PQRI BTC 2022 Webinar

Approaches to Establishing Bioequivalence Safe Space for Orally Administered Drug Products: Applications and Case Studies

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Bios

Moderator:

Andreas Abend, Ph.D., Senior Principal Scientist
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Andreas Abend received his PhD degree in Organic Chemistry from the University of Karlsruhe in Germany. Prior to joining Merck and Co., Inc. as a Senior Project Chemist, Andreas spent 3 years as a Post-Doctoral Fellow at the University of Wisconsin's Enzyme Institute. He is currently a Senior Principal Scientist in the Biopharmaceutical Sciences group in MRL's Development Sciences and Clinical Supply Department. Throughout his career at Merck, he provided analytical support to small molecule API and drug product development spanning all clinical phases. Andreas is a member of Merck's Biopharmaceutical Advisory Team, co-chair of PQRI's BTC, and a member of IQ's Analytical Leadership Group. He presented at many national and international meetings, published several manuscripts on Clinically Relevant Dissolution specifications and he was a co-organizer of two workshops at the Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI).

Speakers:

Filippos Kesisoglou, Ph.D. Distinguished Scientist
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Filippos Kesisoglou is a Distinguished Scientist at Merck & Co., Inc., (Kenilworth, NJ) where he is currently leading the Biopharmaceutics team and oversees the translational biopharmaceutics efforts in the Pharmaceutical Sciences department. Filippos has more than 15 years of experience in the fields of biopharmaceutics and formulation development, pharmacokinetics, PBPK and IVIVC modeling as related to clinical, drug product development and CMC regulatory applications. He has been a key contributor to more than 10 new drug applications across therapeutic areas. He has authored/co-authored more than 80 manuscripts/book chapters and more than 80 conference abstracts/podium presentations in several national/international meetings in the fields of biopharmaceutics, PBPK modeling, formulation development and drug delivery. Filippos has been involved in several cross-industry and academia consortia such as PQRI where he was a chair of the Biopharmaceutics Technical Committee, IQ Consortium where he's currently co-chairing the Food Effect PBPK WG, OrBiTo and UNGAP. He is currently serving as an Editor for the Journal of Pharmaceutical Sciences and as an Editorial Advisory Board member for the AAPS Journal and Pharmaceutical Research. In 2017 he was elected an AAPS Fellow.

Xavier Pepin, Pharm.D, Ph.D., Associate VP Regulatory Strategy SimulationsPlus

Xavier is a pharmacist (University Paris XI). He has a Ph.D. in granulation technology where he studied powder surface energy and liquid bridges during wet high-shear granulation. He has more than 25 years' experience in the pharmaceutical industry and has occupied several positions from preformulation, clinical and commercial formulation development, industrial transfer, regulatory CMC and biopharmaceutics. He's worked in biopharmaceutics for 15 years using in vitro, in silico, and in vivo tools to support evaluation of drugs along the development value chain and post marketing. He was the co-leader of WP4 in silico tools for the OrBiTo IMI project 2012-2018.

He has 30 publications in the field of powder surface energy, granulation technology and biopharmaceutics.