SPEAKER BIOGRAPHIES (in alphabetical order)

Patrick Axtell, Ph.D.
Senior Tools & Templates Engineer, Office of Regulatory Products, CDRH
Patrick Axtell, Ph.D., is a biomedical engineer and software developer at the FDA. He graduated from The College of William and Mary with a bachelor’s degree in Biology, and he graduated from The University of Illinois in Chicago in 2007 with a doctorate’s degree in Biomedical Engineering with a specialization in Neural Engineering. Patrick was a reviewer for restorative and neurological devices for 6 years and is now the Senior Tools and Templates Engineer for OPEQ. While at the FDA, Patrick has developed several templates and tools intended to aid reviewers in the evaluation and processing of several types of medical devices. He has also developed templates intended for use in constructing 510(k)s and other submission types.

Michael Billig
Co-Founder & CEO, Experien Group, LLC
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.

Kit Cariquitan
Chief Regulatory Officer, Experien Group, LLC
Kit is a highly regarded medical device executive possessing 20 years of industry experience with both start-ups and large public corporations. His professional background includes senior management responsibility for regulatory affairs and clinical research as well as supporting roles in sales and marketing. Kit has successfully led wide-ranging device programs through development and
into global commercialization. He has been personally responsible for directing successful U.S. and OUS clinical trials and he has secured numerous device approvals/clearances.

At Experien Group, Kit is responsible for translating client companies’ strategic visions for their products into executable and commercially viable regulatory plans. He manages clients’ regulatory and clinical requirements to ensure alignment with Quality Management System requirements and operational efficiency. Kit is responsible for formal and informal communications with FDA, Notified Bodies and other regulatory agencies as well as all aspects of regulatory submissions.

Kit returned to Experien Group from SentreHEART where he was Vice President of Regulatory and Clinical Affairs. Prior to that, he was Sr. Director of Regulatory Affairs and Global Management and Board member at Acclarent, a Johnson & Johnson company. Kit previously held several senior positions at Experien Group, including Vice President of Regulatory Affairs. Kit’s earlier career involved roles at several successful medical device companies, including Cardiometrics, CardioThoracic Systems, Converge Medical, Guidant, and Boston Scientific. He was Boston Scientific’s Global Principal Product Manager for neurovascular access products. Kit has particular expertise in cardiovascular and neurovascular medical devices. Kit received a BS degree in Biological Sciences from Pepperdine University in Malibu, California.

Craig Coombs
President, 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 startups, 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 M. de del Castillo, RAC**  
RAC, De Novo Program Lead, Premarket Notification & Classification Team, DRP1, Office of Product Evaluation & Quality, CDRH

Sergio M. de del Castillo serves as the De Novo Program Lead for the 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 management in the development of new policies. Sergio has served as a scientific reviewer of orthopedic devices, and as a Regulatory Advisor, working with the review divisions in the formulation of new regulations, guidance documents, policies, and procedures. Sergio received a Bachelor of Science degree in Biomedical Engineering from Johns Hopkins University.

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**Lili Duan**  
Tools & Templates Engineer, Office of Regulatory Products, CDRH

Dr. Lili Duan is a Policy Analyst in the Office of Regulatory Programs (ORP) at FDA’s Center for Devices and Radiological Health (CDRH). Dr. Duan started her career at FDA as a Scientific Reviewer in 2012. She is currently responsible for developing and implementing IVD device related 510(k) templates for both internal reviewers and external applicants. Prior to joining FDA, Dr. Duan worked in IVD industry for more than a decade and was a Diplomat of American Board of Clinical Chemistry (DABCC).

