CDER SBIA REdI Conference 2019

Presenter and Facilitator Biographies

Lois Almoza, MS

Regulatory Health Project Manager
Division of Transplant and Ophthalmology Products (DTOP)
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Lois Almoza is currently a Regulatory Health Project Manager for the Division of Transplant and Ophthalmology Products in Center for Drug Evaluation and Research (CDER) at the FDA. She has over 10 years of federal government service and over 18 years of Regulatory experience. Prior to joining the FDA, she excelled at different jobs from Quality Control Chemist/Auditor to Protocol Reviewer. Lois earned her BS degree in Biology from Morgan State University and a MS degree in Biotechnology from John Hopkins University.

James Bertram, PhD, RAC

CDRH Product Jurisdiction Officer
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH) | FDA

James Bertram is currently a Policy Analyst in the Office of Device Evaluation and Product Jurisdiction Officer in CDRH at FDA. In this capacity, Dr. Bertram collaborates across the Agency on cross-cutting policies, many of which apply to the review and regulation of combination products. Dr. Bertram joined the FDA in 2009 as a Regenerative Medicine Fellow in the Commissioner's Fellowship Program. Dr. Bertram received a BS in Mechanical Engineering from Pennsylvania State University and a MS/PhD in Biomedical Engineering from Yale University.

Steven Bowen PhD

Chemist
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ) | CDER | FDA

Dr. Bowen is a Product Quality Team Leader in the Office of Biotechnology Products (OBP) within the Center for Drug Evaluation and Research at FDA. OBP is responsible for the regulation of Chemistry, Manufacturing, and Controls (CMC) for therapeutic biologics throughout the product lifecycle from pre-clinical development through post-marketing activities. Dr. Bowen received his Ph.D. from the University of Maryland, Baltimore in 2012. Before joining the FDA in 2014, Dr. Bowen was a post-doctoral fellow at the National Cancer Institute where he studied the DNA damage response associated with V(D)J recombination in developing lymphocytes.

Callie Cappel-Lynch, PharmD, RAC

Senior Regulatory Project Manager
Division of Metabolism and Endocrinology Products (DMEP)
Office of Drug Evaluation (ODE) II
OND | CDER | FDA

Callie is a graduate of Temple University School of Pharmacy in Philadelphia. Prior to joining FDA she worked for Acme pharmacy in Philadelphia. She has been with the FDA in the Division of Metabolism and Endocrinology Products since 2013. In 2015 she received her Regulatory Affairs certification. In 2017 she began teaching the Drug Development elective course at Temple Pharmacy School. In her free time she enjoys traveling, painting, and attending sporting events.

Chao (Ethan) Chen, PMP, MSE, MBA

Director
Division of Data Management Services and Solutions (DDMSS)
Office of Business Informatics (OBI)
Office of Strategic Programs (OSP)
CDER | FDA

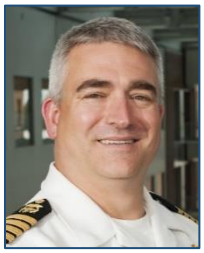
Ethan Chen provides overall leadership to CDER in streamlining electronic and traditional submissions and delivering solutions to enable rapid adoption of emerging electronic data standards. Since joining the FDA in 2012, Mr. Chen has led the several critical initiatives as the CDER Informatics Architect, including Data Management and Business Intelligence programs. Ethan has over 20-years' experience in Data Management, Enterprise Architecture, Solution Development and System Integration.

Kenneth Chen, MS

Lieutenant Commander, United States Public Health Service
Senior Regulatory Officer
Medical Device Single Audit Program Team
Office of Compliance (OC)
CDRH | FDA

Kenneth Chen is a Senior Regulatory Officer in the Medical Device Single Audit Program Team, CDRH, and leads efforts associated with MDSAP development and implementation with other regulatory authorities and industry. He began with the FDA over 10 years ago as a Biomedical Engineer for the Office of Compliance, CDRH, 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.

