

SPEAKER BIOGRAPHIES

(alphabetical order)



Mike Billig

Co-founder & CEO, Experien Group

Mike co-founded Experien Group in 2003 with his wife and business partner Darlene Crockett-Billig as a full-service consulting firm for the medical device industry. As CEO, Mike provides strategic regulatory guidance to the firm's clientele, frequently representing companies in FDA interface, notified body negotiations, board of directors' meetings, due diligence activities and more. Mike's entire professional career has been involved with regulatory affairs, quality systems, clinical research and general management for medical device companies. He entered the industry in 1973 at Medtronic and went on to work for a number of other successful companies, including Guidant, Oximetrix, Abbott and Syntex. Mike held executive-level positions for over 20 years at early stage start-up companies, including Converge Medical, Systems, CardioThoracic Systems, Cardiometrics, and Timi3 Systems where he was President and CEO. Mike has secured U.S and international regulatory approval for hundreds of medical devices. He has been involved with a variety of product areas, including sterile disposables, electronic instruments, capital equipment and wireless health. Mike has been instrumental with multiple successful IPOs, as well as substantial fundraising and corporate acquisitions. Mike earned his B.S. degree in Microbiology from the University of Minnesota.



Sean Boyd

Deputy Director for Regulatory Affairs, Office of Compliance, FDA

CAPT Sean M. Boyd serves as the Deputy Director for Regulatory Affairs in the Office of Compliance at FDA's Center for Devices and Radiological Health (CDRH). In this capacity he is responsible for managing the Center's quality initiatives, as well as regulatory compliance and enforcement programs for the medical device industry. Over the course of his career, CAPT Boyd's experience includes that of a regulatory researcher and engineering analyst, compliance reviewer, and manager of several organizations within FDA. He has been responsible for all aspects of medical device premarket, postmarket and compliance activities and, prior to joining the Office of Compliance in 2015, led and transformed many aspects of CDRH's electronic product radiation control program. He is an expert in FDA's requirements for a variety of consumer, commercial and industrial electronic products, as well as radiation-emitting medical devices. He received his undergraduate degree in Biomedical Engineering from Boston University and his Masters in Public Health from the Uniformed Services University of the Health Sciences. CAPT Boyd is an active duty commissioned officer in the United States Public Health Service (USPHS). He is also the Team Commander for one of two Washington DC-based medical response teams (PHS-1 Rapid Deployment Force); and has deployed in response to several disasters and crises, both domestically and abroad. Most recently, this includes response to Hurricanes Irma and Maria, where officers provided medical care to individuals displaced from the Florida Keys and U.S. Virgin Islands, and Puerto Rico. His experience also includes serving as Executive Officer of the Monrovia Medical Unit (an Ebola Treatment Unit) in Liberia, Africa; where the USPHS Commissioned Corps provided care to healthcare workers infected with Ebola Virus Disease.



Craig Coombs
President & CEO, Coombs Medical Device Consulting, Inc.

Craig Coombs has been the President of Coombs Medical Device Consulting (CMDC) since 2000. His company specializes in hands-on, innovative US, European and Asian regulatory strategies for start-ups and companies that need to change their strategies. CMDC is highly experienced in organizing effective FDA/NB meetings and all types of regulatory submissions (510(k), PMA, deNovo, Design Dossier, Medical Device License, etc.). CMDC skills include cost-effective First-In-Human (& VC milestone) clinical trial design, management and analysis. During his 26 years of medical device regulatory work, he has been instrumental for the early regulatory success of dozens of start-ups, and has been a Vice President of Medtronic in the areas of Regulatory Affairs, Quality Assurance and Clinical Studies. Mr. Coombs received his BS (Biology) from Stanford University. Mr. Coombs is adjunct faculty for the University of California (Santa Cruz) in Medical Device Submissions.



