Speaker Biographies

Lawrence Allan is a Regulatory Health Project Manager and has been with the FDA since 2015. He recently joined the Business Process Operations Staff, in the Office of New Drugs Immediate Office in CDER. Prior to this, he was a Regulatory Project Manager in the Division of Gastroenterology and Inborn Errors Products (DGIEP) and has experience managing products used to treat Crohn's disease. Before joining the FDA, he was a Drug Safety Specialist in the Division of AIDS (DAIDS) at the National Institute for Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), and has more than 25 years of experience in various roles related to clinical research conducted in military, academic, commercial, and federal environments.

Kimberly Brown Smith, MD, PhD
Assistant Director (Acting)
Clinical and Scientific Policy Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Kimberly Brown Smith, M.D., Ph.D., is the Acting Assistant Director in the Office of Product Evaluation and Quality (OPEQ), Clinical and Scientific Policy Staff, in the Center for Devices and Radiological Health (CDRH). In this capacity, she oversees work on a range of medical device issues, including health hazard evaluations, benefit-risk assessments, and OPEQ's Focal Point Program. Dr. Brown Smith is also an ophthalmologist, glaucoma expert, biomedical engineer, and American Society for Quality (ASQ)-certified Lean Six Sigma Green Belt. She obtained an undergraduate degree in chemical engineering from Howard University and a PhD in biomedical engineering from Johns Hopkins. She began her career as a Corporate Research Fellow at AT&T Bell Laboratories. Later, she became an assistant professor at the University of Maryland, College Park in the Biological Resources Engineering Department. After deciding to pursue clinical medicine, she completed medical school at Duke University, an ophthalmology residency at the University of Illinois at Chicago, and a glaucoma fellowship at Johns Hopkins University. She joined CDRH in 2006, where her work has been focused on premarket review and postmarket safety issues. In addition, for over twelve years she has cared for patients at the Walter Reed National Military Medical Center Ophthalmology Clinic.

LCDR Kenneth Chen
Senior Regulatory Officer
Medical Device Single Audit Program Team
Regulatory Inspections and Audits Team
Division of Regulatory Programs 2: Establishment Support
Office of Regulatory Programs
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LCDR Kenneth Chen is a Senior Regulatory Officer in the Medical Device Single Audit Program (MDSAP), Regulatory Inspections and Audits Team, Division of Regulatory Programs 2: Establishment Support, in the Office of Product Evaluation and Quality (OPEQ), Office of Regulatory Programs (ORP), in the Center for Devices and Radiological Health (CDRH). He leads efforts associated with MDSAP development and implementation with other regulatory authorities and industry. He began with the FDA over 12 years ago as a Biomedical Engineer for CDRH's Office of Compliance,

specializing in orthopedic devices. LCDR Chen received a Bachelor of Science degree in Biomedical Engineering from Rutgers University and Master of Science degree from Johns Hopkins University.

Sergio M. de del Castillo, RAC
De Novo Program Lead
Division of Regulatory Programs 1: Submission Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
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Sergio M. de del Castillo serves as the De Novo Program Lead in the Office of Regulatory Programs (ORP), Office of Product Evaluation and Quality (OPEQ), in the Center for Devices and Radiological Health (CDRH). In this role, he maintains the daily operations of the De Novo Program and works with OPEQ and Center management in the development of new policies, procedures, and initiatives. He also has served as a scientific reviewer of orthopedic devices, and as a Regulatory Advisor, working with the various review divisions in the formulation of new medical device regulations, guidance documents, policies, and procedures. He received a Bachelor of Science degree in Biomedical Engineering from Johns Hopkins University.

John Concato, MD, MS, MPH, BEng
Deputy Director
Office of Medical Policy Initiatives
Center for Drug Evaluation and Research

John Concato, MD, MS, MPH, BEng, is Deputy Director of the Office of Medical Policy Initiatives in the Center for Drug Evaluation and Research (CDER). After almost 30 years generating research—as both an independent investigator and research center director at Yale University School of Medicine and the U.S. Department of Veterans Affairs—he now works to develop, coordinate, and implement medical policy programs and strategic initiatives. These efforts seek to improve medical product development and post-marketing processes, including in emerging areas such as the use of real-world evidence.