Scott Colburn, BSN, MS



Captain, United States Public Health Service
Director, CDRH Standards and Conformity Assessment Program
Office of the Center Director
CDRH | FDA

Scott A. Colburn is the Director of the Standards and Conformity Assessment Program at the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). In this role, CAPT Colburn is responsible for the Center's standards recognition and related development activities in 600+ national and international consensus standards committees. In addition, he oversees the program's Accreditation Scheme for Conformity Assessment [ASCA] pilot program and the Center's efforts in optimizing standards for regulatory authorities within the International Medical Device Regulators Forum (IMDRF). CAPT Colburn has served in numerous roles as a lead nurse consultant in the area of premarket review and voluntary consensus standards development and implementation for medical devices. Scott is a member to numerous national and international standards organizations and sits on several policy and leadership committees. Captain Colburn earned his BSN from Marquette University in 1999 where he then received his commission in the US Army. He transferred to the U.S. Public Health Service Commissioned Corps in January 2004 where he began his career with the FDA. Since then, he has earned a MS in Biomedical Technology Development and Management from Georgetown University and Virginia Polytechnic Institute and State University.

Rachael Conklin, MS, RN, RAC

Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)
Office of Medical Policy (OMP) | CDER | FDA

Rachel Conklin has been a reviewer with the Office of Prescription Drug Promotion for the past four years. Prior to OPDP, Conklin worked in CBER's Consumer Affair's branch. Her background is in nursing and before federal services, she was a radiation oncology nurse.

Angela DeMarco, MS

Policy Analyst
Office 510(k) Program
Office of Device Evaluation | CDRH | FDA

Angela DeMarco is currently a member of the 510(k) Staff in the Office of Device Evaluation (ODE) within the Center for Devices and Radiological Health (CDRH). Her work focuses primarily on interpreting, updating, and developing policy related to both 510(k) and 513(g) submissions. Ms. DeMarco began her career at FDA as a research fellow in the Office of Surveillance and Biometrics (OSB) from 2012-2013 where she performed literature reviews for medical devices, aided in the preparation of advisory panel meetings, and coordinated registry workshops. She then worked as a senior lead reviewer in the Physical Medicine and Rehabilitative Devices Branch (PMDB) from 2013-2016. Her work focused primarily on the review of neurorehabilitative devices, and she continues to sit on several standards committees for wheelchair devices. Prior to her work at FDA, she performed research with robots intended for use in stroke rehabilitation at the MedStar National Rehabilitation Hospital. She received a Bachelor of Science and Master's Degree in Biomedical Engineering from The Catholic University of America, Washington, D.C.

Maureen Dreher, PhD

Director (Acting)
Investigational Device Exemption Program
Office of Device Evaluation
CDRH | FDA

Maureen Dreher is currently a Policy Analyst in the Clinical Trials Program at CDRH's Office of Device Evaluation and the Acting IDE Program Director. She is actively involved in multiple initiatives to support medical device innovation and clinical studies including policy and operations of Investigational Device Exemptions, FDA's Breakthrough Devices Program, and the Early Feasibility Study Program. Prior to her current role, Dr. Dreher was a Biomedical Engineer in CDRH's Office of Science and Engineering Laboratories where she conducted research on medical device durability and served as an expert pre-market review consultant. She earned her PhD in Biomedical Engineering from Duke University in 2007.

Forest "Ray" Ford, Jr., PharmD

Commander, United States Public Health Service
Consumer Safety Officer
CDER Small Business and Industry Assistance (CDER SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM)
CDER | FDA

Ray is a Consumer Safety Officer in the Office of Communication's Division of Drug Information and has been with the FDA since 2011. Prior to joining the FDA, he served in the Indian Health Service as a Clinical Pharmacist and Safety Officer for the Fort Yuma Service Unit. He graduated from the Medical University of South Carolina in 1999, and 2001.

Terri T. Garvin, JD

Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
CDRH | FDA

Terri Garvin is a Consumer Safety Officer in the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education (OCE). Her work consists primarily of helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, with a specialization in device labeling including symbols (21 CFR 801) and imports (21 CFR 820). Ms. Garvin joined the FDA in 1999 and has worked as Regulatory Counsel in the Center for Devices and Regulatory Health's Office of Compliance, Promotion and Advertising Policy Staff, the Office of In Vitro Diagnostic Devices and Radiological Health, and the Regulations Staff. Ms. Garvin joined DICE in 2012. Prior to her FDA career, Ms. Garvin worked as a Senior legal reviewer in the Drug Enforcement Administration's Asset Forfeiture Division. Ms. Garvin received a Bachelor's Degree in Psychology from Howard University and a Juris Doctor Degree from the Catholic University School of Law, Washington, D.C.

Vidya Gopal, MS

Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education | CDRH | FDA

Vidya Gopal is a Consumer Safety Officer in the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education (OCE). Her work consists primarily of helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, with a specialization in quality system regulations (21 CFR 820). Ms. Gopal also currently 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 working in the FDA's Office of Compliance as a senior reviewer in the cardiovascular devices branch. 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 Degree in Engineering (Polymer Science) from India, and a Master of Science in Material Science from University of Utah.

