



PQRI BTC 2021 Webinar

Exploring the Development and Utility of an Inhalation-based Biopharmaceutics Classification System (iBCS)

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Bios

Moderator:



Wenlei Jiang, Ph.D., Senior Science Advisor

US Food and Drug Administration

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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.

Speakers:



Jayne Hastedt, Ph.D., Managing Director

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Dr. Jayne E. Hastedt has over 35 years of experience in pharmaceutical product development. She has had management and technical leadership responsibilities for the development of small molecules, peptides, and proteins using various dosage forms, routes of delivery, and technologies and has supported successful US and European regulatory product approvals. Her experience includes leading physicochemical characterization and CMC development activities spanning early drug product development through product registration and launch as well as life cycle management. She has supported the development of oral, transdermal, oral controlled release dosage forms, and specializes in inhaled drug delivery product development. She is currently co-leading an initiative within the PQRI BTC to develop an inhalation-based Biopharmaceutics Classification System (iBCS) for inhaled drugs. Dr. Hastedt is the Managing Director of JDP Pharma Consulting, LLC and throughout her career, she has had the opportunity to work at Johnson & Johnson/ALZA, Inhale, Glaxo/Glaxo Wellcome, and Boehringer Ingelheim. She received her MS and PhD degrees from the University of Wisconsin – Madison School of Pharmacy under the guidance of Professors James L. Wright and George Zografi. She holds adjunct faculty positions at the UW School of Pharmacy in the Pharmacy Professional Development Division and the University of the Pacific Thomas Long School of Pharmacy and Health Sciences. Dr. Hastedt has had the opportunity to support the June Land O'Lakes Conferences for many years and chaired the conference multiple times. She recently collaborated with the Division of Pharmacy Professional Development to design and launch an online graduate level Pharm Sci 750 course on The Drug Development Process in 2020.



Per Bäckman, Ph.D., Senior Adviser, Inhalation Science

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Dr. Bäckman assists clients with the discovery and development of inhaled medicines. This includes for example: establishing in vitro-in vivo correlations in support of specifications and product design targets and IVIVC model-based batch selection for BE studies. His contribution is based on more than 20 years of industry experience encompassing discovery and development of large and small molecule inhaled medicines. During the last 8 years, Dr. Bäckman has focused on the application and development of computer-based models to link in vitro critical drug product attributes and clinical performance. Dr. Bäckman is the author of 25+ original research papers and a frequently invited lecturer at international conferences.

Panelists:



Bing Cai, Ph.D., Director, Division of Liquid-based Drug Products

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Dr. Bing Cai is Director of the Division of Liquid-based Drug Products in CDER/OPQ/OLDP at the FDA. In his twenty-year tenure within the FDA, he has been promoted to CDER Senior Review, Team Lead, Chemistry Division Deputy Director and Division Director. He has been involved in the development of several important Agency's initiatives, including the current ANDA Integrated Quality Assessment process. He has coordinated the implementation of the comprehensive review assessment using the Quality by Design and Risk-based Review concepts for various drug dosage forms to ensure a uniform drug quality program across generic and new drug products.



Renishkumar Delvadia, Ph.D., Drug Product Reviewer

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Dr. Delvadia has 16 years of combined academic, industry and regulatory experience in area of inhalation and nasal drug product development. In his Ph.D. research, he developed a novel in vitro method capable of predicting in vivo drug deposition from inhaler as a function of inspiratory profiles and airway geometries. In the Office of Generic Drugs (OGD) at FDA, he worked towards development of guidances and new in vitro approaches for bioequivalence assessment of generic inhalation and nasal products. He is currently working as a drug product reviewer in the Office of New Drug Products (ONDP) at FDA.



Ajit Narang, Ph.D., VP, Head of CMC

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Ajit Narang works for the Department of Pharmaceutical Sciences at ORIC Pharmaceuticals in South San Francisco, CA responsible for the preclinical and clinical CMC deliverables of the development portfolio.

He holds about two decades 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. Prior to ORIC, he has worked for Genentech; Bristol-Myers Squibb; Ranbaxy (currently Daiichi Sankyo); and Morton Grove Pharmaceuticals (currently, Wockhardt).

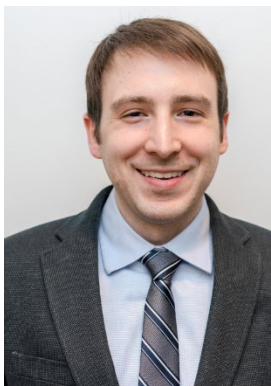
He holds undergraduate Pharmacy degree from the University of Delhi, India and graduate degrees in Pharmaceutics from the Banaras Hindu University, India and the University of Tennessee Health Science Center (UTHSC) in Memphis, TN.

He has served as Adjunct Faculty at several schools including the Universities of Tennessee; Phoenix Nebraska Pacific, Campbell, and Western Michigan University.