Heather Crandall has been with the FDA for over 6 years, working in CDER's Office of Business Informatics. She currently focuses on standards and processes around electronic submissions.

Laureen Geniusz
Acting Director, Foreign Branch Operations
Office of Medical Device and Radiological Health Operations, Division 1
Office of Regulatory Affairs

Laureen Geniusz is a Medical Device Specialist and Acting Director of the Foreign Branch Operations in the Office of Medical Devices and Radiological Health (OMDRHO), Division 1, in the Office of Regulatory Affairs (ORA). She has been with FDA for 30 years and has focused on medical device inspections for the last 25 years. She has conducted numerous domestic and international inspections and has worked with FDA's Office of Criminal Investigations (OCI) and local and federal law enforcement agencies. She was an auditor for FDA's internal medical device certification program. She is a Lead ISO 13485 Auditor and is part of FDA's work group for the implementation and transition from 21 CFR 820 to ISO 13485. She has served as Acting Supervisory Investigator. Ms. Geniusz earned a Bachelor of Science Degree in Biology and Chemistry from Bowling Green State University.

Valerie M. Gooding has been with FDA since October 2008. Valerie has over 20 years of Regulatory experience. She is currently a Project Management Officer (Team Lead) with Office of Business Informatics.

As member of CDER's Electronic Submissions Team, Valerie advises on eCTD submissions and validation, eCTD guidance and Specifications, electronic submission policies, etc., Valerie is the primary trainer for the eCTD viewer tool to CDER Review Community.

Vidya Gopal
Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health

Vidya Gopal is a Consumer Safety Officer in the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH). In this role, she advises and guides external stakeholders to locate and understand various regulatory resources and requirements established by FDA, with a specialization in the Quality System regulation (21 CFR 820).

Ms. Gopal serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) Quality System Requirements and Industry Practice Course, Design Controls Course and Corrective and Preventive Action (CAPA).

In 2012, Ms. Gopal began her FDA career as a Senior Reviewer in the Cardiovascular Devices Branch in CDRH's Office of Compliance and has been with DICE since 2016. Prior to her FDA career, Ms. Gopal has over 15 years of experience in FDA-regulated device industry. She worked as a Research and Development engineer in cardiovascular and women's health device companies primarily responsible for design and clinical trials.

Ms. Gopal received a Bachelor of Engineering (Polymer Science) Degree from India, and a Master of Science in Material Science from the University of Utah.

Melissa Hall, MS
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health

Melissa Hall is a Consumer Safety Officer in the Premarket Programs Branch, Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH). Her work consists primarily of educating external stakeholders about the various regulatory resources and requirements established by FDA. Prior to working in DICE, she was the Assistant Director for the Spinal Devices Division in the Office of Orthopedic Devices, in CDRH's Office of Product Evaluation and Quality (OPEQ) for two and a half years. Prior to that she was a lead reviewer for four and a half years within the same Division.

Ms. Hall received a Bachelor of Science in Biological Sciences from the University of Maryland Baltimore County (UMBC) and a Master of Science in Biomedical Engineering from the New Jersey Institution of Technology (NJIT).

Donna Headlee, RN, BSN, CCRP
Branch Chief, Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health

Donna Headlee is the Premarket Programs Branch Chief in the Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH). In this role, Ms. Headlee leads the branch in the development of medical device industry education on premarket resources. She joined FDA in 2004 as a Consumer Safety Officer with CDRH's Office of Compliance, Division of Bioresearch Monitoring in the Special Investigations Branch. In 2009, she joined the Premarket Approval Application (PMA) Section of the Program Operations Staff, in the Office of Device Evaluation. She joined DICE in February 2016.

Prior to her FDA career, Ms. Headlee served as a Research Nurse Coordinator at the National Institutes of Health (NIH), with the National Cancer Institute (NCI), where she served as a Research Coordinator for Phase 1 oncology clinical trials. Ms. Headlee received a Bachelor of Science Degree in Nursing from Salisbury State College and a Masters Certificate in Regulatory Compliance from Hood College.