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**Owen Faris, Ph.D.**  
Principal Deputy Director, Office of Product Evaluation and Quality, CDRH

Dr. Owen Faris is the Principal Deputy Director of the Office of Product Evaluation and Quality (OPEQ) in the Center for Devices and Radiological Health at the FDA. Dr. Faris received his B.S. in Mechanical Engineering from Rice University, and his Ph.D. in Biomedical Engineering from Johns Hopkins University. Dr. Faris joined the FDA in 2003. Prior to his current role, Dr. Faris was the Director of the CDRH’s Office of Clinical Evidence and Analysis, an office within OPEQ. In his role as Principal Deputy of OPEQ, Dr. Faris oversees and guides CDRH’s decisions and actions related to pre and post-market activities across OPEQ’s seven Offices of Health Technology as well as the Office of Clinical Evidence and Analysis and the Office of Regulatory Programs.
Michael Gaba  
Shareholder/Practice Vice Chair, Polsinelli, LLP  
Michael Gaba provides strategic FDA regulatory, Medicare reimbursement, and public policy counsel to medical device and biotech companies. His primary goal is to bring companies to market and then help them remain there in the most efficient, effective manner possible.

Working as an extension of each company’s legal and business teams, Michael draws on a 20+ year history to navigate the FDA pre-market regulatory pathways, counsel companies on FDA post-market compliance matters, and resolve Medicare coverage, coding, and reimbursement disputes with the Centers for Medicare and Medicaid Services. By using his FDA and CMS experience during the product development phase, Michael is able to help maximize companies’ opportunities to be appropriately compensated in the proper treatment venues, whether it’s the physician’s office, the hospital outpatient department or home care.

Recognizing that there are times when federally-regulated life science companies would benefit from changes to public policy, Michael works with members of Congress and Executive Branch officials to help modify or create the necessary policies that not only redound to the benefit of life science companies, but also to the patients they serve.

Mark Gordon, MS, RAC, FRAPS,  
Senior Vice President and Global Head, Regulatory Affairs, Alcon  
Mark Gordon, MS, RAC, FRAPS, is the Senior Vice President and Global Head, Regulatory Affairs, for Alcon. He has close to 40 years of experience in the medical device industry, including Regulatory Affairs, Clinical Affairs, Quality Assurance, and Research and Development.

Mark has previously held the position of Vice President, Regulatory Affairs, Clinical Affairs, and/or Quality Assurance, at Abbott, Synthes/Johnson & Johnson, Boston Scientific, and Medtronic, as well as early-stage (Series A to Pre-IPO) organizations. In these roles, Mark has established a track record of successful leadership, transforming functional teams towards excellence, strengthening relationships with regulatory agencies, achieving timely global regulatory approvals, effectively managing preclinical and clinical investigations, and sustaining lean and compliant quality systems. In addition, he has led the worldwide regulatory efforts on the buy and sell side for M&A deals ranging from $100 million to more than $20 billion in value.

He is a long-standing member of the MDMA FDA Strategy Group, the AdvaMed FDA Strategy, Technology and Regulatory, and International Groups, and is a member of the Board of Directors of National Alliance for Eye and Vision Research (NAEVR/AEVR).

Mark has previously served as Chairman of the RAPS Board of Directors, Co-Chair of the AdvaMed Technology and Regulatory Group, industry representative for FDA MDUFA
negotiations and associated US Congressional reauthorizations, member of Global Harmonization Task Force Study Group 5 (Clinical Studies), and member of the California Healthcare Institute. He is a RAPS Regulatory Affairs Fellow accomplishing US and EU RAC, and is a Senior Member of ASQ. Mark received a Bachelor’s and Master’s degree in Bioengineering from the University of California, San Diego.

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.

Mir Imran  
Chairman and 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 a B.S. in electrical engineering from Rutgers. He also attended CMDNJ/Rutgers Medical School.
Amanda Klingler  
**Partner, King & Spalding**
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 Leahey  
**President & CEO, MDMA**
Mark Leahey is the President & CEO for the Medical Device Manufacturers Association (MDMA), a national trade association in Washington, DC that represents hundreds of 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 has been named one of the medical device industry's top lobbyists and sits on 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.
William Maisel, MD, MPH,  
Director, Office of Product Evaluation & Quality and CDRH Chief Medical Officer  
William H. Maisel, MD, MPH is Director of the Office of Product Evaluation and Quality and Chief Medical Officer 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.

