# 5TH PQRI/FDA CONFERENCE ON ADVANCING PRODUCT QUALITY

Biographies

Day 1 – December 1, 2021

Biopharmaceutics Track

| Welcome to Conference and PQRI Overview | |
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| **Ajit Narang, Ph.D.**<br>VP, Head of CMC<br>ORIC Pharmaceuticals<br>ajit.narang@oricpharma.com<br>  | **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.<br><br>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).<br><br>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.<br><br>He has served as Adjunct Faculty at several schools including the Universities of Tennessee, Phoenix Nebraska Pacific, Campbell, and Western Michigan University.<br><br>He has served in several volunteer roles with PQRI, AAPS, and the scientific peer reviewed journal editors in various capacities.<br><br>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.<br><br>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. |

## Introduction to the 5th PQRI/FDA Conference

**Lawrence X. Yu**, Ph.D.
Director, Office of New Drug Products
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**Lawrence X. Yu**, Ph.D., is the Director, Office of New Drug Products, Food and Drug Administration. Dr. Yu implemented Biopharmaceutics Classification System at the FDA, created the Question-based Review, described the Pharmaceutical Quality by Design (QbD), inaugurated the FDA modern review system - Integrated Quality Assessment (IQA), developed the FDA historic concept of operations agreement to integrate review and inspection, and originated the Knowledge-aided Assessment and Structured Applications (KASA) initiative. Dr. Yu is also an adjunct Professor at the University of Michigan. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the *AAPS Journal*. Dr. Yu has authored/co-authored over 150 papers and given over 400 invited presentations. He is a co-editor of the books entitled "*Biopharmaceutics Applications in Drug Development*", "*FDA Bioequivalence Standards*", and "*Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, 2nd Ed.*"

## KEYNOTE: *Advancing Pharmaceutical Product Quality*

**Michael Kopcha, Ph.D., R.Ph.**
Director, Office of Pharmaceutical Quality (OPQ),
Center for Drug Evaluation & Research (CDER)
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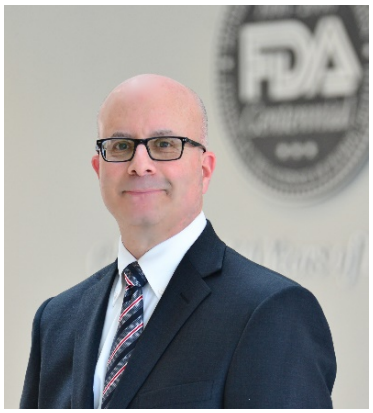

**Michael Kopcha**, Ph.D., R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities.

Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project management, change management, and off-shoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc.

Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

## SESSION 1: Patient-centric Dissolution and International Harmonization

### Moderator:

**Filippos Kesisoglou**, Ph.D.
Distinguished Scientist
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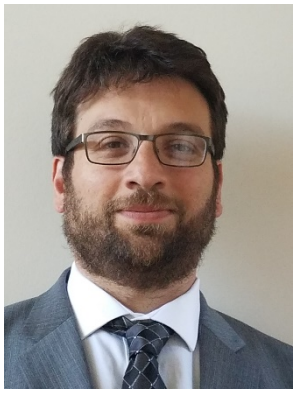

**Filippos Kesisoglou** is a Distinguished Scientist at Merck & Co., Inc., (Kenilworth, NJ) where he is currently leading the Biopharmaceutics team and oversees the translational biopharmaceutics efforts in the Pharmaceutical Sciences department. Filippos has more than 15 years of experience in the fields 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.

### Speakers:

**Swati Nagar, Ph.D.**
Professor
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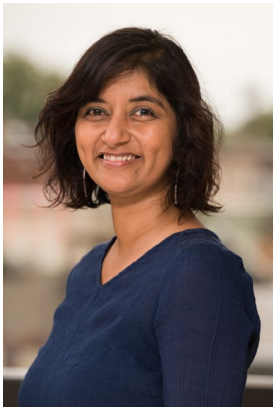

**Swati Nagar** is a Professor in the Department of Pharmaceutical Sciences at Temple University School of Pharmacy. She obtained her Ph.D. in Pharmaceutics at the University of Minnesota in 2003. She completed a postdoctoral fellowship in Pharmacology at Fox Chase Cancer Center in 2005. Swati joined Temple University School of Pharmacy, Department of Pharmaceutical Sciences in 2005 as Assistant Professor, and was promoted to the rank of Associate Professor with tenure in 2011, and Professor in 2018. She teaches Pharm D and graduate pharmacokinetics.

Swati's lab has a long-standing interest in understanding the disposition of conjugated metabolites, specifically the pharmacokinetics of metabolites with respect to their formation and transport. Further, in collaboration with Dr. Ken Korzekwa, she is developing methods to better understand complex kinetics of time-dependent inhibition. Another key collaborative area of research with the Korzekwa lab is developing models to predict intracellular concentrations in the presence of drug transporters.

