PQRI 2020 BTC Webinar
The Challenge and the Promise:
Developing Complex Drug Products
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Bios

Moderator:

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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.

Speakers:

Wenlei Jiang, Ph.D., Senior Science Advisor
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Dr. Wenlei Jiang currently serves as a Senior Science Advisor in the Office of Research and Standards (ORS)/Office of Generic Drugs (OGD)/Center for Drug Evaluation and Research (CDER). She has been championing regulatory research in the areas of generic nanomaterials, narrow therapeutic index drugs, and modified release products to support review standards development and ensure post-market safety and efficacy of these drug products. Currently she is leading complex drug product classification and research, as well as promoting global bioequivalence harmonization. She also serves as Chair at Product Quality Research Institute (PQRI) Biopharmaceutical Technical Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, and advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

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Adrian Goodey is a Principal Scientist in the Analytical Sciences group within Merck Research Laboratories, focusing on specialty dosage forms. In this role, Dr. Goodey leads the development of drug products delivered via alternate routes of administration, including inhalers, nasal sprays and sub-dermal implants. Prior to joining the pharmaceutical industry in 2007, Dr. Goodey earned a B.Sc. in chemistry from Emory University, completed a PhD in chemistry from the University of Texas at Austin, and then served as an ACS/PRF Alternative Energy Postdoctoral Fellow at the Pennsylvania State University. Dr. Goodey currently chairs the IPAC-RS Cascade Impactor working group. His research interests include advancing the science of aerodynamic particle sizing and the development of clinically relevant analytical methods for pharmaceutical testing. To date, he has authored fourteen peer-reviewed scientific articles and two patents.