Joshua Nipper  
Director, Office of Regulatory Programs I, Office of Product Evaluation & Quality, 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.
Kathryn M. O’Callaghan
Deputy Director, Office of Strategic Partnerships & Technology, CDRH, FDA

Kathryn (Katie) O’Callaghan has over 15 years of experience in medical device innovation and evaluation. She currently serves as a Deputy Division Director within FDA CDRH’s Office of Strategic Partnerships and Technology Innovation (OST). In that role, Katie oversees a broad program portfolio with teams supporting a variety of strategic partnerships and programs, including the Patient Engagement Advisory Committee (PEAC), the Medical Device Innovation Consortium (MDIC), the Medical Device Development Tools (MDDT) Program, the CDRH Network of Experts, and the Patient and Care-Giver Connection (P&CC). Previous roles at FDA include as a Senior Advisor in the Office of the Center Director, where she led and supported various strategic initiatives around Clinical Trials Innovation, Real World Evidence, and efforts to improve diversity and inclusion in medical product development. She began her FDA career in the Division of Cardiovascular Devices, leading multi-disciplinary teams in evaluating an array of life-saving and sustaining technologies, and conducting research and outreach projects working with industry, academia, professional associations, patient organizations, and across government agencies, to advance device innovation and reduce sex/gender disparities in cardiovascular device evaluation and care. Katie is a biomedical engineer by training and spent some time in MedTech industry as well as academic research prior to her time at FDA. She can be contacted at kathryn.ocallaghan@fda.hhs.gov.

Bakul Patel, MSEE, MBA
Director, Digital Health, CDRH

Bakul Patel is the Director of Digital Health Division, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.

This includes responsibilities in leading the development on policies for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.

Mr. Patel, in 2013, created the term “software as a medical device” (SaMD) and under his leadership the International Medical Device Regulators Forum (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD documents. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA.
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Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC).

Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program in collaboration with all stakeholders to reimagine a regulatory approach for Digital health that that aims for patients and providers to have timely access to safe and effective digital health products.

Prior to joining FDA, Mr. Patel held key leadership positions 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.

Cesar Perez, PhD, CQA, RAC
Director, DRP2: Division of Establishment Support, Office of Regulatory Programs, Office of Product Evaluation & Quality, CDRH, FDA

Dr. Cesar Perez is currently the Director for the Division of International Compliance Operations, Office of Compliance (OC), CDRH/FDA. He manages the day-to-day operations for the Division, which focuses on foreign device manufacturer and importer assessment; international audit program, compliance policy, and guidance development; and export operations and policy. From 2015-2018, he was the Branch Chief for the Surveillance and Enforcement Branch I, Division of Premarket Labeling and Compliance, OC/CDRH, responsible for enforcing premarket requirements, as well as labeling and promotion/advertising requirements for medical devices. He previously worked for more than 7 years as a Microbiologist/Consumer Safety Officer in different branches within the Office of Compliance, CDRH. He received his doctoral degree in Microbiology from New York University School of Medicine in 2008

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
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(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.

Jodi Scott  
Partner, Hogan Lovells

Jodi Scott developed and honed her practical, real-world sensibility and business acumen during the time she spent as an in-house FDA counsel with the world's largest medical device manufacturer. Today, she uses that background to solve the challenges that confront her clients in areas that include MDRs, regulatory due diligence, importing and exporting medical devices, advertising and promotion, preparing for and managing FDA inspections, and developing systems to mitigate the risks associated with the unapproved use of approved products (AKA off-label uses).

Jodi assists the medical device industry in navigating the complex requirements so as to maintain compliance with the U.S. Food and Drug Administration's (FDA) quality system (QSR) and other post-market regulatory rules. She spends much of her time developing and implementing strategies to manage FDA-initiated enforcement actions, such as FDA inspections that result in FDA Form 483s, untitled letters, Warning Letters, investigations, and consent degrees of permanent injunction. She has received ISO 13485 auditor certification and assists companies in preparing for managing and responding to ISO and MDSAP audits.

