Harmonizing Medical Device Regulation

Speaker Profiles

Susan Bain, DRSc is currently an Assistant Professor of Regulatory and Quality Sciences at USC and formerly a Professor of Practice and Program Director for Clinical, Regulatory and Quality at Keck Graduate Institute's (KGI) and Adjunct Professor of Practice and Concentration Coordinator for Clinical and Regulatory in KGI's School of Pharmacy. She is an accomplished quality and regulatory professional with experience in the medical device, pharmaceutical, and biotechnology industries. She has a diverse regulatory compliance background in a broad range of FDA-regulated industries. Her most recent corporate experience includes serving as a Vice President of Quality/Regulatory Assurance and Operations at a medical device company and has held various management positions in Quality Control/Assurance and Regulatory Affairs over the past 25 years with firms including Baxter Healthcare, Grifols, Medegen, Inc., Peregrine Corporation, and Watson Pharmaceuticals. Additionally, Susan also worked at the FDA as an Investigator, focusing on drugs and medical devices.

Susan received a Doctorate of Regulatory Science (DRSc), a Master of Science in Regulatory Science (MSc) from the University of Southern California (USC) and a Bachelor of Science in Biological Science from Cal Poly, Pomona. She holds a graduate certificate in Effective Supervision from Cal Poly Pomona and is a member of the Orange County Regulatory Association (OCRA), DIA, PDA and RAPS.

C Benson Kuo PhD, RAC, Patent Agent is the Director of the Regulatory Consulting Center and a faculty member in the Department of Regulatory and Quality Sciences at the School of Pharmacy. The Regulatory Consulting Center serves as a beacon of guidance to both academic researchers and members of the community, illuminating the intricate paths of regulatory compliance, submission prerequisites, and strategic roadmaps for innovative products.

Dr. Kuo's career spans two decades in the realm of regulatory affairs and underscores a deep engagement across the entire spectrum of medical product development and regulatory initiatives. His portfolio encompasses diverse product categories such as chemical drugs, microbiome, stem cell therapies, implanted muscle stimulators, AI/ML-enabled devices, as well as dietary

supplements and cosmetics. He been instrumental in overseeing quality management, audit processes, and the orchestration of clinical trials across numerous ventures.

Dr. Kuo's expertise extends beyond regulatory domains and extends to various facets of the field. His professional capabilities range across a spectrum of foundational research, bioinformatics, and patent prosecution. Dr Kuo's academic voyage includes postgraduate distinctions from USC, a PhD earned through UCR/UCLA Biomedical Sciences program and a postdoctoral tenure at Stanford University. Dr. Kuo holds certifications from both the US Patent and Trademark Office (USPTO) and the Regulatory Affairs Professional Society (RAPS). chiaoyun.kuo@usc.edu

Dr. You Kyoung Lee is currently working at Soonchunhyang University Bucheon Hospital as a clinical pathologist and a professor. She has over 30-year experience in the clinical laboratory, including a 15-year director position. Her main interests are Evidence-based Medicine (EBM) and Quality Medicine. In this aspect, she published articles and book chapters relating to a pragmatic evidence synthesis between quality and downstream effects in the laboratory or clinical practices.
She has extended her research field to medical devices since 2013. Currently, she is trying to develop the 'CLinical Unmet nEeds Based Intended Use Establishment Process for medical devices (tentatively CLUE-Intended Use)' to support a medical device development process in collaboration with multidisciplinary experts (medical engineering, medicine, and regulatory sciences). She carries her role as a director of the APEC Regulatory Training Center of Excellence for medical devices at Soonchunhyang University.

She now actively contributes as an expert for interdisciplinary collaboration between professional medical societies and engineering societies as a Board Member of the Korean Academy of Medical Sciences (KAMS) and the Member of Regulatory Innovation Committee under the Prime Minister's Office of Korea.

