Regulatory Science Symposium:
Principles of Global Clinical Research for Medical Devices
Speaker Bios

Eunjoo Pacifici (PharmD, PhD) is Chair and Associate Professor of Regulatory and Quality Sciences and Associate Director of the International Center for Regulatory Science. Dr. Pacifici received a BS in Biochemistry from the University of California Los Angeles and PharmD and PhD in Toxicology from the University of Southern California. She conducted her graduate research in the laboratory of Dr. Alex Sevanian in the Institute for Toxicology where she studied the mechanism of oxidative damage and repair in endothelial cell membrane. Before returning to USC as faculty, Dr. Pacifici worked at Amgen and conducted clinical research with a special focus on Asia Pacific and Latin America. She initially worked in the clinical development group managing U.S. investigational sites and central laboratories, then in the Asia Pacific/Latin America group interfacing with local clinical and regulatory staff in Japan, the People's Republic of China, Taiwan, and Mexico. She represented regional clinical and regulatory views on therapeutic product development teams and led satellite task forces to align local efforts with U.S. activities. Her professional experience includes community pharmacy practice in various settings and clinical pharmacy practice at the Hospital of the Good Samaritan in Los Angeles. Her current focus is on developing the next generation of regulatory scientists and pharmacy professionals with the knowledge, tools, and skills to expedite the development of innovative, safe, and effective biomedical products. epacific@usc.edu

Maria E. Donawa (MD), is President of Donawa Lifescience (headquartered in Rome, Italy) and has over 30 years regulatory experience including six years with the US Food and Drug Administration in medical device regulation. Donawa Lifescience provides clinical services to life science companies worldwide and US and European quality system and regulatory services. Dr. Donawa has assisted a wide range of medical device and IVD medical device companies in complying with European requirements. She is an active member of ISO TC 194 Working Group 4, was responsible for the development and revision of ISO 14155 (Clinical investigation of medical devices for human subjects – Good Clinical Practices) and is a stakeholder observer actively participating in the work of the European Clinical Investigation and Evaluation subgroup of the Medical Devices Coordination Group (MDCG). She has developed expert guidance documents for BSI on clinical data, clinical evaluation, and clinical investigation and a white paper on clinical investigation. For five years, Dr. Donawa served as a registered lead auditor, providing notified body auditing services to a German notified body. For over 25 years until closure of the publication, she was the regulatory columnist for European Medical Device Technology. Dr. Donawa has US degrees in pharmacy and medicine and post-doctoral specialization in clinical and anatomical pathology. medonawa@donawa.com

Danielle Giroud (RN, MBA) is founder and CEO of MD-Clinicals (https://www.md-clinicals.com), a medical device-focused CRO with offices in Switzerland, Frankfurt, and Beijing. Ms. Giroud has over 30 years of experience within the medical device industry. She is an internationally recognized clinical research and regulatory expert, having shared her extensive knowledge and experience with hundreds of multi-national companies, organizations, and start-ups from around the globe to help bring their products to market quickly and efficiently. Ms. Giroud was founder and senior faculty board member of the World Medical Device Organization (https://www.wmdo.org). She was also a convener for the expert group on clinical investigations (TC 194 WG4) for the ISO 14155, and liaison with the EU Commission - Clinical Investigation and Evaluation (CIE) task force and other regulatory authorities throughout the world. dgiroud@wmdo.org

Cheryl Hergert (MPH) is Principal Clinical Quality Specialist at Medtronic overseeing quality and compliance of global clinical operations. With more than 20 years of experience in product development for medical devices, pharmaceuticals and combination products, Ms. Hergert's experience ranges from feasibility to launch with expertise in clinical and regulatory operational management for US and OUS. She holds a Master's in Public Health, and Bachelors in Biochemistry and is currently working towards a Doctorate of Regulatory Science at USC. Her research interests pertain to the use of routine clinical patient health data in clinical research, specifically focusing on the adoption of the use of real-world patient data for regulatory decision making. Cheryl is involved in several global initiatives such as World Health Day and International Women's Day. Through her leadership, World Health Day is celebrated as an annual event at a university level and International Women's Day is celebrated across Medtronic's global enterprise. cherylmhergert@gmail.com

Evangeline Loh (PhD, RAC) is Global Regulatory Manager at Emergo by UL consulting group. During her 14-year plus tenure at Emergo, Dr. Loh has assisted hundreds of manufacturers with global regulatory strategy, registration and consulting projects. Her areas of expertise include European CE marking, clinical evaluation and performance evaluation reports, global vigilance, and device classification in markets worldwide. She has been intimately involved in the transition from the Directives to the Regulations, and all related regulatory requirements. Dr. Loh is a key architect in developing tools for Emergo's Regulatory Affairs Management Suite (RAMS) software. Her previous work experience includes regulatory scientist at Cook Medical and at a non-profit lobbying for medical schools. Dr. Loh holds a PhD in Pharmacology from the University of Texas Health Sciences Center, and a BS in Microbiology from Cornell University and is RAC certified in US and EU. evangeline.loh@ul.com