FDA/PQRI Workshop: Challenges and Opportunities for Modified Release Oral Drug Product Development

A Forum for Stakeholder Engagement

Speaker/Moderator/Panelist Bios

Tausif Ahmed, PhD
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Dr. Tausif Ahmed is currently working as Vice President & Head-Biopharmaceutics & Bioequivalence in the Global Clinical Management group, IPDO at Dr. Reddy's Laboratories Limited (DRL), Hyderabad. He is responsible for managing all Bioequivalence studies supporting global complex generic products at DRL. He is also involved in PK/Modelling and Simulation activities supporting global generic development. Prior to joining DRL, he was Associate Director and Head-DMPK (preclinical discovery, Clinical dev., and Generic) & Dy. Test Facility Mgt. GLP toxicology dept. at Piramal Enterprises Limited, Mumbai. Dr. Ahmed has been associated with different pharmaceutical companies such as Dr. Reddy's Research Foundation (DRF), Ranbaxy Research Laboratories, Sai Life Sciences Limited, and Piramal Enterprises Limited in the past. He obtained MS in Pharmaceutics from NIPER and PhD in Pharmaceutical Medicine (specialization: Biopharmaceutics and PK/PD) from Hamdard University (Ranbaxy, now Sun Pharma Sponsored). He has been working in the field of drug discovery, development, phase I/II, and generic BA-BE studies for more than 23 years. His area of specialization includes DMPK, metabolite-ID, population PK, PK-PD modelling, and simulation, generic BA/BE studies and GLP bioanalysis. In recent years his focus is on use PBBM/PBPK modelling in generic drug development. He has extensive experience in outsourcing preclinical and clinical studies to CROs both in and outside of India. Dr. Ahmed has contributed to >15 IND filings, multiple ANDAs, and Phase I/II/III regulatory submissions, nationally and globally. He has co-authored two book chapters and over 50 papers and presentations. He is a reviewer for many international journals and is on the Editorial board of Int. J. Pharma Research. Dr. Ahmed is a guest faculty at Hamdard University, NMIMS (Mumbai), NIPER, and various other universities in India. He has also supervised many Master's and PhD students.

Josephine Aimiuwu, PhD
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Dr. Josephine Aimiuwu is a Lead Pharmacologist in the Division of Bioequivalence II (DB II), Office of Bioequivalence (OB), Office of Generic Drug (OGD), CDER, US FDA. In this role, Dr. Aimiuwu lead a team of assessors and perform secondary assessment of the bioequivalence portion of Abbreviated New Drug Applications (ANDAs) and post-approval supplements to support the Generic Drug Program. She has experience evaluating bioequivalence studies for various dosage forms such as immediate/modified release formulations, topical dermatological, ophthalmic, narrow therapeutic, vaginal drug products and abuse deterrent formulations. Dr. Aimiuwu stepped away from the US FDA for four years and gained experience working with USAID-funded Non-Governmental Organizations to leverage resources with consortia of global partners to strengthen and provide technical support to the Generic Drug Regulatory Program in Bangladesh and Nigeria while living abroad. Dr. Aimiuwu obtained her Bachelors in Pharmaceutical Sciences and PhD in Pharmaceutics from The Ohio State University, Columbus, Ohio.