He has served in several volunteer roles with PQRI, AAPS, and the scientific peer reviewed journal editors in various capacities.

Ajit has contributed to several preclinical, clinical, and commercialized drug products including NDAs, ANDAs, and 505B2s; and is credited with several peer-reviewed papers and books.

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.



Bryan Newman, Ph.D., Pharmacologist

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Bryan Newman, Ph.D., is a pharmacologist and acting team lead for inhalation and nasal drug products in the Division of Therapeutic Performance 1 (DTP-1), Office of Research and Standards (ORS), under the Office of Generic Drugs (OGD). Dr. Newman's work focuses on developing product-specific guidances, and addressing controlled correspondences, citizen petitions, consults, and Pre-ANDA meeting requests. He also serves as a project officer and contracting officer's representative for regulatory science research initiatives related to inhalation and nasal drug products. Dr. Newman received his B.S. degree from Louisiana State University in Biochemistry and his M.S. and Ph.D. degrees from the University of Michigan in Pharmaceutical Science.



Bhagwant Rege, Ph.D., Division Director, Division of Immediate and Modified Release Products III

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Dr. Bhagwant Rege is the Division Director for the Division of Immediate and Modified Release Products III in CDER/OPQ/OLDP at the FDA. Prior to joining FDA in 2010, he worked at Merck & Co. for about 9 years in oral biopharmaceutics and formulation development groups. His division at FDA is responsible for collaborative evaluation and assessment of Abbreviated New Drug Applications (ANDAs) for immediate and modified release oral drug products, transdermal and topical systems, intravaginal and intrauterine systems, subcutaneous implants, and inhalation (MDI/DPI) drug products and making risk-informed recommendations on their approvability. Bhagwant has served as a team leader and review chemist in the Office of Generic Drugs where he was part of the team that developed the QbD examples for the generic industry. He is a member of the FDA Emerging Technology Team (ETT) and ICH Q12 Expert/Implementation Working Group. He served as FDA liaison on the USP expert committee on dosage forms general chapter (2015-2020). Bhagwant received his BS and MS in pharmacy from the University of Mumbai, India and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore.



Barbara Schug, Ph.D., Founder

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Dr Barbara Schug studied pharmacy at Rheinische Friedrich-Wilhelm-Universität, Bonn, she received a scholarship from the "Studienstiftung des Deutschen Volkes" and was awarded a doctor's degree for experimental pharmacological work.

She started her professional career at Zentrallaboratorium Deutscher Apotheker, Eschborn. In 1998 she founded, together with Prof Dr Henning Blume, an independent research institute, SocraTec R&D. In 2007 she founded SocraMetrics, an independent biometrical institute. She is currently managing shareholder in both companies.

Her area of work covers the planning and realisation of early phase (I and II) trials in healthy subjects and patients and she is also responsible for phase-III and phase-IV studies realized by her companies. Alongside the chemically defined medicinal substances, work is focusing on biotech medicines including biosimilars, non-biological complex drugs, herbal medicines and endogenous compounds. This work has led to more than 90 scientific publications so far.

Dr. Schug is a member of numerous national and international scientific societies, including Deutsche Pharmazeutische Gesellschaft (DPhG)¹, Arbeitsgemeinschaft für angewandte Humanpharmakologie (AGAH)², Deutsche Gesellschaft für Pharmazeutische Medizin (DGPharMed)³, European Federation of Pharmaceutical Sciences (EUFEPS) and Gesellschaft für Dermopharmazie⁴.

She has been an active member of the organisational committee of the German Pharmacokinetic / Pharmacodynamic Experts Conference for many years. Furthermore, she is active member of the EUFEPS Network on Bioavailability and Biopharmaceutics and in this function she is co-chair of the organising committee of the Global Bioequivalence Harmonisation Conference (next: April 2022 in Amsterdam, The Netherlands). Furthermore, she is co-founder and active member of the EUFEPS Network on Dermatopharmacy. And finally she is currently Regent of AGAH.

¹ German Pharmaceutical Society

² Association for Applied Human Pharmacology

³ German Society for Pharmaceutical Medicine

⁴ Society for Dermopharmacy



Ross L. Walenga, Ph.D., Chemical Engineer

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Dr. Ross L. Walenga joined the FDA in 2015 as an Oak Ridge Institute for Science and Education (ORISE) Fellow. He is currently a Chemical Engineer in the Division of Quantitative Methods and Modeling (DQMM), which is in the Office of Research and Standards (ORS), a sub-office of the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research (CDER). He began his career at Virginia Polytechnic Institute and State University (Virginia Tech), where he earned a Bachelor Science in Aerospace Engineering. He later earned his PhD in Engineering (mechanical track) from Virginia Commonwealth University in 2014, where he also spent seven months as a postdoctoral fellow prior to joining the FDA. His research interests include computational fluid dynamics (CFD) modeling of orally inhaled, nasal, ophthalmic, and dermal drug products to answer questions pertaining to bioequivalence.