Swati has co-authored several peer-reviewed research and review articles, and she co-edited a book titled 'Enzyme Kinetics in Drug Metabolism: Fundamentals and Applications' (Springer/Humana Press; 1st edition 2014; 2nd edition 2021). Swati is a past Chair of the Delaware Valley Drug Metabolism Discussion Group, a past Chair of the AAPS PPDM Drug Metabolism Focus Group, Chair of the 2018 Gordon Research Conference on Drug Metabolism, past member of the steering committee of the International Transporter Consortium, and a member of several professional organizations including ISSX. She currently serves on the editorial board of Drug Metabolism and Disposition and Xenobiotica. She is currently serving as a standing member of the XNDA study section of the NIH CSR.

**Bart Hens, Pharm.D., Ph.D.**
Biopharmaceutics Scientist &
Drug Product Design Biomodeler
Pfizer, Sandwich, UK
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During his dissertation research, **Bart Hens** (Pharm.D., Ph.D.) focused on the behavior of oral drug products in the human gastrointestinal tract under the supervision of Prof. Dr. Patrick Augustijns (KU Leuven, Belgium). Based on the results of these studies, he started to use these data as a reference for optimization and validation of different in vitro and in silico models to increase their predictive power towards the in vivo outcome of an oral drug product. His Ph.D. project was part of a bigger European project between academic institutions and pharmaceutical companies (www.orbitoproject.eu). In January 2017, Bart started to work as a postdoctoral research fellow in the laboratory of Prof. Dr. Gordon L. Amidon, where they both explored the impact of gastrointestinal physiology on oral drug behavior by performing clinical aspiration studies. The gathered knowledge was used as a reference to develop a formulation predictive dissolution (fPD) test for oral drug products. This work was supported by the U.S. Food and Drug Administration (FDA). From 2018 on, Bart was assigned as a postdoctoral researcher at the department of pharmaceutical and pharmacological sciences (Drug Delivery & Disposition lab) focusing on the impact of 'real-life' intake conditions on the behavior of a drug product along the gastrointestinal tract. This project was granted by a postdoctoral scholarship from the Flemish Research Council (FWO). Since November 2020, Bart moved to Pfizer UK to work as a biopharmaceutics scientist and drug product design biomodeler under the supervision of Dr. Mark McAllister.

**Elsbeth Chikhale, Ph.D.**
Biopharmaceutics Team Leader
Division of Biopharmaceutics
Office of New Drug Products
(ONDP)/OPQ/CDER/FDA

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**Dr. Chikhale** is currently a Team Leader in the Division of Biopharmaceutics, Office of New Drug Products in the Office of Product Quality at CDER/FDA. She first joined the FDA in 1998 as a Chemist Reviewer in the Division of Metabolic and Endocrine Drug Products. In 2012 she joined the Division of Biopharmaceutics as a Senior Biopharmaceutics Reviewer. During her tenure at FDA, Dr. Chikhale made significant contributions to the approval and regulation of numerous new and generic drug products belonging to a wide range of therapeutic areas. At her current position, she oversees Biopharmaceutics review activities and participates in key regulatory decision-making processes for Antiviral and Anti-infective new and generic drug applications. Prior to joining FDA, Dr. Chikhale completed her Bachelor's degree in Pharmacy at the University of Utrecht, her Master's degree in Medicinal Chemistry at the University of Florida, and a Ph.D. in Pharmaceutical Chemistry at the University of Kansas. After completing her education, before joining FDA, she completed a post-doctoral fellowship at the National Institute on Aging, at NIH.

## SESSION 2: Biopharmaceutics for Complex Drug Products

### Moderator:

**Wenlei Jiang, Ph.D.**
Senior Science Advisor
ORS/OGD/CDER
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
JDP Pharma Consulting, LLC
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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.

**Hao Zhu, Ph.D.**
Deputy Division Director
Division of Pharmacometrics
OCP/OTS/CDER/FDA
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**Dr. Hao Zhu** is the deputy division director at the Division of Pharmacometrics, Office of Clinical Pharmacology, Center of Drug Evaluation and Research, U.S. Food and Drug Administration. Dr. Zhu received his Ph.D. in pharmaceutical sciences and Master in statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 14 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than 6 years and a QT-IRT scientific lead for 2 years. His division reviews the pharamcometrics related submissions and supports pharamcometrics-related policy development across CDER.

**Diane J. Burgess, Ph.D.**
Distinguished Professor,
Pfizer Distinguished Chair in
Pharmaceutical Technology,
University of Connecticut
d.burgess@uconn.edu

B.Sc. Pharmacy, University of Strathclyde (1979) and Ph.D. Pharmaceutics, University of London (1984). Fellow of AAPS, CRS, APSTJ, and AIMBE. 2010 CRS President; 2002 AAPS President. Editor of International Journal of Pharmaceutics (2009 – 2018). Editorial board member of 13 international journals. Recipient of: 2018 AAPS Wurster Award in Pharmaceutics; 2014 AAPS Research Achievement Award; 2014 AAPS Outstanding Educator Award; 2014 CRS Distinguished Service Award; 2013 AAPS IPEC Ralph Shangraw Award; 2010 CRSI Fellowship, 2011 APSTJ Nagai International Woman Scientist Award. Over 245 refereed publications, over 675 research presentations, over 315 invited presentations, 24 keynote and plenary addresses.