Heather J. Boyce, PhD Lead Pharmacokineticist DTP II | ORS | OGD | CDER | FDA heather.boyce@fda.hhs.gov 	**Dr. Heather Boyce** serves as a Lead Pharmacokineticist for the Modified Release Oral Drug Products Team in the Division of Therapeutic Performance II (DTPII), Office of Research and Standards (ORS), Office of Generic Drugs, Center for Drug Evaluation and Research at the Food and Drug Administration in White Oak, MD. Dr. Boyce brings 13 years of experience in the pharmaceutical industry with expertise in good manufacturing processes (GMP), pharmaceutical manufacturing and product development, clinical trial design and analysis, and Title 21 Code of Federal Regulations (CFR) interpretation and compliance. Prior to her current role, Dr. Boyce served as Acting Team Lead for the Immediate Release Oral Drug Products Team in DTPII. In both roles, Dr. Boyce leads the development of product specific guidance (PSG) for oral drug products. Heather received her PhD in Pharmaceutical Sciences at the University of Maryland, Baltimore, School of Pharmacy where her research focused on excipient properties and formulation design of pharmaceutical drug products. She received her Bachelor of Science degree in chemistry with a minor in mathematics from Temple University of Philadelphia, PA.
Yuqing Gong, PhD Pharmacologist DQMM | ORS | OGD | CDER | FDA yuqing.gong@fda.hhs.gov 	**Dr. Yuqing Gong** is currently a Pharmacologist at the Quantitative Clinical Pharmacology Team in the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Her current role in the division is to utilize quantitative tools such as population pharmacokinetics, modeling and simulations, to address specific questions relate to generic drug development process and/or regulatory decision making. Before joining the FDA, she received comprehensive trainings in pharmaceutical sciences with focuses on drug delivery, pharmacokinetics, and drug-drug interactions. Dr. Gong received her Ph.D. degree in Pharmaceutical Sciences at the University of Tennessee Health Science Center (Memphis, TN, US) in 2020. Her Ph.D. thesis work was to develop a nanoformulation for antiretroviral drugs to suppress the viral load in in the central nervous system across the blood-brain barrier. She also worked on projects that focused on pharmacokinetics and pharmacodynamics of antiretroviral drugs, especially on drug-drug interactions relate to cytochrome P450s

Yoriko Harigaya, PharmD Senior Staff Fellow DB II | OB | OGD | CDER | FDA yoriko.harigaya@fda.hhs.gov 	**Dr. Yoriko Harigaya** is a pharmacologist and staff fellow at the Division of Bioequivalence II, Office of Bioequivalence within the Office of Generic Drugs, CDER/FDA. Prior to joining the Office of Generic Drugs, she served as a clinical pharmacologist and staff fellow of Office of Clinical Pharmacology, Office of Translational Sciences, FDA. In the Office of Generic Drugs, she assesses a wide array of generic drug products. Area of focus for Dr. Harigaya includes the in vitro alcohol dose dumping in modified release dosage forms, complex ophthalmic drug products and topical dermatological drug products with the recent developments in the characterization-based in-vitro approaches.
Rebeka Jereb, PhD Senior Scientist Lek, Sandoz rebeka.jereb@sandoz.com 	**Dr. Rebeka Jereb** is a Senior Scientist in Clinical Pharmacology and Modeling & Simulation group, Sandoz Development Center Ljubljana, Slovenia. She received her Master's degree and PhD in Pharmaceutics at the University of Ljubljana, Faculty of Pharmacy. Dr. Jereb has expertise in physiologically based pharmacokinetic (PBPK) modeling, IVIVC/IVIVR, population PK modeling, model-based BE assessment and has developed various PBPK models for regulatory purposes, e.g., to set drug product specification criteria. She has published several research articles with focus on using PBPK modeling in generic drug development.
Wenlei Jiang, PhD Senior Advisor for Innovation and Strategic Outreach ORS | OGD | CDER | FDA wenlei.jiang@fda.hhs.gov 	**Dr. Wenlei Jiang** is a Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) Expert and currently serves as a Senior Advisor for Innovation and Strategic Outreach in the Office of Research and Standards/Office of Generic Drugs. She is leading complex product classification and research, promoting global harmonization of bioequivalence criteria, and developing opportunities for scientific outreach. She is current US Co-Chair for Global Bioequivalence Harmonization Initiative (GBHI) to facilitate science-driven regulations in the field of bioequivalence assessment. She also chairs International Pharmaceutical Regulator Programme (IPRP) Nanomedicine Working Group, and supports ICH M13, generic drug cluster, and other global regulatory affairs activities. She serves at National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) Scientific Oversight Committee and was the immediate past Chair for Product Quality Research Institute (PQRI) Steering Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