Sergio de del Castillo
De Novo Program Lead, Office of Device Evaluation, CDRH, FDA

Sergio M. de del Castillo serves as the De Novo Program Lead for the Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health (CDRH). In this role, he works with ODE management in the development of policy and procedures for the Office's rapidly evolving De Novo Program. Since his arrival at FDA over 16 years ago, Mr. de del Castillo has served as a scientific reviewer in the Orthopedic Devices Branch and Orthopedic Spine Devices Branch in the Office of Device Evaluation (ODE). From 2012-2015, he served as Regulatory Advisor to the Director of ODE, working with the ODE review divisions in the formulation of new regulations, guidance documents, policies, and procedures, as well as providing counsel to external stakeholders for various device regulatory programs (510(k), IDE, PMA, De Novo, etc.). Mr. de del Castillo received a Bachelor of Science degree in Biomedical Engineering from Johns Hopkins University.



Mark Deem
Managing Partner, The Foundry, LLC

Mr. Deem joined The Foundry in 1998. In addition to spearheading the research and invention process on new clinical opportunities, Mr. Deem leads the early stage effort in The Foundry's new companies until the company's CEO and Senior Staff is hired. Prior to joining The Foundry, Mr. Deem served in a founding role as consulting Director of Research and Development for Ventrica, Inc. Previously, Mr. Deem was a senior member of the Research & Development team at Medtronic Micro Interventional Systems. Mr. Deem joined MIS as one of the initial members of the company's engineering team and remained there through the acquisition by Medtronic.

Previously, Mr. Deem held engineering positions with Devices for Vascular Engineering, Cordis Corporation and the USCI Division of C.R. Bard.

Mr. Deem has spent over twenty years in the design, testing and manufacture of medical devices. His is a co-inventor on over 150 issued and pending U.S. patents. Mr. Deem earned his B.S. degree in biomedical engineering from Boston University.

Mr. Deem serves as a Director for Cabochon Aesthetics, Coteria, Holaira, Twelve, and as Chairman of Miramar Labs.



Abiy Desta
Ombudsman, CDRH, FDA

Abiy Desta joined CDRH's radiation biology branch in 1995 to conduct researcher looking at biological effects associated with exposure to low frequency electromagnetic fields. In 2008 Abiy joined the Office of the Center Director in CDRH where he helped coordinate the CDRH's response to complex and crosscutting scientific issues including use of BPA in medical devices. In 2010 Abiy joined the Office of Device Evaluation where he helped develop a number of crosscutting scientific policies including how cybersecurity risks should be addressed in premarket submissions and on the use of color additives in medical devices. In 2014 Abiy was appointed to his current position as Ombudsman for CDRH.



Rachael Fleurence, PhD
Executive Director, NESTcc, MDIC

Rachael L. Fleurence, PhD is the inaugural Executive Director of the newly formed National Evaluation System for health Technology (NEST) Coordinating Center. Under the umbrella of a public-private partnership, NESTcc's mission is to establish clear pathways within the medical device ecosystem to support the timely, reliable, and cost-effective development of evidence using Real-World Data sources for key stakeholders, including the medical device industry, regulators, payers, patients, clinicians, and health systems. Dr. Fleurence joins NEST from the Patient-Centered Outcomes Research Institute (PCORI) where she was the Program Director for PCORI's initiative to build the National Patient-Centered Clinical Research Network, or PCORnet, since 2012. PCORnet has been a transformational effort to engage patients and leverage electronic health data to improve the speed and efficiency of clinical research in the United-States. A 350 million dollar investment involving 130 health institutions across the country, 20 patient powered research networks and covering 110 Million patients, PCORnet launched as an independent foundation in March 2017. Dr. Fleurence was also the inaugural director for the PCORI Methods Program in 2012, working closely with the PCORI Methodology Committee on this effort in its initial years. Dr. Fleurence has served on a number of Boards and Steering Committees, including most recently the National Medical Device Evaluation System Planning (NEST) Planning Board, the Medical Device Innovation Consortium (MDIC) Board and the SMART IRB Steering Committee, an effort to streamline IRB reviews across academic research institutions. She chaired the PCORnet Executive Committee from 2015-2017, and served as the vice-chair of the PCORnet Council. A health economist and health services researcher by training, Dr. Fleurence received a BA from Cambridge University (United-Kingdom), a MA in business management from ESSEC-Paris (France), and a MSc and PhD in health economics from the University of York (United-Kingdom).