She also guides her clients through complex medical device recalls by helping them work through the difficult decisions of whether a recall is warranted and, if so, how to execute it in a way that best achieves a balance between patient and customer risk and the agency's interests, while also demonstrating the company's commitment to safety and its regulatory obligations. She also applies her regulatory knowledge in assisting clients with regulatory due diligence related to mergers and acquisitions and funding, such as private equity deals, initial public offerings, and other financial transactions.

Daniel Schultz, M.D  
Principal, Medical Devices & Combination Products, Greenleaf Health, Inc.

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).
Dan continues his commitment to public health at Greenleaf, where as Principal 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 in August of 2009.

During his FDA stint, Dan also used 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, Bethesda, MD.

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 Medal.

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, Global Quality Assurance & Regulatory Affairs, Thermo Fisher Scientific, Inc.*  
Peter Shearstone is Vice President of Global Quality Assurance and Regulatory Affairs for Thermo Fisher Scientific. He joined the company in July 2018. Headquartered in Waltham, Massachusetts, Thermo Fisher is the world leader in serving science; our mission is to enable our customers to make the world healthier, cleaner and safer.
Peter has led global regulatory and quality organizations in some of the most complex, demanding and technically advanced areas of the healthcare industry, including Ciba Corning, Dade Behring, Abbott Diagnostics, Hospira, and Sysmex. During his 30 years of healthcare experience, Peter has held executive positions in regulatory and quality assurance functions and has performed key roles in the technical support, sales, operations and research and development (R&D) functions.

He builds on an organization’s greatest strengths by incorporating leading edge best practices around the highest standards of compliance and quality. Over the course of his career, he has built quality-centric and customer-focused cultures, improved employee engagement and empowerment, implemented innovative compliance solutions, increased efficient processes and created organizational effectiveness programs. He has also improved infrastructure, production and quality system operations that resulted in better products, regulatory compliance, customer satisfaction and patient outcomes.

Peter is active in the advancement of the regulatory/quality science profession. He represents Thermo Fisher Scientific at number of healthcare industry groups, including the Medical Device Innovation Consortium (MDIC), the Regulatory Affairs Professional Society (RAPS), the American Association of Clinical Chemistry (AACC), the Clinical and Laboratory Standards Institute (CLSI) and the American Society for Quality (ASQ). In support of these organizations, he has served on industry-wide committees and shared his expertise as a speaker and panel member.

Peter began his career in biotechnology sales for a small startup in Boston in 1989. He holds a bachelor’s degree in biology from Salem State University in Salem, Massachusetts. A native of Taunton, Massachusetts, he currently resides in Lake Forest, Illinois.

Marjorie Shulman
Assistant Director 510(k), DeNovo, 513(g), Device Determinations & Custom Devices Lifecycle Team, Office of Product Evaluation & Quality, 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 Heath (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

Timothy Stenzel, MD, PhD
Office Director, Office of Health Technology 7, Office of Product Evaluation & Quality, CDRH, FDA

Tim joined the FDA in July 2018 and has an extensive background, spanning more than 20 years, in executive leadership, innovation, companion diagnostics, research and development, FDA regulations, and clinical laboratory operations. He received his M.D. and Ph.D., in Microbiology and Immunology, focusing on the Molecular Biology of DNA Replication, from Duke University after graduating with Honors in Chemistry from Grinnell College.

Following his residency at Duke University, Tim was recruited to create Duke’s Clinical Molecular Diagnostics Laboratory and served as the Director, Clinical Molecular Diagnostics and Medical Director, Cytogenetics. Tim also joined the faculty of the Duke University School of Medicine and served as an Assistant Professor of Pathology where his research focused on cancer and genetics, as well as directed the Clinical Cytogenetic and Molecular Diagnostics Laboratories and taught in the School of Medicine. While at Duke, his research laboratory was funded by the NIH/NCI and private agencies to study the molecular genetics and develop novel molecular diagnostics testing for the early detection of breast cancer and the diagnosis and treatment of brain tumors and by the CDC to perform research in the area of performance evaluation and quality assurance for genetic testing. Tim is board certified in Molecular Genetic Pathology and Anatomic and Clinical Pathology, and previously held board certification in Clinical Molecular Genetics.

