

Moderator:



Margareth R. C. Marques, M.Sc., Ph.D.

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Margareth R. C. Marques is Principal scientific liaison at the Science Department at the United States Pharmacopeia. Scientific liaison to the USP Expert Committee on Dosage Forms working on general chapters for performance tests (dissolution/drug release), and for some pharmaceutical dosage forms (products applied to the skin, ophthalmic products, etc.), responsible for the USP general chapters on osmolality, titrimetry, and UV/Vis spectrophotometry. Dr. Marques is also responsible for developing specifications for reagents, test solutions, buffer solutions, etc., used in USP – NF monographs. She manages the USP database on chromatographic columns, the USP database on dissolution methods and the USP web site on column equivalency. She has a B.Sc. and an M.Sc. both in Pharmacy by the University of Sao Paulo, Brazil. She has a Ph. D. in Analytical Chemistry by the State University of Campinas, Brazil. She managed analytical laboratories at Ciba-Geigy, Sandoz, and Astra.

Speakers:

Stacey Ricci, M.Eng., Sc.D.

Director of Scientific Review Staff

Office of Therapeutic Biologics and Biosimilars (OTBB)

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Dr. Ricci is the Director of the Scientific Review Staff in the Office of Therapeutic Biologics and Biosimilars within the Office of New Drugs, CDER, FDA. Dr. Ricci leads a multidisciplinary team that provides oversight of biosimilar and interchangeable products at all stages of their development and ensures consistency in the cross-disciplinary scientific and regulatory advice provided to sponsors for their products. During her 15-year tenure at FDA, Dr. Ricci's work has focused primarily on the scientific and regulatory review of biotechnology-derived therapeutic proteins, including making major contributions to FDA guidance and standards development for biosimilars and other protein therapeutics. Prior to joining FDA, Dr. Ricci completed post-doctoral research at the University of Pennsylvania, received a Doctor of Science from Tulane University, and a Master of Engineering and Bachelor of Science from Cornell University.



Leah Christl, Ph.D.

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Dr. Christl is currently an Executive Director of Global Regulatory and R&D Policy at Amgen. She supports Global Biosimilars and serves as the ICON GRR&D Policy Lead. Prior to joining Amgen, Dr. Christl served as the Associate Director for Therapeutic Biologics in the Office of New Drugs (OND) in the FDA's Center for Drug Evaluation and Research (CDER). In this role, she developed and led CDER's approach to implementation of the Biologics Price Competition and Innovation Act (BPCIA) of 2009. Dr. Christl was also the director of the Therapeutic Biologics and Biosimilars Staff (TBBS) at the US FDA and served as a scientific, regulatory, and policy expert to FDA, HHS, and external stakeholders, on biosimilar products. Dr. Christl also engaged in international activities by serving as a CDER and FDA strategist and lead for international activities related to biosimilars, including serving as FDA lead for the FDA-EMA-Health Canada-PMDA biosimilars cluster and the International Pharmaceutical Regulators Programme – Biosimilars Working Group. Dr. Christl received her PhD in Molecular and Cellular Biology and Pathobiology – Marine Biomedicine and Environmental Science from the Medical University of South Carolina in Charleston.



Sundar Ramanan, Ph.D.

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Dr. Ramanan is a seasoned regulatory affairs executive with expertise across biopharmaceutical drug development, operations, clinical & commercial strategy, policy and regulatory affairs. Prior to Biocon, he was responsible for Amgen's International Regulatory Strategy and Policy for Biologics & Biosimilars, and helped shaped biosimilar standards globally. He has successfully led teams in the development of biopharmaceutical drug candidates from the early stages through commercialization, and life-cycle management across multiple therapeutic areas. He is also an internationally recognized expert in biologics, including biosimilars, for science-based policy engagement with regulators, health-ministry and industry trade organizations.

Sundar is also an accomplished author and speaker. He is a Chemical Engineer by training; holds a Ph.D. in Bioengineering from Oregon State University and MBA from the University of Michigan.