Nada Hanafi
Chief Strategy Officer, Experien Group

Nada joined Experien Group in 2017 after working 12 years at FDA's Center for Devices and Radiological Health (CDRH). Since 2010, she had been a CDRH Senior Science Health Advisor, serving as an expert consultant and senior advisor in the Center Director's office. Nada combines her deep institutional knowledge with innovative approaches to help companies successfully communicate product information to FDA throughout the total product life cycle. Leveraging her years of reviewer experience and broad FDA exposure, she develops actionable premarket strategies to guide programs through successful submission. She also orchestrates compliance activity. While at FDA, Nada led postmarket investigations for ob-gyn devices, wrinkle fillers, tanning devices, breast implants, negative pressure wound therapy (NPWT) devices and metal-on-metal hip implants and she applies this knowledge to help companies effectively manage postmarket requirements.



Elizabeth Hillebrenner

Associate Director for Programs and Performance, Office of In Vitro Diagnostics & Radiological Health, CDRH, FDA

Elizabeth Hillebrenner is Associate Director for Programs and Performance in the Office of In Vitro Diagnostics and Radiological Health (OIR) at FDA's Center for Devices and Radiological Health (CDRH). She provides leadership across premarket programs as well as in the development of in vitro diagnostic regulatory policy.

Elizabeth joined CDRH in 2002 as a reviewer of interventional cardiology devices, focusing primarily on coronary drug-eluting stents. In 2010, she shifted focus to policy work, first on reauthorization of the Medical Device User Fee program, then as Special Assistant to the Associate Commissioner for Compliance Policy, and ultimately as an Associate Director in OIR, where she has been since 2012.

Elizabeth received undergraduate and masters degrees in biomedical engineering from Tulane University.



Mir Imran

CEO & Founder, InCube Labs

Mir Imran founded InCube Labs to focus on his passion: creating medical solutions that change the standard of care in critical healthcare markets. After attending medical school, Mir began his career as a healthcare entrepreneur in the late 1970's and has founded numerous game-changing companies since those early days. Over the decades, he has become one of the leading inventors and entrepreneurs in the field. Mir now holds more than 200 issued patents and is perhaps most well-known for his pioneering contributions to the first FDA-approved Automatic Implantable Cardioverter Defibrillator. As an entrepreneur, Mir has founded more than 20 life sciences companies; 15 of his companies have seen "liquidity events" (IPO/Acquisition). Mir's expertise spans a wide range of clinical areas from interventional cardiology to chronic pain, obesity and CNS disorders. Mir actively collaborates with the nation's top universities on research and development including Stanford, Rutgers, Johns Hopkins, UTSW, etc. Mir also founded InCube Ventures, a life sciences venture fund, where he has led investments in a range of promising ventures. Mir sits on Boards of several life sciences companies, He holds an M.S. in bioengineering and B.S. in electrical engineering from Rutgers. He also attended CMDNJ/Rutgers Medical School.



Soma Kalb, PhD

Director, IDE Program, Clinical Trials Program, Office of Device Evaluation, CDRH, FDA

Dr. Soma Kalb is the Director of the Investigational Device Exemption (IDE) Program in the Office of Device Evaluation's (ODE) Clinical Trials Program in the Center for Devices and Radiological Health (CDRH), a position she has held since 2013. As part of the Clinical Trials Program, she oversees the operations of the IDE and Q-submissions programs in ODE and engages in analysis, development and implementation of regulatory policies for medical device clinical trials.

Dr. Kalb started her career at FDA in 2005, sharing her time between the Office of Science and Engineering Laboratories (OSEL) and the Office of Surveillance and Biometrics (OSB). In OSEL, she conducted research to support CDRH's regulatory mission in the area of cardiac electrophysiology. In OSB, she served as an analyst in the Division of Postmarket Surveillance in the area of cardiac rhythm devices, such as implantable defibrillators. In 2007, she transitioned to ODE, where she served as a premarket reviewer in the Division of Cardiovascular Devices, leading reviews in several program areas (PMAs, IDEs, 510(k)s, and Pre-submissions) for implantable cardiac electrophysiology devices until moving into her current role. Dr. Kalb received a Bachelor of Science degree in Electrical Engineering at 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.