Donna Headlee, RN, BSN, CCRP

Chief
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education | CDRH | FDA

Donna Headlee is the Premarket Programs Branch Chief, Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education. In this role, Ms. Headlee leads the branch in the development of medical device industry education on premarket issues and the Small Business Determination (SBD) program. She joined FDA in 2004 as a Consumer Safety Officer with the Office of Compliance (OC), Division of Bioresearch Monitoring in the Special Investigations Branch. In 2009, she joined the Premarket Application 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 Institute 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.

Renu Lal, PharmD

Lieutenant, 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.

Sharon K. Lappalainen, BA

Deputy Director, CDRH Standards and Conformity Assessment Program
Office of the Center Director
CDRH | FDA

Sharon Lappalainen has worked for the US Food and Drug Administration for the past 29 years. She is currently the Deputy Director of the Standards Management Staff located within the Office of the Center Director in the Center for Devices and Radiological Health. Prior to her FDA career, she worked in clinical laboratories from Florida Hospital Medical Center, Walter-Reed Army Medical Center, and the National Institutes of Health. During her FDA career, Ms. Lappalainen was a scientific reviewer specializing in clinical chemistry and toxicology in vitro diagnostics, cardiac markers, OB/Gyn/ART, and cardiovascular electrophysiology and monitoring devices. Throughout her FDA career, she has been a liaison on standards committees, notably AAMI's TC198 Sterilization Committee and AAMI Standards Board. Her career includes applied research in industrial sterilization, bacterial endotoxin, reprocessing, cleaning and disinfection. She received her BA degree from Randolph-Macon Women's College in Biology and Medical Technology and completed her Medical Technology internship from Lynchburg General Hospital.

Kristina Lauritsen, PhD

Combination Product Policy Advisor
CDRH | FDA

Kristina Lauritsen, PhD serves as a Combination Product Policy Advisor within the Center for Drug Evaluation and Research (CDER) at the FDA. In this role, she is responsible for engaging in development of CDER's policies related to combination product review and regulation, including activities such as guidance development, facilitating coordination with the FDA's Office of Combination Products, CBER and CDRH, and representing CDER in cross-center combination product working groups. Prior to joining CDER in 2014, she spent four years in the Center for Devices and Radiological Health, followed by seven years in the Office of Combination Products. She holds a B.S. in Biology from Shippensburg University, and a Ph.D. in tumor biology from Georgetown University.

William H. Maisel, MD, MPH

Chief Medical Officer
Director, Office of Device Evaluation
Acting Director, Office of Compliance
CDRH | FDA

William H. Maisel, MD, MPH is Chief Medical Officer, Director of the Office of Device Evaluation, and Acting Director of the Office of Compliance at FDA's Center for Devices and Radiological Health (CDRH). He is responsible for providing leadership in the development, implementation, execution, management and direction of the Center's broad national and international premarket, postmarket and compliance programs. Prior to joining FDA, Dr. Maisel was Associate Professor of Medicine at Harvard Medical School with more than 15 years of clinical experience as a Board-certified cardiologist. He is former Chair of the FDA Circulatory System Medical Device Advisory Committee and is a former member of the Center for Medicare and Medicaid Services Coverage Advisory Committee. Dr. Maisel received his undergraduate degree in biology from MIT, his medical degree from Cornell Medical College, and his Masters in Public Health from the Harvard School of Public Health. He has published more than 120 research manuscripts, book chapters, and scientific abstracts on regulatory science, device innovation, and medical device safety and effectiveness.

Elias Mallis, BS

Director
Division of Industry and Consumer Education
Office of Communication and Education
CDRH | FDA

Elias Mallis is the Director of the Division of Industry and Consumer Education in CDRH's Office of Communication and Education, a position he has held since August 2011. In this role, Mr. Mallis leads a division whose mission is to educate our industry and consumer stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products. Mr. Mallis began his 25-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 and implanted heart failure diagnostics. Mr. Mallis also served in the ODE Front Office as a Policy Analyst where he contributed to various policy effort ts such as the 510(k) Program Guidance and Pivotal Clinical Studies Guidance, device reclassifications and de novo requests. Mr. Mallis received a Bachelor of Science Degree in Electrical Engineering at the University of Maryland at College Park.

