunizer and MTM Coordinator in a retail setting. Tasneem received her Doctor of Pharmacy degree from Howard University.