Jyothy John, PhD, RPh Senior Staff Fellow DB I | OB | OGD | CDER | FDA jyothy.john@fda.hhs.gov 	**Jyothy John** is a bioequivalence reviewer in the Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), within the Office of Generic Drugs (OGD). During her tenure in DBI, Dr. John has fulfilled various roles related to bioequivalence and has actively participated in numerous scientific and regulatory assessments of Abbreviated New Drug Applications (ANDAs), including those for complex generic drug products. Dr. John obtained her Ph.D. in Pharmaceutical Sciences from Texas Southern University in Houston, followed by post-doctoral training at the University of Texas, M.D. Anderson Cancer Center, before joining DBI in 2014.
Myong-Jin Kim, PharmD Division Director DTP II | ORS | OGD | CDER | FDA myongjin.kim@fda.hhs.gov 	**Myong-Jin (MJ) Kim** serves as a director of Division of Therapeutic Performance II, Office of Research and Standards, Office of Generic Drugs, CDER, US FDA. MJ leads the group that leverages expertise in clinical pharmacology, formulation science, and human subject protection to conduct research that ensures therapeutic equivalence of generic versions of oral drug products, and to develop product-specific guidances for generic drug developers. MJ graduated from Georgia Institute of Technology in Atlanta, GA, with a Bachelor of Science in chemistry. Subsequently, she received a Doctor of Pharmacy from the Temple University School of Pharmacy in Philadelphia, PA and completed her postdoctoral training in Clinical Pharmacology at Bassett Healthcare in Cooperstown, NY.
John Kirsch, PhD, RPh Head of Product Development Viatris john.kirsch@viatris.com 	**John Kirsch** is the Head of Product Development for Viatris (formerly Mylan), whose group is focused primarily on the development of solid oral dosage forms and the manufacturing processes for their production. Over the past 20+ years, he and his team have developed, gained regulatory approval, and successfully launched well over 100 products, distributed in markets around the globe as generic equivalents to branded products. Prior to joining Viatris, John worked in Formulation Design of Merck Research Laboratories at the West Point, PA site of Merck & Co., where he led a group conducting early stage formulation and process development for tablet and capsule products. He began his career at Merck as a Technical Services Scientist. John is a B.S. Pharmacy graduate from Duquesne University, where he also completed M.S. Pharmaceutics, MBA, and Ph.D. (Pharmaceutics) degrees.

Robert Lionberger, PhD
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Robert Lionberger, PhD serves as Director of the Office of Research and Standards (ORS) in the Office of Generic Drugs (OGD). Dr. Lionberger leads OGD's implementation of the GDUFA science and research commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. ORS also provides pre-submission advice on complex generics through pre-ANDA meetings, product specific guidance and correspondence responses.

He received his undergraduate degree from Stanford University in Chemical Engineering, and a PhD from Princeton University in Chemical Engineering. After his Ph.D., he conducted post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining the FDA 20 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

Haritha Mandula, PhD
Lead Senior Pharmaceutical Quality Assessor
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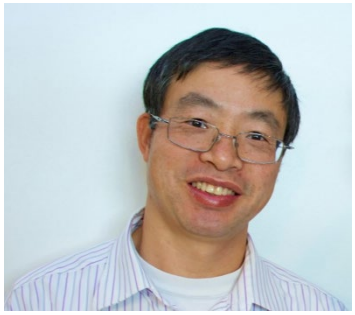
Dr. Mandula is a Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Biopharmaceutics at DPQA VI (Unit 2) \OPQA I\OPQ\CDER\FDA). She is involved with the review of the biopharmaceutics aspects of new and generic drug product submissions. Dr. Mandula also serves on several review committees at the FDA including the biopharmaceutical classification system (BCS) committee and Modeling and Simulation (M & S) committee. Prior to joining OPQA I, Dr. Mandula assessed bioequivalence of generic applications in the Office of Generic Drugs at FDA. Prior to joining FDA, Dr. Mandula was employed as a Pharmacokineticist at Pharmaceutical Product Development (PPD) where she was involved with the design and conduct of Phase 1-Phase 3 pharmacokinetic and biopharmaceutics drug development studies. Dr. Mandula graduated with a Ph.D. in Pharmaceutical Sciences from Texas Tech University with an emphasis on transport pharmacokinetics of drugs/molecules across the blood-brain barrier (BBB). Dr. Mandula is well published in the literature related to drug transport across blood-brain barrier, Biopharmaceutical Classification System, and clinically relevant dissolution testing. Dr. Mandula received several awards at FDA including CDER Regulatory Science Excellence Awards, CDER Special Recognition Awards and FDA Commissioner's Special Citation Awards.