## HOT TOPIC: Biopharmaceutics for Nano-Drug Delivery

### Moderator:

**Mehran Yazdanian, Ph.D.**
Vice President, R&D Operations
Teva Pharmaceuticals
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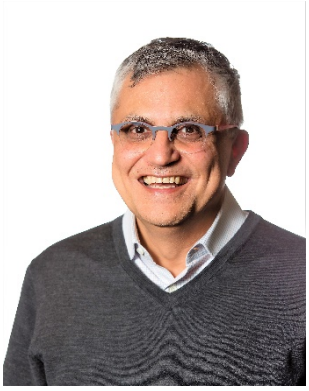

**Mehran Yazdanian** is the Vice President of R&D Operations at Teva Pharmaceuticals and the R&D Site Head for Teva's West Chester, PA facility. He leads CMC project managers to develop and implement strategies for development of innovative biologicals and biosimilars for a seamless transition of activities from clone selection to regulatory submission. He also leads the technical evaluation team for external development of sterile generics.

He received his BS in biochemistry and MS and PhD in pharmaceutics from the University of Wisconsin-Madison. His career has been focused on directing formulation and analytical development activities from early drug discovery support and preformulation to formulation development. He has extensive experience in manufacturing for clinical programs and commercialization support for both small molecule and biological drug candidates.

The focus of his research has been on drug delivery from two perspectives: optimization of biopharmaceutical properties and formulation strategies to enhance oral absorption of small molecules. In the area of cellular permeability his efforts were centered on the development and application of cell culture systems for studying drug transport and metabolism in intestinal mucosa. In terms of formulation effects on oral absorption, his research was on characterizing the interactions between drugs, formulation components, and the intestinal membrane to better understand and design the most effective delivery systems.

Previously he led an integrated Pharmaceutics department at Cephalon comprised of analytical and formulation development scientists as well as manufacturing engineers supporting product development. Before that he headed the Physical Pharmaceutics section of the pharmaceutics department at Boehringer Ingelheim Pharmaceuticals Inc. His first job was at Merck Research Laboratories where he worked on formulation development of transdermal and liquid dosage forms for veterinary applications.

**Speaker:**

**Duxin Sun**, PhD.
Charles Walgreen Jr. Professor of Pharmacy
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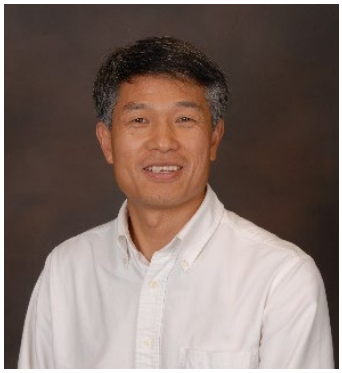

**Dr. Duxin Sun** is the Charles Walgreen Jr. Professor of Pharmacy and Professor of Pharmaceutical Sciences in the College of Pharmacy at the University of Michigan. Dr. Sun serves as the Director of Pharmacokinetics (PK) Core. Dr. Sun also has joint appointment in the Chemical Biology program, the Interdisciplinary Medicinal Chemistry program, and University of Michigan's Comprehensive Cancer Center.

Dr. Sun's research interests focus on drug discovery, nanomedicine and pharmacokinetics. Dr. Sun has published more than 240 papers, mentored 35 PhD students and 40 postdoctoral fellows/ visiting scientists. Dr. Sun is a Fellow of American Association of Pharmaceutical Scientists (AAPS) and has served as chair of the PPB (Physical Pharmacy and Biopharmaceutics) in AAPS. Dr. Sun served on FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee (2017-2020). Dr. Sun is the President of the University of Michigan Association of Chinese Professors (UMACP) (2020-2022) and Vice President of American Chinese Pharmaceutical Association (ACPA) (2013-2019).

**Wrap up and End of Day 1**

**Jennifer D. Ahearn**
Director of Regulatory and Compliance, Pharmaceutical and Medical Devices
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jdahearn@engsys.com

Ms. **Jennifer Ahearn** specializes in pharmaceutical and medical device regulatory compliance. She has served numerous roles within the FDA including bench chemist, domestic and international investigator, technical liaison for FDA's Office of Criminal Investigations, and member of FDA's National Training Cadre making her an expert in the interpretation and application of cGMP regulations relating to pharmaceutical manufacturing. Ms. Ahearn has assisted pharmaceutical and medical device companies preparing for FDA inspections, as well as responding to FDA 483 observations after an inspection. She has worked to resolve technical and FDA compliance issues for virtually all pharmaceutical dosage forms, medical devices and dietary supplements.