Speaker Biographies

Julian Chun is currently 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.

Troy Cu is a Technical Information Specialist with the Food and Drug Administration's Drug Registration and Listing Staff (DRLS). He has worked with the DRLS data and processes, specializing in CDER Direct and SPL issues, for more than 5 years. Previously, he worked for the International Monetary Fund as a System Administrator. He has an Associate of Computer Information Systems, MCSE, CCNA.

Donovan F. Duggan, II is a Lead Consumer Safety Officer with DRLS, CDER/Office of Compliance. Don started out in Operations and Quality Management for Boise Cascade. He later worked for Unisys and Booz Allen & Hamilton as a contractor as an IT desktop and network technician and as a trainer. Don has been working with Electronic Submissions for over 15 years and has been involved in various CDER projects and programs including the ESG, eCTD, SPL, and DRLS. He received his B.S. and M.B.A. degrees from the University of Maryland.

Lalnunpuii (Puii) Huber is a Technical Information Specialist with DRLS, 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.

Tasneem Hussain is a pharmacist with the Drug Registration and Listing staff in CDER's Office of Compliance. She is a member of the Data Quality and Compliance team, where she strives to improve the integrity of the registration and listing data. In addition to her other duties, she conducts random and focused reviews of the data submitted by firms to find inaccuracies and takes subsequent actions to get the errors resolved. Previously she has worked as a Staff Pharmacist, Immunizer and MTM Coordinator in a retail setting. She received her PharmD from Howard University.

Paul Loebach has worked for the FDA and specifically Drug Registration and Listing for more than 27 years. He has served as the Director of Drug Registration and Listing since 2010. He received his bachelor's degree in Mathematics from the University of Maryland Baltimore County and a Certificate of Public Health from Georgetown University.

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 12 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.

LCDR Soo Jin Park is a Senior 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) staff 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 in DRLS Staff.

Leyla Rahjou-Esfandiary is the team lead on the Data Quality and Compliance Team which monitors registration and listing compliance. She started her FDA carrier with DRLS in 2008 at the time of electronic registration and listing implementation. She helped creating the DRLS compliance program in 2015 which works towards a complete and accurate registration and listing database. 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.

Regie Samuel has worked with the FDA, and specifically Drug Registration and Listing, for over 7 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 4 years, he holds the position of Technical Information Specialist on the DRLS staff. He graduated 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.