CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE

CDER COMPLIANCE CONFERENCE

VIA WEBCAST
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U.S. FOOD & DRUG ADMINISTRATION

Speaker Biographies

In order of appearance.

Donald 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 protect 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 same standards.

Mr. Ashley joined FDA after more than 18 years of criminal enforcement and investigation experience with the Department of Justice (DOJ). His many positions with DOJ included serving as a Trial Attorney in the Office of Consumer Litigation (now the Consumer Protection Branch), where he prosecuted consumer fraud offenses and violations of the Food Drug and Cosmetic Act (FD&C Act), and as Associate Director of the Office of International Affairs, where he managed international criminal law enforcement cooperation with countries throughout the world, represented DOJ's interests within the United Nations, and negotiated law enforcement cooperation treaties.

In addition, Mr. Ashley served as the DOJ Attaché stationed at the U.S. Embassy in Rome, Italy, where he was responsible for facilitating closer cooperation between Italy and United States in organized crime and terrorism investigations. Mr. Ashley also served as the DOJ Attaché at the U.S. Embassy in Manila, Philippines, where he managed international law enforcement collaboration on behalf of the United States with the Philippines, Singapore, Malaysia and Indonesia. His work focused on money laundering, public corruption, bribery, and fraud investigations.

Before joining DOJ, Mr. Ashley served as senior litigation associate with a major D.C. law firm, representing clients under investigations 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 teaching a course on the role of federal prosecutors. He also served as vice president of the Board of Trustees at the International School Manila while in the Philippines.

Mr. Ashley received a bachelor's degree in political science from John Carroll University in Ohio and earned a law degree from Harvard Law School.

Djamila Harouaka
Microbiologist
Division of Drug Quality III (DDQIII)
Office of Manufacturing Quality (OMQ) | OC | CDER

Djamila Harouaka is a Microbiologist working in the Division of Drug Quality III, Office of Manufacturing Quality, Office of Compliance in FDA's Center for Drug Evaluation and Research. She is responsible for evaluating the compliance of compounding pharmacies (503A and 503B) with federal laws. She also served as the Technical Course Lead for the development of the Environmental Monitoring course, which was delivered as in-person and virtual trainings as part of the Compounding Quality Center of Excellence. Djamila began her FDA career in the Office of Regulatory Affairs (ORA), where she worked as a certified Drug Investigator. She has inspected pharmacies, outsourcing facilities, and drug manufacturing facilities engaged in the production of sterile (aseptically processed, terminally sterilized) and non-sterile drug products. She earned her PhD in Microbiology from the University of Alabama at Birmingham.

Connie T. Jung
Captain, USPHS
Senior Advisor for Policy Office of Drug Security, Integrity and Response (ODSIR)
CDER | US FDA

Dr. Jung is currently Senior Advisor for Policy in the Office of Drug Security, Integrity, and Response (ODSIR) in FDA's Center for Drug Evaluation and Research, Office of Compliance. Her work focuses on development of policy and regulatory strategies to improve the security and integrity of the U.S. drug supply to protect patients from counterfeit or stolen product. She received her B.S. in Pharmacy from The Ohio State University and her Ph. D. in Pharmaceutical Sciences from the University of Cincinnati. Dr. Jung joined the FDA in 1999 as a toxicology researcher in the Center for Food Safety and Applied Nutrition, and later served as a Regulatory Reviewer of bioequivalence studies in the Office of Generic Drug before working on supply chain issues.

Cristina Dar
Lieutenant Commander, USPHS
Imports Team Lead Division of Global Drug Distribution & Policy (DGDDP)
ODSIR | CDER | US FDA

LCDR Cristina Dar is the Imports Team Lead in the Office of Compliance in the Center for Drug Evaluation and Research (CDER). She is responsible for developing the operational architecture of the imports program and managing workload. LCDR Dar has 5+ years of imports experience (Section 801) and 5+ years of medical device compliance (21 CFR Part 820). She has also contributed to policy development and operations in the area of medical device cybersecurity. For the U.S. Public Health Service, LCDR Dar deployed on multiple occasions, including in Liberia for the Ebola outbreak, and for Hurricanes Irma and Maria. During her free time, she enjoys reading cartoons and quality time with her family.

Haley Seymour
Consumer Safety Officer
Division of Enforcement and Postmarketing Safety (DEPS)
Office of Scientific Investigations (OSI)
CDER | US FDA

Haley Seymour is a Consumer Safety Officer on the Risk Evaluation Mitigation Strategy (REMS) Compliance team in CDER's Office of Compliance. She graduated with a Bachelor of Science degree from Howard University in Clinical Laboratory Science and a master's degree from Johns Hopkins University in Bioscience Regulatory Affairs. She serves as subject matter expert with the Office of Regulatory Affairs field investigators during REMS inspections. She monitors and assesses industry compliance with REMS statutory requirements and regulations, including selecting, directing and reviewing inspections of regulated industry. As a Consumer Safety Officer, she provides guidance and expertise and has mastery of the regulatory cycle and processes.