Dr. Lee's educational background; Graduated Soonchunhyang University College of Medicine (B.S.) in 1990; Doctor's License in Medicine, Republic of Korea in 1990; M.S. in Clinical Pathology, Soonchunhyang University in 1995; National Board Certification in Clinical Pathology, Republic of Korea in 1995; Ph.D. in Clinical Pathology, Soonchunhyang University in 2003.
Dr. Lee specializes in Evidence-based Laboratory Medicine, evidence based clinical implementation of medical devices and Medical Device Vigilance

Lawrence (Larry) E. Liberti, PhD, BPharm, RAC has worked in the fields of pharmaceutical regulatory affairs, communications, and clinical R&D for the past four decades. He began his career at Wyeth Laboratories working in product development, then as a regulatory writer in clinical R&D, and manager of safety surveillance in medical affairs. From 11 years he served as the Executive Director of CIRS (the Centre for Innovation in Regulatory Science) and then as Head of Regulatory Collaborations. He began his role as the Director of the DK Kim International Center for Regulatory Science in 2023. He has been actively involved in promulgating best practices in the regulatory aspects of medicines development, especially in the emerging markets. Dr Liberti received his doctorate in International Regulatory Policy through the WHO Collaborating Centre for Pharmaceutical Policy and Regulation based in the Utrecht Institute for Pharmaceutical Sciences, Utrecht University, the Netherlands, where his research centred on expedited regulatory pathways. He received both his Bachelor of Science in pharmacy and Master's degree in pharmacognosy from the Philadelphia College of Pharmacy and Science. He was awarded an honorary Doctor of Science degree by his alma mater. He attained the status of Regulatory Affairs Certified (RAC) with the Regulatory Affairs Professional Society and serves on its Board of Directors. He is a Fellow of the American Medical Writers Association and is a recipient of their Golden Apple award for excellence in teaching.

Gerald Loeb is Professor of Biomedical Engineering and Director of the Medical Device Development Facility at the University of Southern California. He received B.A. and M.D. degrees from Johns Hopkins University and surgical training at the University of Arizona. From 1973 to 1988, he was an intramural research scientist and Chief of the Section on Neurokinesiology in the Laboratory of Neural Control at the National Institutes of Health. He was Professor of Physiology and Director of the Biomedical Engineering Unit at Queen's University in Kingston, Canada, until 1999.
Dr. Loeb is an inventor on over 70 US patents, a Fellow of the National Academy of Inventors, and a consultant to the medical device and instrumentation industry. He served as Chief Scientist to Advanced Bionics Corp. and is a founding director of SynTouch Inc., designated a Technology Pioneer by the World Economic Forum. Dr. Loeb's research activities are in sensory-motor neurophysiology and implantable electronic devices. He has published over 400 articles, most available at http://mddf.usc.edu email: gloeb@usc.edu https://en.wikipedia.org/wiki/Gerald_E._Loeb

Dr. Darin S. Oppenheimer is Vice President of Regulatory Affairs, Medication Management Solutions, focusing on Medical Devices at BD. Darin joined BD with 20 years of experience in many facets of the Product Development Lifecycle, including regulatory submissions and due diligence. He has actively participated with industry trade organizations and on standards committees. His time as a research and development scientist focused on pharmaceuticals and medical device diagnostic applications for biomarker and drug discovery.

Darin's educational background includes an undergraduate degree in Molecular Biology from the University of Tampa, two Masters Degrees from Johns Hopkins University in Biotechnology and Regulatory Science, and a graduate Certificate in Biotechnology Enterprise also from JHU. Darin completed his Doctorate degree in Regulatory Science from the University of Southern California in 2016. Darin is also a 2017 Regulatory Affairs Professional Society Fellow.

Darin has contributed to more than two dozen journal articles in the areas of medical devices, drug discovery, and regulatory affairs. He's lectured at more than three dozen symposia and participated in panel discussions and poster presentations at industry conferences.

Darin serves on the Editorial Board of the Regulatory Affairs Professionals Society, as well as the Editorial Board of the Institute of Validation Technology.

Dr. Frances Richmond is currently Emerita Professor of Regulatory and Quality Science at the University of Southern California. She was previously the Director of the D.K. Kim International Center for Regulatory Science and founding Chair of the Department of Regulatory and Quality Sciences at USC.

Dr. Richmond was educated as a neurophysiologist (BNSc, MSc, PhD) at Queen's University, Kingston, Canada, then completed post-doctoral studies at the Université de Montréal and the U. S. National Institutes of Health. She returned to the faculty of Queen's University, where she served during her tenure as a professor, Associate Dean of Life Sciences (1989-1992) and Director of the MRC Center for Sensory-Motor Research (1992-2000). Research there focused on the neurological basis of normal and abnormal motor control. She also served as a policy advisor to Industry Canada and graduated from Canada's

National Defense College. Dr. Richmond was a consulting clinical scientist at the Alfred E. Mann Foundation (1994-1995) Advanced Bionics Corporation (1995-1999). Research focused on implantable electrical devices and microsensors and diverse pharmaceutical products. Dr. Richmond has been part of five US research consortia (NIH Engineering Research partnership, NIH Bioengineering Research partnership, Clinical and Translational Science Institute, Tobacco Center of Regulatory Science, Consortium for Technology and Innovation in Pediatrics).