Evan Jacobs, MS
Product Owner, Electronic Medical Device Reporting (eMDR)
Division of Regulatory Programs 3: Market Intelligence
Office of Regulatory Programs
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Evan Jacobs is a Supervisory Computer Scientist in the MDR Program in the Office of Regulatory Programs, Office of Product Evaluation and Quality, in the Center for Devices and Radiological Health. He is currently serving as Product Owner for the MDR-related IT systems, including eMDR (Electronic Medical Device Reporting), SUS (System for Uniform Surveillance), and the public MAUDE (Manufacturer and User Facility Device Experience) database on FDA.gov. Mr. Jacobs is involved in many efforts to improve post-market surveillance at CDRH, such as the adverse event codes harmonization with the International Medical Device Regulators Forum (IMDRF). He earned his master's degree in Computer Science from James Madison University in 2010.

William Jones, MA
Technical Information Specialist
Exports Certificates and Compliance Team
Imports Exports Compliance Branch
Division of Global Drug Distribution and Policy
CDER/OC/ODSIR

William Jones is the Technical Information Specialist for CDER's Export Certificate Program. In this position, he is the System Administrator for the electronic platform, CDER Export Certification Application and Tracking System (CDEReCATS), used to accept export certificate applications from industry. CDEReCATs also is used internally to review applications and issue export certificates. In addition, he is responsible for extracting data from CDEReCATs to create reports, develops strategies for optimal office efficiency and he is primary point of contact for the overall testing and troubleshooting of CDEReCATS to ensure its proper functionality. He has been involved with information technology for the past three decades and has used knowledge and experience at the FDA for over six years. Before joining CDER, he worked with the Acidified/Low Acid Canned Foods (LACF) team at the Center for Food Science and Nutrition (CFSAN). There he managed the data entry team and developed concise procedures for accurate information accountability. Additionally, Will is a Marine Corps veteran and an adjunct Professor at Montgomery Community College.

Connie Jung
CAPT, USPHS
Senior Advisor for Policy
Office of Drug Security, Integrity, and Response (ODSIR)
Office of Compliance| CDER

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.

Soma Kalb, PhD
Director
Division of Clinical Evaluation and Analysis 1: Clinical Science and Quality
Office of Clinical Evaluation and Analysis
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Soma Kalb, PhD is the Director of the Division of Clinical Evaluation and Analysis 1 (DCEA1) for Clinical Science and Quality in the Office of Clinical Evaluation and Analysis (OCEA), Office of Product Evaluation and Quality (OPEQ), in the Center for Devices and Radiological Health (CDRH).

Dr. Kalb started her career at FDA in 2005, sharing her time between the Office of Science and Engineering Laboratories as a researcher and the Office of Surveillance and Biometrics as an analyst in the Division of Postmarket Surveillance in the area of cardiac rhythm devices. In 2007, she transitioned to Office of Device Evaluation, where she was a premarket reviewer in the Division of Cardiovascular Devices until December 2013. There, she gained experience leading reviews in several program areas (PMAs, IDEs, and Pre-submissions) for implantable electrophysiology devices. From 2013 through 2018, Dr. Kalb served as the Director of the Investigational Device Exemption Program, where she oversaw the operations of the IDE Program and engaged in analysis, development and implementation of regulatory policies and procedures for medical device clinical trials. Currently, as Director of DCEA1, Dr. Kalb oversees activities related to clinical trials, bioresearch monitoring, epidemiology and real-world evidence methods, and outreach through FDA's MedSun program. Dr. Kalb received a Bachelor of Science degree in Electrical Engineering from the University of Maryland, a Master of Science degree in Biomedical Engineering from the Johns Hopkins University, and a Doctorate degree in Biomedical Engineering from Duke University.

Renu Lal, PharmD
Lieutenant Commander
United States Public Health Service Pharmacist SBIA | DDI | OCOMM | CDER | FDA

Renu Lal joined the Food and Drug Administration in October 2002, where she has worked for the Division of Drug Information (DDI) in CDER's Office of Communications. In DDI, Renu is also part of the Small Business Assistance Program. She is responsible for answering questions from the public regarding a wide range of topics, from drug safety to drug development. She also is active in maintaining and developing the Small Business Assistance Program, along with increasing its visibility and outreach. In addition to her time at FDA, Renu has spent time in industry, retail pharmacy, and hospital pharmacy. Renu received her Doctor of Pharmacy from the Medical University of South Carolina, and her Bachelor's degree in Pharmacy from the University of Connecticut.

