PQRI BTC/DTC 2021 Webinar
Development and Biopharmaceutics of Long-Acting Injectables
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Bios

Moderators:

Ajit Narang, Ph.D., Principal Scientist
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Ajit Narang works for the Small Molecule Pharmaceutical Sciences Department of Genentech, Inc., in South San Francisco, CA responsible for the pharmaceutical development of new chemical entities through preclinical and early clinical stages. He has served as Adjunct Faculty at the Universities of Tennessee, Memphis, TN; University of Phoenix, Phoenix, AZ; University of Nebraska Medical Center, Omaha, NE; University of the Pacific, Stockton, CA; Campbell University, North Carolina; and Western Michigan University, Kalamazoo, MI. He serves as Co-Chair of the Biopharmaceutics Technical Committee (BTC) of the Pharmaceutical Quality Research Institute (PQRI) in Arlington, VA; a panel member of the International Pharmaceutics Excipient Council (IPEC) committees; Chair of the Formulation Design and Delivery (FDD) section of the American Association of Pharmaceutical Scientists (AAPS); a member of the Systems-based Pharmaceutics (SBP) alliance of the Process Systems Enterprise, Inc. (PSE) in London, UK; and a Scientific Advisor to the Editors of JPharmSci.

He holds over 15 years of pharmaceutical industry experience in the development and commercialization of oral and parenteral dosage forms and drug delivery platforms across preclinical through commercialization stages for both small and large molecule drugs. In addition to Genentech, he has worked for Bristol-Myers Squibb, Co., in New Brunswick, NJ; Ranbaxy Research Labs (currently a subsidiary of Daiichi Sankyo, Japan) in Gurgaon, India; and Morton Grove Pharmaceuticals (currently, Wockhardt USA) in Gurnee, IL. He holds undergraduate Pharmacy degree from the University of Delhi, India and graduate degrees in Pharmaceutics from the Banaras Hindu University, India and the University of Tennessee Health Science Center (UTHSC) in Memphis, TN.

Ajit has contributed to several preclinical, clinical, and commercialized drug products including NDAs, ANDAs, and 505B2s. He is credited with 54 peer-reviewed articles; 22 editorial contributions; 5 books; 10 patent applications; 47 invited talks; and 85 presentations at various scientific meetings. His current research interests are translation from preclinical to clinical and commercial drug product design; incorporation of QbD elements in drug product development; and mechanistic understanding of the role of material properties on product performance.

Diane Paskiet, Senior Director – Scientific Affairs
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Diane Paskiet has over twenty-five years of experience in the pharmaceutical industry. She is currently Director of Scientific Affairs at West Pharmaceutical Services where she is involved in science and regulatory programs associated with safety and compatibility of pharmaceutical packaging and delivery systems. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories. She is Chair of Product Quality Research Institute (PQRI) Development Technical Committee (DTC) and the Extractables and Leachables Parenteral Drug Product Working Group. Diane is also on the faculty of the Parenteral Drug Association Training Institute and a Board Member of Xavier Health Innovation Training Center of Excellence (ITCE). She has author/co-author a number of papers and book chapters related to pharmaceutical packaging, delivery systems and combination products.

Speakers:

Liang Zhao, Ph.D., Director, Director of Division of Quantitative Methods and Modeling
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Dr. Liang Zhao is currently the Director of Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Dr. Zhao has a broad spectrum of scientific and management experience from industry and the regulatory agency. Through his 16-year professional career, he has established his leadership in industrial R&D, quantitative methods and modeling, and model based strategic decision makings in regulatory and industrial settings for generic and new drugs.

Dr. Liang Zhao has been serving as Director of DQMM since 2015. He initially joined the FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune for biotech products, BMS for small molecule drug development, and Pharsight as an associate consultant for new drug R&D. Dr. Zhao has authored and coauthored 80 peer reviewed articles and book chapters, and has been a seasoned speaker in FDA workshops, major national and international conferences.

Dr. Zhao has a diversified educational credentials including PhD in Pharmaceutical Sciences and Master in Applied Statistics from the Ohio State University, Master in Pharmaceutics from Shanghai Medical University, BS in Pharmaceutics from China Pharmaceutical University, and Executive MBA from University of Cambridge.

Viera Lukacova, Ph.D., Chief Scientist
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Dr. Lukacova is Chief Scientist at Simulations Plus, Inc. Over the last decade she has been contributing to the research in the area of mechanistic absorption and PBPK modeling and the development of GastroPlus®, DDDPlus™, and MembranePlus™ software packages widely used throughout the pharmaceutical industry in early drug development, formulation, pre-clinical, and clinical research. She also contributes to modeling studies helping companies with their drug development programs in the early discovery stage, formulation development, clinical pharmacology applications and interactions with regulatory agencies.