Amanda Klingler
Partner, FDA & Life Sciences, King & Spalding, LLP

Amanda Klingler is a partner in King & Spalding's Washington, D.C., office and is a member of the firm's FDA & Life Sciences Practice Group. Since joining the firm in 2008, Ms. Klingler has assisted pharmaceutical, medical device and pharmacy compounding clients in a wide range of FDA regulatory matters, civil litigation, internal investigations, and compliance counseling. She has counseled clients on premarket submissions, adverse event reporting, quality system and manufacturing practices for drugs and devices, factory inspections, recalls, product labeling, and advertising and promotion issues. Ms. Klingler also has assisted in the negotiation and management of several consent decrees of injunction for pharmaceutical, medical device, food companies, and compounding pharmacies. Ms. Klingler also has experience in handling FDA issues in products liability litigation, including developing supporting evidence, preparing briefing, and preparing fact and expert witnesses on FDA issues.



Mark B. Leahey
President and CEO, Medical Device Manufacturers Association

Mark Leahey is the President & CEO for the Medical Device Manufacturers Association (MDMA), a national trade association in Washington, DC that represents research-driven medical technology companies. Mr. Leahey's responsibilities include advocating on behalf of the entrepreneurial sector of the medical device industry to Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other federal and state agencies. He has lobbied for a more reasonable user fee for smaller companies, worked to open access to the hospital marketplace by challenging the exclusionary and anti-competitive nature of certain large group purchasing organizations (GPOs), as well as ensure that medical device technologies are reimbursed adequately. Mr. Leahey currently sits on the Medical Devices Committee for the Food and Drug Law Institute (FDLI) and the Editorial Advisory Board of Medical Product Outsourcing. He is a member of the Massachusetts Bar and a graduate of Georgetown University, the Georgetown Law Center and Georgetown's McDonough School of Business.



Anna Libman
Director, Regulatory Affairs, Experien Group

Anna joined Experien Group in 2010 and has developed a specific focus in Digital Health. She primarily supports companies with powered technologies, mobile platform enabled devices and Software as a Medical Device (SaMD). Product areas with notable experience include surgical robotics, wearable devices, Artificial Intelligence/Machine Learning based applications, mobile app operated medical devices, radiation therapy, hospital data aggregation software, and diagnostic devices. Anna works with Digital Health companies to scope technology features and use cases that are not regulated by FDA as well as develop a step wise approach from a non-regulated technology to regulated as a medical device.



William Maisel, MD, MPH
Director, Office of Compliance (Acting), Director, Office of Device Evaluation (Acting), Chief Scientist, CDRH, FDA

William H. Maisel, MD, MPH is Chief Scientist and Deputy Center Director for Science 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 biomedical science 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.



Joshua Nipper
Chief of Premarket Approval Staff, Office of Device Evaluation, CDRH, FDA

Josh joined FDA in the Office of Device Evaluation (ODE) in 2002 in the Gastroenterology and Renal Devices Branch, where he primarily reviewed hemodialysis, obesity, and endoscopic devices. Josh moved to the Division of Radiological Health in OIR in 2010, where he reviewed ultrasound devices, medical imaging software, and other medical imaging devices. Beginning in 2013, he took on the role as branch chief of the General Surgery Devices Branch 2 in the Division of Surgical Devices, which focused on laparoscopic, electrosurgical, ablative energy, and robotic assisted surgical devices. Josh started as the Director of the PMA staff in January of 2016. Josh received his Bachelor's degree in Biomedical Engineering in 2000 from Vanderbilt University and his Master's degree from the University of Florida in 2002.



Bakul Patel
Associate Director for Digital Health, Office of Center Director, CDRH, FDA

BAKUL PATEL is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software. Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort. Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.