Elias Mallis
Director
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health

Elias Mallis is the Director of the Division of Industry and Consumer Education (DICE) in the Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH), a position he has held since 2011. In this role, Mr. Mallis leads a division whose mission is to educate industry and consumer stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products.

Mr. Mallis began his 26-year FDA career in 1994 and devoted the next 16 years in the Office of Device Evaluation where he conducted regulatory review and developed policy for a diverse range of medical device programs, such as 510(k)s, IDEs, PMAs and HDEs. He first served as an Electrical Engineer in the Gastroenterology and Renal Devices Branch, responsible for the review of medical products in the fields of hemodialysis, extracorporeal therapeutics, gastric motility and incontinence, and endometrial ablation, and then as Branch Chief of the Cardiac Electrophysiology and Monitoring Branch, responsible for cardiovascular disciplines such as cardiac ablation for treatment of atrial fibrillation, implantable heart failure diagnostics, and non-invasive cardiac monitors. Mr. Mallis also served in the ODE Front Office as a Policy Analyst where he contributed to various policy efforts such as the 510(k) Program, clinical studies, device reclassifications and the De Novo program. Mr. Mallis received a Bachelor of Science Degree in Electrical Engineering at the University of Maryland at College Park.

Judit Milstein was born and raised in Buenos Aires, Argentina, were she received her degree in organic chemistry (Licenced) from the University of Buenos Aires. Judit immigrated to the United States in 1985 and became a US Citizen in 1986. Judit joined the Center for Drug Evaluation and Research as a consumer safety officer in 1999, in the Division of Anesthetic, Critical Care and Addiction Drug Products. She joined the Division of Anti-Infective Drug Products in 2001 as a Regulatory Health Project Manager and she became a supervisor in the Division of Transplant and Ophthalmology Products in 2005. She is currently the Acting Director of Project Management Staff in the Office of Regulatory Operations, supporting the Office of Specialty Medicine. Before joining the Agency, Judit worked as an organic chemist at Procter and Gamble in Cincinnati, OH and at NABI in Rockville, MD.

Robert Nguyen, PharmD, RAC has been with the Office of Prescription Drug Promotion for the past three years as a Regulatory Review Officer. At OPDP, he currently supports one of the oncology dockets and has served on the Proprietary Name Review team as well as on an Accelerated Approval Working Group. Robert earned his PharmD from Rutgers, the State University of New Jersey. Prior to his career at the FDA, Robert worked in the pharmaceutical industry.

Hasmukh B. Patel is the Division Director in the Division of Post-Marketing Activities 1 (for NDAs) in the Office of Lifecycle Drug Products (OLDP), OPQ, CDER. He is with the FDA for more than 20 years.
Dr. Patel started his career in the FDA as a review chemist in the Division of Medical Imaging and Surgical Products and then moved on to serve as a Chemistry Team Leader and Deputy Division Director in the Office of New Drug Chemistry (ONDC), and as a Branch Chief in the Office of New Drug Quality Assessment (ONDQA) after reorganization of ONDC, Office of Pharmaceutical Science (OPS).
Dr. Patel has extensive technical, regulatory and managerial experience. His work experience includes review of Investigational New Drug Applications (INDs), New Drug Applications (NDAs) and NDA supplements for a wide variety of dosage forms and drug products. He has also served on various technical committees at CDER. Currently he is a member of the Emerging Technology Team (ETT) at CDER. He has several years of industrial research and development experience in the area of natural products and organic synthesis and academic experience in the development of radiopharmaceuticals for medical imaging.

He received his Ph.D. degree in Organic Chemistry from the University of Georgia, Athens, Georgia and M.Sc. in chemistry from the Indian Institute of Technology, Mumbai, India.

Ramesh Raghavachari, Ph.D.