Sai Tatavarty, a passionate Regulatory Affairs professional is currently working as a Sr. RA Manager for Abbott Diabetes Care (ADC). She joined Abbott in 2014 as a Regulatory Affairs Specialist with ADC & during this time, she led & supported the submissions for ADC sensing, BGMs and digital technologies throughout Asia-Pacific region. She is also experienced in the regulatory activities for US, Asia Pacific and Latin America regions including new product registrations, on-market product changes, license renewals and regulatory intelligence. She has led the UDI data collection and publishing activities for US BGMs and obtained clearance of Special 510(k)s for BGM products in the US.

Within ADC, Sai has taken new responsibilities for regulatory affairs supporting external partners globally including integration of Sensing/ digital products with Automated Insulin Dosing, Smart Pens, and Data Sharing partnerships

Prior to Abbott, she worked at Novartis/Grifols as a Global Regulatory Affairs Specialist. Sai holds Bachelor's and Master's degrees in Pharmaceutics from Osmania University, India and a Master's degree in Regulatory Science from University of Southern California, Los Angeles, CA.

James Wabby, BSc., MHMS is the Global Head, Regulatory Affairs, Center of Excellence (COE) - Emerging Technologies, Combination Products, and Medical Devices Volwiler Senior Research Industry Fellow – Regulatory Science AbbVie, Inc. He has over 20 years of experience in increasing quality operations, quality compliance and regulatory affairs responsibilities within the GxP regulated environment pertaining to Medical Devices, Medicinal Device Delivery Platforms, Complex Generics, Companion Diagnostics, Digital Medicine, and Combination Product areas. He regularly provides AbbVie therapeutic franchise units

regulatory counsel and strategy to all aspects within the quality management system and regulatory affairs.

Key aspects of his regulatory responsibilities within the AbbVie Regulatory Affairs Center of Excellence (COE) include: CMC Global Dossiers/Global Device Regulatory Strategies, EU MDR/IVDR, Person Responsible for Regulatory Compliance (PRRC), 21 CFR Part 3 and Part 4 - Combination Products, CE Marking, ISO 13485:2016/MDSAP, International Regulatory Affairs, Represent AbbVie as the U.S Agent regarding FDA matters for international medical device facilities, and actively participate in industry trade organizations and serve on standards committees.

James is an internationally recognized leader as he is a member various regulatory and quality work groups including DIA, RAPS, AFDO/RAPS, AAMI, ISPE Combination Products (CoP), OCRA, SDRAN, ASQ Orange Empire Section, and ASQ San Diego. An international speaker, chair, and keynote at various regulatory symposia, Chairman of the DIA Combination Products Committee, a moderator for various global regulatory panel discussions, and has various publications, interviews and podcasts. In addition, he lectures various sections for the RAPS RAC Device Certification Prep Course – SDRAN and he is an Adjunct Assistant Professor at the University of Southern California (USC) – School of Pharmacy – Regulatory and Quality Sciences.

James holds a BSc. in Biology from Duquesne University, MHMS in Health Law and Policy from Duquesne University, Certificate in Health Law and Life Science Regulatory Compliance from Seton Hall University Law School - Center for Health & Pharmaceutical Law, and Certificate, RAPS Executive Development Program from Northwestern University - Kellogg School of Management.

Nozomi Yagi, MAS., RAC (US), is currently a Senior Regulatory Affairs Manager at Infraredx, a Nipro Company. In her current role, she is responsible for US/OUS regulatory strategy and submission for Infraredx devices and US regulatory strategies and submissions for Nipro devices. Prior to joining Infraredx, she was with Edwards Lifesciences, KARL STORZ Endoscopy and Cook Medical in regulatory and engineering roles and has over 16 years of regulatory and clinical research experience. Nozomi holds a BSc. in Biomedical Engineering from UC Irvine and a MAS in Health Law from UC San Diego.