Yarmela Pavlovic
Partner, Hogan Lovells

As a partner with Hogan Lovells' FDA Medical Device group, Yarmela Pavlovic focuses her practice on the U.S. Food and Drug Administration's premarket regulation of medical devices. She works with medical device manufacturers to develop regulatory strategies for obtaining FDA marketing approval for their devices. Yarmela brings extensive experience in product development and product submissions (510(k)s, IDEs, and PMAs), as well as a variety of other device-related regulatory issues. Yarmela has particular experience in the area of FDA regulation of digital and mobile health technology, as well as medical software and applications. From standalone apps to complex systems, Yarmela assists clients in assessing FDA requirements and developing premarket strategies where necessary. Yarmela also regularly counsels manufacturers of In Vitro Diagnostic (IVD) tests. Her knowledge of FDA's premarket requirements assists companies in developing efficient regulatory strategies and successfully navigating the pathway to market. Yarmela regularly counsels clients regarding strategic plans that not only comply with government regulations, but also achieve their business objectives. She has authored a number of articles and been an invited speaker on topics related to mobile health, Health IT, and medical device premarket pathways.



Heather Rosecrans
Vice President of Regulatory Affairs, MDMA

Heather Rosecrans brings more than 30 years of public health and medical device experience to MDMA. Rosecrans continues her commitment to public health at MDMA where she provides strategic consulting services and works with MDMA members to bring innovative devices to patients. Prior to joining MDMA, Rosecrans served as Director of the 510(k) Pre-Market Notification Staff at the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH). In this role, Rosecrans was responsible for implementing administrative and regulatory policy for the 510(k) Program, the 513(g) Program, Classification and Reclassification, de novo petitions and other premarket regulatory requirements. Rosecrans started her FDA career as a biologist in the agency's Bureau of Medical Devices - prior to the formation of CDRH. In 1980, Rosecrans joined the newly organized CDRH Premarket Application (PMA) Staff. For the next seven years, she coordinated the administrative, scientific and regulatory review of PMAs, product development protocols and associated submissions. In 1987, Rosecrans joined the 510(k) Section of CDRH's Program Operations Staff (POS). In this role, Rosecrans served as a Consumer Safety Officer and was a key contact for CDRH and FDA on 510(k) matters. Rosecrans held this position until 1992, at which time she became Director of the 510(k) Staff. Rosecrans' accomplishments include drafting guidance documents and regulations regarding the 510(k) program, training staff, and assisting in the implementation of the Medical Device User Fee Modernization Act (MDUFMA) and Food and Drug Administration Modernization Act (FDAMA). Rosecrans' extensive experience at CDRH, and specifically the 510(k) office, enabled her to become one of the nation's leading experts on the program. Rosecrans' tenure also allowed her to play a pivotal role in the program's development and reform. Since the program's inception in 1976, more than 120,000 products have been cleared via the 510(k) program. Rosecrans has represented and spoken on behalf of CDRH in multiple forums, including national conferences, FDA advisory committee meetings, and international symposiums. Her published work includes numerous guidance and regulatory documents. She has also worked collaboratively with CMS and other regulatory agencies. Rosecrans holds a Bachelor of Science in Biology from Pfeiffer College in Misenhelmer, NC.



Daniel Schultz

Principal, Medical Devices and Combination Products, Greenleaf Health LLC

Dr. Daniel Schultz joined Greenleaf Health following a distinguished 35-year career devoted to supporting and advancing Americans' public health as a physician, teacher, Food and Drug Administration (FDA) official and member of the U.S. Public Health Service (USPHS). He has been recognized many times for his contributions and dedication to public health. Dan continues his commitment to public health at Greenleaf, where as Senior Vice President for Medical Devices and Combination Products he provides strategic consulting services and works with Greenleaf clients to bring innovative devices to patients. As Director of the Center for Devices and Radiological Health (CDRH) at FDA from 2004 to 2009, Dan was responsible for seven FDA offices and more than 1,000 agency employees. He led the development, implementation and evaluation of regulatory policies concerning medical devices and radiation-emitting products. He also established national goals and policies to ensure that FDA and U.S. Department of Health and Human Services (HHS) objectives were met. Dan began his 15-year FDA career in 1994 as a Medical Officer in the General Surgery Devices branch of the CDRH's Office of Device Evaluation, advancing in 1995 to the position of Chief Medical Officer in the Office of Device Evaluation in the division of Reproductive, Abdominal, ENT, and Radiological Devices. He served as division Director from 1998 to 2001. Dan became Deputy Director for Clinical and Review Policy in the Office of Device Evaluation in 2001 and Director of the Office of Device Evaluation the following year. Named Director of CDRH in 2004, he remained in that role until stepping down this year. Prior to joining FDA, Dan served as a member of the U.S. Public Health Service (USPHS). During postings at Indian Health Service hospitals in Arizona and New Mexico, he provided medical care for people living in the Navajo Nation and Indian Pueblos. Dan received multiple awards for his service, including the Public Health Service Outstanding Service Medal. In addition to his role at Greenleaf, he shares his medical knowledge and experience as Assistant Professor of Surgery at the Uniformed Services University of the Health Sciences and as a member of the Surgical Staff at the National Naval Medical Center, both located in Bethesda, MD. Dan is a fellow of the American College of Surgeons, a member of the Commissioned Officers Association (COA). He has written and spoken all over the world about regulatory, medical device and public health issues. A New York City native, Dan is a graduate of the City College of New York. He received his medical degree from the University of Pittsburgh and is Board-certified in Surgery and Family Practice.