Ramesh Raghavachari is currently the Chief of Branch I in the Division of Post-Marketing Assessment I under the Office of Lifecycle Products/ OPQ/CDER. He joined the FDA in 2003 as a reviewer in the Office New Drug Chemistry and was promoted to a team leader in 2005. He became a Master Reviewer in 2012 and later as a Branch Chief. His experience includes Pre-Marketing, Post-Marketing in Pharmaceutical Quality in many therapeutic areas and has experience in many dosage forms and combination products.
He has industry experience from companies like Li-Cor Biotechnology, Promega Corporation and Corning Inc. before joining the Agency.
Obtained his Ph.D. from Temple University, Philadelphia, Post-Doctoral Fellow from the University of Georgia working in the field of Drug Discovery, later as a Research Associate from Baylor College of Medicine/ Rice University/ Texas A & M University in the area of Genome Sequencing and technology development.

Russ Riley is a Compliance Officer with the Office of Pharmaceutical Quality of Operations, which is within FDA's field organization, the Office of Regulatory Affairs. His primary responsibility is the review and pursuit of enforcement activities against entities involved in the manufacture of drug products and active pharmaceutical ingredients (APIs) that are found to be in violation of the Food, Drug, and Cosmetic Act. Prior to this position, Mr. Riley was an Investigator, conducting inspections and other field activities that gathered evidence for enforcement actions. His experience with the FDA includes covering a wide variety of types of drug products and APIs in both domestic and foreign facilities. His office is in the Chicago area.

Prior to working for the FDA, Mr. Riley worked in analytical chemistry and regulatory affairs in the pharmaceutical and medical device industries. He has a BS in Biology from the University of Illinois at Urbana-Champaign.

Jonathan Resnick
Project Management Officer
Electronic Submissions Capability Team Division of Data Management Services and Solutions (DDMSS) OBI | OSP | CDER | FDA

Jonathan Resnick has been with the FDA for over 8 years, working in CDER's Office of Business Informatics. He currently focuses on process, standards, and guidance around electronic submissions. Prior to joining FDA, Jonathan spent 15 years working in IT project management supporting federal and private sector clients

Jason Ryans, PhD
Guidance and Policy Analyst
Regulation, Guidance and Policy Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Jason Ryans, PhD is a member of the Regulation, Guidance, and Policy Staff in the Office of Product Evaluation and Quality (OPEQ), in the Center for Devices and Radiological Health (CDRH). In this capacity, Dr. Ryans provides regulatory support to medical device staff across the Center, including the development and review of technical guidance policy documents to convey FDA's opinions and recommendations to various medical device stakeholders. Dr. Ryans joined the FDA in 2018 as an American Institute for Medical and Biological Engineering (AIMBE) Post-Doctoral Scholar. Dr. Ryans received a BSE and MSE in Biomedical Engineering from Mercer University and a PhD in Biomedical Engineering from Tulane University.

CDR Kelley Simms is a regulatory policy analyst in CDER's Office of Surveillance and Epidemiology (OSE). She is responsible for carrying out activities in support of the OSE scientific disciplines of pharmacoepidemiology, pharmacovigilance, drug safety, risk management, medication errors, adverse events and regulatory science. CDR Simms serves as a pharmacy officer in the U.S. Public Health Service and has been with FDA since 2009 holding prior positions as a safety evaluator in OSE's Division of Pharmacovigilance and as a consumer safety officer on the Pharmacovigilance Compliance Team in CDER's Office of Compliance. Prior to FDA, CDR Simms served as a clinical pharmacist with the Indian Health Service. She received a Doctor of Pharmacy degree from Ohio Northern University and a Master of Science in Pharmaceutical Outcomes and Policy from the University of Florida.

Lisa Simone, PhD
Cybersecurity Program Manager
All Hazards Response and Cybersecurity
Division of All Hazards Response, Science and Strategic Partnerships
Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health

Lisa Simone, PhD is a Cybersecurity Program Manager for All Hazards Response and Cybersecurity, in the Division of All Hazards Response, Science, and Strategic Partnerships (DARSS), Office of Strategic Partnerships and Technology Innovation (OSTPI), in the Center for Devices and Radiological Health (CDRH). She is actively involved in cybersecurity signal management, policy, and standards related to software and medical device security. Prior to her current role, Dr. Simone provided leadership in software and instrumentation premarket review activities in the Center for Biologics Evaluation and Research and served as a Biomedical Engineer in CDRH's Office of Science and Engineering Laboratories where she performed premarket reviews, analysis of software related recalls, and related guidance development. She earned an MS in the Management of Technology from the Wharton School and University of Pennsylvania and a PhD in Biomedical Engineering from Rutgers University.

