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SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Don D. Ashley
Director
Office of Compliance (OC) | CDER | US FDA

As Director of CDER's Office of Compliance, Donald D. Ashley, J.D., leads efforts to shield the American public from unsafe, ineffective, and low-quality drug products through measures designed to assist industry-wide compliance with federal standards for quality and safety, as well as regulatory and enforcement measures to address violations of those standards.

Mr. Ashley joined FDA after more than 18 years of criminal enforcement and investigation experience with the Department of Justice. His positions included serving as a Trial Attorney in the Office of Consumer Litigation (now the Consumer Protection Branch), prosecuting consumer fraud offenses and violations of the Food Drug and Cosmetic Act, as Associate Director of the Office of International Affairs, and as the DOJ Attaché stationed at the U.S. Embassy in Rome and at the U.S. Embassy in Manila, Philippines.

Before joining DOJ, Mr. Ashley served as senior litigation associate with a major D.C. law firm, representing clients under investigation for FD&C Act violations. He also served on active duty as an Army captain assigned to the Office of General Counsel, Department of the Army. Mr. Ashley was an adjunct professor of law at Georgetown, George Washington, American and Catholic Universities.

Mr. Ashley earned his law degree from Harvard Law School.

Paul Loebach
Branch Chief
Drug Registration and Listing Branch (DRLB)
Division of Labeling, Registration and Unapproved Drugs (DLRUD)
Office of Unapproved Drugs and Labeling Compliance (OUDLC) | OC | CDER U.S. FDA

Paul Loebach serves as Chief of the Drug Registration and Listing Branch and has headed up that office for more than eleven years. He has thirty years' experience with FDA in data management, analysis, and programing, as well as regulatory surveillance and enforcement. He has a bachelor's degree in Mathematics and Certificate of Secondary Education from the University of Maryland Baltimore County and Certificate of Public Health from Georgetown University.

Don Duggan
Team Lead
Helpdesk Operations Team (HOT)
DRLB | DLRUD | OUDLC | CDER | US FDA

Don Duggan is the team lead for the Help Desk Operations Team. He has been with the FDA since 1995. He started his career in Information Systems and from there moved on to supporting the eCTD and the ESG and for the last 9 years he's been working in the Drug Registration and Listing Branch. He has a Bachelor's degree in Agronomy - Plant Breeding and a Master's in Business Administration.

Regie Samuel
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER | US FDA

Regie Samuel has worked with the FDA, and specifically Drug Registration and Listing, for over 8 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 5 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.

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

Puii Huber
Technical Information Specialist
HOT | DRLB | DLRUD | OUDLC | CDER | US 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.

Soo Jin Park
LCDR, USPHS
Regulatory Officer
DRLB | DLRUD | OUDLC | CDER| US 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.

David Mazyck
Consumer Safety Officer
DRLB | DLRUD | OUDLC | CDER |US 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.

Troy Cu
Technical Information Specialist
DRLB | DLRUD | OUDLC | CDER | US 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.

Matt Brancazio, Pharm.D., MBA, RAC
CAPT, USPHS
Branch Chief, Policy and Operations Branch
Division of User Fee Management (DUFM) | Office of Management (OM) | CDER US FDA

CAPT Matt Brancazio joined FDA in 2012 serving as a Sr Regulatory Project Manager. In 2015, CAPT Brancazio accepted an assignment as Special Assistant to the Office Director in the Office of Compliance. He now serves as Branch Chief in the Policy and Operations Branch, Division of User Fee Management for the Office of Management. Prior to joining the FDA, CAPT Brancazio served as Deputy Chief Pharmacist for the Indian Health Service.

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

Dr. 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. Previously she has worked as a Staff Pharmacist, Immunizer and MTM Coordinator in a retail setting. She received her Pharm. D. from Howard University.

Leyla Rahjou-Esfandiary
Team Lead
DQCT | DRLB | DLRUD | OUDLC | CDER | US FDA

Leyla Rahjou-Esfandiary is the team lead on the Data Quality and Compliance Team which monitors registration and listing data 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 School of Medical Science in Iran in 1996 and has worked in retail pharmacy and hospital settings prior to joining the federal government. Her main professional focuses are data integrity, compliance and NDC.

Julian Chun
Pharmacist
DQCT | DRLB | DLRUD | OUDLC | CDER | US 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.