Jason Mao, PhD Senior Pharmacologist DB III | OB | OGD | CDER | FDA jinzhe.mao@fda.hhs.gov 	**Jason Mao** is a senior pharmacologist in the Division of Bioequivalence III, within FDA's Office of Bioequivalence in OGD. Jason has been with the FDA since 2014. During his tenure in FDA, he has been reviewing every aspect of ANDA application for all kinds of drug products and involved in developing guidance pertaining to ANDA (including complex drug products). Prior to joining the agency in 2014, she spent around 10 years in academia, doing research in understanding the physiology of human body and pathogenesis of human diseases (for instance, endocrine disorder, neural tube defects, iron deficiency and overload) as well as developing anti-bacterial enzymes against infectious disease. He received a bachelor's degree in animal Physiology and Biochemistry, master's degree in Veterinary Pharmacology and Toxicology in China Agricultural University and PhD in Neurobiology from Georgia State University.
Patrick Marroum, PhD Distinguished Research Fellow AbbVie patrick.marroum@abbvie.com 	**Dr. Marroum** obtained his pharmacy degree from the University of Pittsburgh in 1984 and a Ph.D. in pharmacokinetics from the University of Florida in 1990. In 1991, he joined the FDA as a reviewer in the Division of Biopharmaceutics. In 1995 he became the team leader in clinical pharmacology and Biopharmaceutics for the Cardio-Renal team. Dr. Marroum was a founding member of the Pediatric Exclusivity Implementation Team (PEDEX) within the Office of Clinical Pharmacology at FDA and served for 14 years. In 2000 Dr. Marroum became the FDA Regulatory Science Expert on in vivo in vitro correlations for modified release formulations. In 2008 Dr. Marroum became the Head of the Biopharmaceutics Group in the Office of New Drug Quality Assessment where he was responsible for all the review, policy and research activities related to Biopharmaceutics and evaluation of the quality of formulations. In 2011, Dr. Marroum became an independent consultant for the pharmaceutical industry. In April 2014, Dr. Marroum took a senior director position in Clinical Pharmacology and Pharmacometrics at AbbVie. In August 2021 Dr. Marroum became a Distinguished Research Fellow within AbbVie. Dr. Marroum also heads the pb/pk modeling group within the clinical pharmacology department at AbbVie.
Iilun Murphy, M.D. Director Office of Generic Drugs | CDER | FDA iilun.murphy@fda.hhs.gov 	**Iilun Murphy, M.D.** is the Director for Office of Generic Drugs since June 2023. Dr. Murphy began her FDA career in 2007, joining CDER's Office of New Drugs, Division of Gastroenterology and Inborn Errors of Metabolism Products as a medical officer. In 2011, Dr. Murphy transitioned to the Center for Tobacco Products serving in various leadership roles within the Office of Science until she returned to CDER in 2020 as the Deputy Director for Clinical and Regulatory Affairs in the Office of Generic Drugs. Dr. Murphy holds a Bachelor of Arts from Cornell University and a Doctor of Medicine from Stanford University School of Medicine. She completed the Harvard University and Boston University Combined Residency Program in Pediatrics and is board certified in pediatric medicine. Dr. Murphy practiced pediatrics in both the private practice and inpatient hospital settings prior to joining the FDA. Dr. Murphy continues to be involved in clinical teaching as an Assistant Clinical Professor of Pediatrics at George Washington University School of Medicine.

James E. Polli, PhD
Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics, University of Maryland
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Dr. James Polli is Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption, involving laboratory and clinical research. He has served as the advisor to 24 PhD graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Center for Research on Complex Generics, each an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program. He is a fellow of the American Association for Pharmaceutical Scientists (AAPS) and served as an editor of Pharmaceutical Research for 12 years. He is the 14th recipient of the APhA Takeru Higuchi Research Prize. He was the recipient of the 2024 AACP Volwiler Research Achievement Award, the 2022 AAPS Global Leadership Award, and the 2021 TOPRA Education Award. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB). He is a member of the Scientific Advisory Board of Simulations Plus.

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Yihong Qiu is the founder of QPD Solutions LLC, a technical service company providing a broad range of scientific and technical expertise, hands-on guidance and trainings on science-based design, development of pharmaceutical products & processes, intellectual properties and commercial manufacturing. Prior to establishing QPD Solutions in 2022, he was a Senior Research Fellow, Formulation Sciences at AbbVie. He has in-depth knowledge and extensive hands-on experience in different stages of drug product lifecycle, from preformulation, biopharmaceutics/pharmacokinetics, drug delivery technology to product/process design & development, scale-up, technology transfer, manufacturing troubleshooting, IP, product line-extension, and regulatory filing. During his 30-year tenure with Abbott/AbbVie, his work resulted in many successful products and processes, patented delivery technologies and products, IVIVC's and biowaivers. His research interests include modified-release delivery, enhancing dissolution and oral bioavailability, IVIVC and science-based regulatory approaches. He is an elected fellow of AAPS with more than 60 publications in journals and books, over 35 patents granted or pending, and numerous invited presentations. He received BS in Pharmacy, MS. in Pharmaceutics from China Pharmaceutical University, and Ph.D. in Pharmaceutics from The University of Iowa.

