Small Business and Industry Assistance
Electronic Drug Registration and Listing (eDRLS)
Using CDER Direct 2024

SPEAKER BIOGRAPHIES

Thursday, September 12, 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.

Matthew Lash, JD
Deputy Director, Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Matthew (Matt) Lash, J.D., serves as Deputy Director with the Center for Drug Evaluation and Research (CDER), Office of Compliance. In this role, Matt helps lead the Office's talented team in its efforts to protect the public health through effective risk-based enforcement actions and the promotion of voluntary compliance.

Matt joined CDER in 2023 from the Department of Justice's Consumer Protection Branch (CPB), where he served for 13 years as a trial attorney and Assistant Director. He represented the United States in criminal and civil cases implicating the Food, Drug, and Cosmetic Act (FDCA) and other statutes impacting consumers. As an Assistant Director, Matt supervised attorneys on many of CPB's cases related to opioids, other prescription drugs, medical devices, and food products. He also represented CPB at stakeholder conferences, conducted training for attorneys and law enforcement professionals, and served on task forces related to important Department of Justice initiatives.

Before joining the government, Matt worked at a major law firm in Washington, D.C. Matt graduated cum laude from Georgetown University Law Center in 2006.

Nora Lim, PharmD, BCPS
Lieutenant Commander, USPHS | *Pharmacist,* SBIA
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER) |Food and Drug Administration (FDA)

LCDR Nora Lim is a pharmacist within the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA) Program. She has served as a Drug Information Specialist in the Division of Drug Information for six years. LCDR Lim received her PharmD from the University of Maryland Baltimore School of Pharmacy and BS in Biochemistry & Molecular Biology from the University of Maryland, Baltimore County. She is also a Board-Certified Pharmacotherapy Specialist (BCPS) and has had experience in hospital pharmacy practice prior to her current position.

Regie Samuel
Technical Information Specialist, Drug Registration and Listing Branch (DRLB)
Division of Labeling, Registration, and Unapproved Drugs | Office of Unapproved Drugs & Labeling Compliance (OUDLC)
Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA)

Regie Samuel has worked with the FDA, and specifically Drug Registration and Listing (DRLS), for nearly 11 years. For 3 years, he worked as an FDA contractor supporting the Electronic Drug Registration and Listing (eDRLS) and Center for Drug Evaluation and Research (CDER) Direct systems on the software development team. Currently, and for the past 8 years, he has held the position of Technical Information Specialist on the DRLS staff. He graduated in 2009 with a Bachelor of Science 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.

Jose Cabrera
Technical Information Specialist, Drug Registration and Listing Branch (DRLB)
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Jose Cabrera served as a program analyst/software developer for FDA/CVM for 2 years. Prior to that, he was the Information systems coordinator at CFSAN in the Office of Analytics and Outreach. Jose also served as a C 17A Loadmaster in the U.S. Air Force as a Non-commissioned officer for 10 years. Jose earned his Bachelor and Master degrees from University of Maryland Global Campus in Management Information Systems.

Tasneem Hussain, PharmD
Pharmacist, Drug Registration and Listing Branch
Division of Labeling, Registration, and Unapproved Drugs | Office of Unapproved Drugs & Labeling Compliance
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Tasneem Hussain is a pharmacist and consumer safety officer in the Drug Registration and Listing Branch in the Center for Drug Evaluation's (CDER) 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.

Puii Huber
Technical Information Specialist, Drug Registration and Listing Branch (DRLB)
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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.

Laurie Simonds, GWCPW
Technical Information Specialist, Drug Registration and Listing Branch (DRLB)
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Laurie Simonds has over 14 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 in 2022, she worked for over 12 years as a Program Analyst for the U.S. Census Bureau specializing in developing training and knowledge management. She now works on drug registration and listing, creating and maintaining training resources, as well as managing the branch's SharePoint site. 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.

Vikas Arora, PharmD
Consumer Safety Officer, Drug Registration and Listing Branch
Division of Labeling, Registration, and Unapproved Drugs | Office of Unapproved Drugs & Labeling Compliance (OUDLC)
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Vikas Arora is a pharmacist and has been working at the U.S. Food and Drug Administration for 11 years. He currently serves as a Consumer Safety Officer in the Office of Unapproved Drugs and Labeling Compliance with the Drug Registration and Listing Branch with their compliance program. Prior to his current position, he served as a Senior Regulatory Project Manager with the Office of Generic Drugs managing the ANDA approval process and as Health Science Project Manager with the Office of Program and Regulatory Operations in the Office of Compliance working on the implementation of the Drug Supply Chain Security Act. Vikas received his Doctorate of Pharmacy degree from Virginia Commonwealth University and his Bachelor of Science degree in Biology from George Washington University.

Troy Cu
Technical Information Specialist, Drug Registration and Listing Branch (DRLB)
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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 an Associate of Computer Information System and obtained an MCSE and CCNA.

Yogesh Paruthi, PharmD
Consumer Safety Officer, Drug Registration and Listing Branch (DRLB)
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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.

David Mazyck
Consumer Safety Officer, Drug Registration and Listing Branch (DRLB)
Division of Labeling, Registration, and Unapproved Drugs | Office of Unapproved Drugs & Labeling Compliance (OUDLC)
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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.

Leyla Rahjou-Esfandiary, PharmD
Branch Chief, Drug Registration and Listing Branch (DRLB)
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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.

Soo Jin Park, PharmD, MS
Lieutenant Commander (LCDR), United States Public Health Service (USPHS)
Regulatory Officer, Drug Registration and Listing Branch (DRLB)
Division of Labeling, Registration, and Unapproved Drugs | Office of Unapproved Drugs & Labeling Compliance (OUDLC)
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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.

Julian Chun, PharmD, MBA
Pharmacist, Drug Registration and Listing Branch (DRLB)
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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 the 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.

Obinna Ugwu-Oju, MS
Division Director, Office of Pharmaceutical Quality (OPQ) | Office of Surveillance
Center for Drug Evaluation & Research (CDER) | Food and Drug Administration (FDA)

Obinna Ugwu-Oju is currently a Division Director in CDER OPQ Office of surveillance, He leads the Integrated Project Team that is tasked with managing the CARES Act Drug and Biological Products Amounts Reporting Portal. He is also involved with CDER efforts to promote stronger drug supply chain.

Before joining FDA, Obinna worked with McFadden Associates (now part of PAE) as an enterprise search architect. Obinna earned his B.S. in Electrical Engineering from University of Nigeria, and his M.S. in Telecommunication and Computers from The George Washington University.