CDR Emily Thakur, R.Ph., is a Team Leader with the Drug Shortage Staff at the FDA. She joined the FDA in 1999 as a Consumer Safety Officer for the Regulatory Support Branch in the Office of Generic Drugs. She then joined the Office of Regulatory Policy in the Center for Drug Evaluation and Research in 2005. She has been in her current position, with the Drug Shortage Staff since February 2011. Prior to joining the FDA, she held a position as a staff pharmacist with CVS/Pharmacy and held a part-time position until 2014. She received her Bachelor of Science degree from Rutgers College of Pharmacy in 1999.

Joseph Tartal
Deputy Director
Division of Industry and Consumer Education
Office of Communication and Education
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Joseph Tartal is the Deputy Director of the Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH). In this role, he directs the division's effort to educate the medical device industry to understand its regulatory requirements and responsibilities with medical devices. Mr. Tartal also serve as FDA faculty for the Association for the Advancement of Medical Instrumentation (AAMI) and is a member of the Regulatory Affairs Professionals Society (RAPS) education committee. Prior to his 14-year FDA career, Mr. Tartal served as a Quality Assurance Manager for small medical device manufacturers, primarily responsible for implementing and maintaining compliant quality management systems. Mr. Tartal has over 26 years of experience in the medical device industry, including premarket submissions. Mr. Tartal received a Bachelor's Degree in Biology from Pennsylvania's Slippery Rock University.

Francisco Vicenty
Program Manager, Case for Quality
Compliance and Quality Staff
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Cisco Vicenty is the Program Manager for the Case for Quality (CfQ) in the Office of Product Evaluation and Quality (OPEQ), in the Center for Devices and Radiological Health (CDRH). The Case for Quality has been strategic priority for CDRH to improve access and outcomes for patients and improve device quality by engaging industry, payers, providers, and patients to focus on the quality and performance of medical devices.

Tonya A. Wilbon
Chief, Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health

Tonya A. Wilbon is the Branch Chief for the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH). Ms. Wilbon leads DICE's efforts to educate and inform the medical device and radiation health industry on its FDA regulatory requirements for marketing medical devices and radiation-emitting products. In addition, she leads the division's efforts to educate and inform consumers, health care professionals, and patients on issues with these medical devices and radiation-emitting products. Ms. Wilbon has been with FDA for approximately 20 years with more than 10 years of clinical laboratory experience. She began her FDA career as a Microbiology Scientific Reviewer for CDRH's Office of *In Vitro* Diagnostics and Radiological Health and served as the Quality System Specialist within OIR.

Ms. Wilbon also currently serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) new Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements, Integrating Risk Management into the Product Life Cycle Course, and Design Control Requirements-Integrating the QSR and AAMI/ANSI/ISO 13485 Course. She assisted with updating the course ancillary document, The Quality System Compendium. She also serves on FDA's Content Advisory Group and serves as an instructor for the FDA Basic Medical Device Course for FDA Investigators and Staff. Ms. Wilbon has previously served as a member of the Consensus Committee for Quality System and Laboratory Practices and the Subcommittee on Antimicrobial Susceptibility testing of Human Mycoplasmas for the Clinical and Laboratory Standards Institute (CLSI).

Ms. Wilbon received a Bachelor of Science Degree in Microbiology from Howard University and is a certified Microbiologist by the American Society of Clinical Pathology (ASCP).

Rose Xu got her undergraduate degree in Fudan University school of Medicine. She came to US to pursue her graduate education, first in Arizona State University, followed by Johns Hopkins University school of Medicine. She joined FDA 12 years ago after spent almost 10 years in Industry. Rose is currently an acting Quality Assessment team lead in the office of Pharmaceutical Manufacturing Assessment (OPMA)/OPQ, conducting the manufacturing process review, facility evaluation, and compliance review. In addition to the review work, she is also conducting many pre-approval inspections on many domestic and international manufacturers. The topic she is giving today is "Facility Submission Expectations in view of the 356H Form".