In his last position, from 2014 to 2018, Tim served as Chief Operating Officer (COO) at Invivoscribe, focusing on Companion Diagnostics and Next Generation Sequencing/Massively Parallel Sequencing in Oncology. During his career, he has played important roles in the development and launch of more than 30 IVD products, as well as numerous unique LDT services, including the FDA approved companion diagnostic for Novartis’ drug Rydapt and the world’s first clinical microRNA assay (for pancreatic cancer detection). Other experience includes serving as Chief Scientific Officer and founder of the Molecular Diagnostics franchise at Quidel, Chief Medical Officer and Vice President of Research and Development at Asuragen, and Senior Director for Medical, Regulatory and Clinical Affairs at Abbott Molecular. Dr. Stenzel served as a Board Director at the ACMG Foundation for Genetic and Genomic Medicine from 2008 to 2013. He has served on the ACMG/CAP Biochemical and Molecular Genetics Resource Committee from 1996 to 2005, the AMP Finance Committee from 2012 to 2018, the AMP Strategic Planning Committee from 2007 to 2009, as the AMP Chair-Elect and Chair of the Solid Tumor Division from 2003 to 2004, the CAP Molecular Oncology Committee from 2013 to 2018, and as a Member of the CAP House of Delegates from 2011 to 2017.
As the OIR Director, Tim will advise Center leadership on all regulatory (premarket and postmarket) in vitro diagnostic, radiological medical device, and radiation-emitting product issues that have an impact on Center and Agency level decisions, policy development, nationwide program execution and short and long-range program goals and objectives as well as provide executive leadership and scientific direction to the OIR staff.

Michelle Tarver, M.D., Ph.D.
Director, Patient Science & Engagement, Office of Strategic Partnerships & Technology Innovation, CDRH, FDA
Michelle Tarver is the Director of the Patient Science and Engagement Program at the Center for Devices and Radiological Health (CDRH). The Patient Science and Engagement Program fosters innovative approaches to collecting, analyzing and integrating the patient perspective in the development, evaluation and surveillance of medical devices, including digital health technologies. Under her leadership, CDRH is making the integration of the patients’ perspectives throughout the total product lifecycle of medical devices part of its daily business. She also leads the CDRH Patient Engagement Advisory Committee efforts, an advisory panel comprised entirely of patients and caregivers providing their perspectives on general issues related to the regulation of medical devices. In addition to her experience in patient-focused efforts, Dr. Tarver has extensive experience in premarket and postmarket review of various medical devices, developing guidance documents and standards, and fostering external collaborations.

Dr. Tarver attended Spelman College in Atlanta, GA where she received a B.S. in Biochemistry. She completed the M.D./Ph.D. program at The Johns Hopkins University Bloomberg School of Public Health (Ph.D. in clinical epidemiology) and The Johns Hopkins University School of Medicine. Following her internal medicine internship, she completed a residency in ophthalmology with fellowship training in ocular inflammation (uveitis) both at the Wilmer Eye Institute (Johns Hopkins). As an epidemiologist and board-certified ophthalmologist, she has worked on longitudinal epidemiological studies, clinical trials, registries, developing patient-reported outcome measures as well as surveys to capture patient preferences with medical devices. Her research has resulted in numerous peer-reviewed publications and published book chapters. As a dedicated clinician, she continues to evaluate and treat ophthalmology patients at Solomon Eye Associates in Bowie, MD.
Elaine Tseng
Partner, King & Spalding

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.

Ms. Tseng has been invited to speak on topics of FDA regulation for groups including the American Conference Institute (ACI), the Advanced Medical Technology Association (AdvaMed), the Biotechnology Industry Organization (BIO), and the Center for Business Intelligence (CBI). She received her law degree from Harvard Law School and her undergraduate degrees from Cornell University.

John Weiner
Associate Director for Policy & Product Classification Officer, Office of Combination Products, CDRH

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.