Sean Marcsisin, PhD, RAC

Lieutenant, United States Public Health Service
Office of Pharmaceutical Quality Operations
Pharma Division 1 | Investigations Branch 1
Office of Regulatory Affairs (ORA) | CDER | FDA

Lieutenant Sean Marcsisin has been with the Food and Drug Administration for three years, all of which have been with the Office of Pharmaceutical Quality Operations conducting domestic and foreign pharmaceutical inspections. Prior to joining the FDA, Lieutenant Marcsisin served on active duty with the U.S. Army as a scientist where he contributed to the pharmaceutical development of therapies for neglected tropical diseases.

Joseph S. Matrisciano Jr.

Program Division Director and District Director
Division 1 | Office of Medical Devices and Radiological Health Operations and New England District Office | ORA | FDA

Joseph Matrisciano Jr., “Joe,”is currently serving as Director for FDA’s New England District Office and Director of the Office of Medical Devices and Radiological Health Operations Division 1. Previously Joe served as Director of Engineering at FDA’s Winchester Engineering and Analytical Center, FDA's sole field engineering laboratory responsible for medical devices and radiation emitting products and safety. Joe has served in numerous managerial roles at FDA with responsibilities for various field investigative, compliance and laboratory operations within FDA. Prior to joining FDA, as a registered professional engineer, licensed attorney and registered patent attorney, Joe held various management and senior level positions in private industry, encompassing engineering, legal as well as intellectual property disciplines.

Lubna Merchant, MS, PharmD

Director (acting), Division of Medication Error Prevention and Analysis (DMEPA)
Deputy Director, Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE) | CDER | FDA

Dr. Merchant currently serves as the acting Director of the Division of Medication Error Prevention and Analysis. She is also the Deputy Director of the Office of Medication Error Prevention and Risk Management in FDA's Center for Drug Evaluation and Research's (CDER) where she is responsible for the Center's programs in risk management and medication error prevention. She provides expertise on development and implementation of programs and initiatives to support the Center's policies related to Risk Evaluation and Mitigation Strategies (REMS). She serves as expert/scientific advisor on medication errors associated with drug and biological products within the Center and outside agencies. In her capacity as the acting Division Director for DMEPA, she provides oversight, coordination, and technical expertise for the pre and post-marketing activities involving medication error prevention and analysis of regulated drug and drug/device products, including the review of proposed proprietary names for CDER. Dr. Merchant graduated from Massachusetts College of Pharmacy and Health Sciences with Master of Science in Industrial Pharmacy and Doctorate of Pharmacy and completed a PGY1 Pharmacy Practice Residency. She has worked in a variety of health care settings including retail pharmacy, Industry and hospital pharmacy as an inpatient pharmacist and as clinical specialist.

Ethny Obas, BS

Lead Consumer Safety Officer
CDRH Exports Team
Office of Compliance
CDRH | FDA

Ethny Obas is the Team Lead of the FDA CDRH Exports team. Prior to working at the FDA, Mr. Obas was the Lead Quality Assurance Analyst for the Armed Forces DNA ID Laboratory, then served as Technical Supervisor of the Chemistry department at Walter Reed National Military Medical Center. With over 20 years of experience in quality management, in-vitro diagnostic device testing, and quality system regulations, Mr. Obas has been serving as a senior member of the Exports team since 2013. During his tenure, he has made significant contributions to the program by setting overarching policies as a member of the Export Certificate Working Group and streamlining the Exports program to ensure expeditious issuance requested documents. Mr. Obas has a BS in Medical Technology from Andrews University.

Swati Patwardhan, MS, RAC

Senior Regulatory Project Manager
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)
ODE II | OND | CDER | FDA

Swati Patwardhan joined FDA in 2008 as a Regulatory Project Manager in the Office of New Drug Quality and later in the Division of Anesthesia, Analgesia, and Addiction Products, in the Office of New Drugs. Prior to joining FDA, Ms. Patwardhan worked at a contract research organization, Covance for 5 years. Ms. Patwardhan received a Master of Science Degree in Biotechnology with Regulatory Affairs from Johns Hopkins University and a Bachelor of Science Degree in Biology from George Mason University.