Peter Shearstone

Vice President, RA/QA/Clinical and Medical Affairs, Sysmex America, Inc.

Peter is a twenty-four year quality professional with exceptional global leadership and medical device industry experience. Prior to joining Sysmex America, Shearstone served as the Senior Director of Regulatory Communication for Hospira, Inc. Before then, Shearstone was Division Vice President of Global Quality Assurance at Abbott Diagnostics. He also served in senior level positions with Power medical Interventions and Dade Behring (known now as Siemens Healthcare Diagnostics) as Senior Vice President of Regulatory Affairs and Quality Assurance and Vice President of Global Quality Assurance respectively. Shearstone has spent 22 of his 24 years in the diagnostics industry.



Marjorie Shulman

Director, Premarket Notification (510(k)) Program, Program Operations Staff, Office of Devices, CDRH, FDA

Marjorie Shulman is the Director for the Premarket Notification (510(k)) Program in the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Ms. Shulman has been with CDRH since 1984. Before serving on the 510(k) Staff she was on the Premarket Approval Staff. Ms. Shulman is also the Reclassification/Classification Coordinator for CDRH. Some of her accomplishments include drafting guidance documents and regulations regarding the 510(k) program, training staff, and assisting in the implementation of the Medical Device User Fee Modernization Act (MDUFMA), FDA Modernization Act

(FDAMA) and the Food and Drug Administration Safety and Innovation Act (FDASIA). Ms. Shulman has been on numerous policy setting groups within the FDA. Most recently she has been very active with the 510(k) Working Group whose mission it is to evaluate the 510(k) program and explore actions CDRH could take to enhance 510(k) decision making, 21st Century Cures and reauthorization of MDUFMA. Ms. Shulman received her undergraduate degree from the University of Maryland, University College, and received her MBA from Hood College in May 1997.



Elaine Tseng

Partner, FDA & Life Sciences Group, King & Spalding, LLP

Elaine Tseng is a partner with King & Spalding's FDA & Life Sciences Practice Group. After prior practice with the group as an associate and partner-elect, Ms. Tseng rejoined the group following service as Regulatory Counsel at the Food and Drug Administration, where she received the Department of Health and Human Services Secretary's Award for Distinguished Service and other FDA honors. In her practice, Ms. Tseng advises medical device, pharmaceutical, and biotechnology companies on a variety of FDA approval, compliance, and enforcement matters. She received her law degree from Harvard Law School and her undergraduate degrees from Cornell University.



John Weiner

Associate Director for Policy, Office of Combination Products

John Barlow Weiner is the Associate Director for Policy in the Food and Drug Administration's Office of Combination Products, which is tasked with the classification and assignment for regulation of therapeutic products (drugs, devices, biological products, and combination products), and with ensuring the sound and consistent regulation of combination products. Prior to joining OCP, Mr. Weiner was an Associate Chief Counsel in FDA's Office of Chief Counsel, advising the agency on various issues including regulation of drugs and cross-cutting topics including the regulation of products that use nanotechnology. Before coming to FDA, Mr. Weiner was in private practice in the areas of food and drug, environmental, and related aspects of public international and trade law. He has published and lectured on topics in all three areas. Mr. Weiner received a BA from Princeton University and a JD with honors from the Columbia University School of Law.