Kimberly Piermatteo, BS, MHA

Commander, United States Public Health Service
Consumer Safety Officer

Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
CDRH | FDA

Kimberly Piermatteo is a Commissioned officer in the U.S. Public Health Service and currently serves as a Consumer Safety Officer in the Center for Devices and Radiological Health's Office of Communication and Education, Division of Industry and Consumer Education, Premarket Programs Branch. She has been with the FDA in various capacities since 2006 spanning premarket review and postmarket adverse event and compliance work. Commander Piermatteo received her Bachelor of Science degree in Engineering Science and Minors in Bioengineering and Mathematics from the Pennsylvania State University and her Master of Health Administration (MHA) from the University of Maryland.

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.

Maura Rooney, MS

Supervisory Consumer Safety Officer
Office of Medical Device and Radiological Health Operations
Division 1 | Office of Regulatory Affairs
CDRH | FDA

Maura Rooney has worked for FDA on medical device inspections for the past 10 years. She currently supervises a team of investigators in New York and New England who conduct domestic and international Medical Device and Radiological Health inspections. Prior to FDA, she worked as a product development engineer in the medical device industry. She has an MS in Mechanical Engineering from Worcester Polytechnic Institute and is an ASQ Certified Manager of Quality and Organizational Excellence.

Balajee Shanmugam, PhD

Branch Chief

Division of New Drug Products (DNDP)
Office of New Drug Products(ONDP)
Office of Pharmaceutical Quality (OPQ | CDER | FDA

Virginia M.W. Sheikh, MD, MHS

Medical Officer

Orange Book Staff
Division of Antiviral Products (DAVP)
OAP | OND | CDER | FDA

Dr. Virginia Sheikh is a medical officer in the Division of Antiviral Products (DAVP) at the FDA's Center for Drug Evaluation (CDER). Since joining the FDA in 2016, she has reviewed numerous antiviral products, including products brought forward by small businesses. Prior to joining the FDA, Dr. Sheikh performed clinical research in the HIV Pathogenesis Section at the National Institutes of Allergy and Infectious Diseases (NIAID) where she focused on the HIV/AIDS and idiopathic CD4 lymphocytopenia (ICL). She served as a member of the NIAID Institutional Review Board from 2013 to 2015. She trained in internal medicine at Columbia Presbyterian Hospital (2008) and in infectious diseases at the National Institutes of Allergy and Infectious Diseases (NIAID, 2011).

Brenda Stodart, PharmD, BCGP

Captain, United States Public Health Service

Program Director, CDER SBIA

SBIA | DDI | OCOMM | CDER |FDA

CAPT Brenda Stodart is currently the Program Director for the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA). 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 9 years. CAPT Stodart received her BS in Pharmacy from Howard University and her PharmD from the University of Arkansas Medical Sciences. CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

Joseph Tartal, BS

Deputy Director

Division of Industry and Consumer Education
Office of Communication and Education
CDRH | FDA

Joseph Tartal is the Deputy Director (Acting) of the Division of Industry and Consumer Education, in CDRH's Office of Communication and Education. 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 an FDA Instructor for the Association for the Advancement of Medical Instrumentation (AAMI). Prior to his 13-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 25 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.

Douglas Throckmorton, MD

Deputy Director for Regulatory Programs
Office of the Center Director
CDER | FDA

As Deputy Director for Regulatory Programs, Dr. Throckmorton shares the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.

Eva Temkin, JD

Acting Director
Policy Staff
Office of Therapeutic Biologics and Biosimilars (OTBB)
OND | CDER | FDA

Eva Temkin is the Acting Director for Policy in CDER's Office of Therapeutics and Biologics. She has been at FDA since 2013, and joined CDER after several years in FDA's Office of the Chief Counsel, where she was counsel to CDER on complex issues relevant to drug development and approval. Previously, Eva was a litigator at the law firms of Cravath, Swaine & Moore LLP and Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP.

Ann Marie Trentacosti, MD

Medical Lead
Labeling Development Team (LDT)
OND | CDER | FDA

Ann Marie Trentacosti is the Medical Lead for the Labeling Development Team (LDT) [Office of New Drugs (OND) Policy staff] in the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). As the LDT medical lead, Dr. Trentacosti participates in CDER labeling policy initiatives to promote consistency in and improve labeling practices, assists in the development and review of the prescribing information, provides oversight of labeling quality, develops labeling resources, and provides labeling review training.

Tonya A. Wilbon, BS

Chief
Postmarket and Consumer Branch
Division of Industry and Consumer Education
Office of Communication and Education
CDRH | FDA

Tonya A. Wilbon is the Branch Chief for the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education. 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 initially began with the FDA as a Microbiology Scientific Reviewer for CDRH's Office of In Vitro Diagnostics and Radiological Health (OIR) 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)..