Bhagwant Rege, PhD Division Director, Biopharmaceutics OPQA I | OPQ | CDER | FDA bhagwant.rege@fda.hhs.gov 	**Dr. Bhagwant Rege** is the Division Director for Biopharmaceutics in CDER/OPQ/OPQA I at the FDA. His division at FDA is responsible for assessment of clinically relevant in vitro release specifications for drug products, in vitro-in vivo correlations (IVIVC), physiologically-based biopharmaceutics models (PBBM), scientific bridging strategies, biowaivers, and BCS classification requests. Most recently he served as a division director for CDER/OPQ/OLDP/ Division of Immediate and Modified Release Products III. Prior to joining FDA in 2010, he worked in industry for many years in oral biopharmaceutics and formulation development groups. 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.
Partha Roy, PhD Director, Office of Bioequivalence (OB) OGD | CDER | FDA partha.roy@fda.hhs.gov 	**Dr. Partha Roy** is a senior regulatory expert with 23 years of drug development experience. He currently serves as the Director of the Office of Bioequivalence in the Office of Generic Drugs, an FDA/CDER Office that oversees assessment of all bioequivalence (BE) data required to support Abbreviated New Drug Application (ANDA) applications. Partha manages a multi-disciplinary program, providing leadership and management oversight to OB Division Management and primary and secondary assessors. Prior to his current role, Partha was Vice President in PAREXEL's Regulatory and Access Consulting Global Business Unit, providing executive management, regulatory strategy and thought leadership focused on driving corporate growth and delivery. Partha spent many years in the pharmaceutical industry as a clinical pharmacologist with increasing responsibility in both brand and generic companies and previously worked as an assessor in the Office of Clinical Pharmacology, CDER, FDA. Partha completed his Postdoctoral Fellowship in Drug Metabolism and Pharmacokinetics (DMPK) from Boston University, Boston, MA. He obtained his PhD in Biochemical Toxicology from University of South Florida, Tampa Florida and B.S. in Pharmacy degree from Jadavpur University, Kolkata, India.

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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 the Zentrallaboratorium Deutscher Apotheker, Eschborn, where she was responsible for the study planning department. Since 1998 she is managing director of SocraTec R&D, Oberursel, an independent contract research institution. In 2007 she founded SocraMetrics, an independent biometrical institute.

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 realised by her companies. She has been involved in the planning and implementation of bioavailability studies from the very beginning, which has resulted in extensive practical experience. Her contribution to the harmonisation of bioequivalence standards began in the 1990s through her involvement in the BioInternational conferences.

Alongside the chemically defined medicinal substances, work is focussing on biotech medicines including biologics, biosimilars, non-biological complex drugs, herbal medicines and endogenous compounds. This work has led to more than 100 scientific publications so far.
Barbara 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 Dermopharmazie[4].

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 the Global Bioequivalence Harmonisation Conference. And finally, she is Member of the board of AGAH.

Robert Schwabe, B.S.
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Robert Schwabe graduated from University of Illinois at Urbana-Champaign with a degree in Biochemistry. Robert started his career at Watson Laboratories – Analytical R&D based in New York USA, and swiftly moved on to Boehringer Ingelheim Pharmaceuticals based in Ridgefield Connecticut USA where he built his career for the last 19 years. His work began in the Pharmaceutics Formulation Development area with lipid-based formulations filled into hard and soft gelatin capsules. He then progressed into the area of high shear wet granulation, fluid bed granulation, and dry granulation processes yielding tablets. The next challenge was manufacturing amorphous solid dispersions, determining their solid-state properties, and evaluating their performance. He then started to work on material sparing approaches and risk assessments for Drug Product. Currently as a Senior Scientist in the Biopharmaceutics group of Material and Analytical Sciences Department, he is focusing on predicting the Drug Product performance using the Tiny-TIM.

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Dr. Shivaprasad is currently a Principal scientist at USP with responsibility for the development of documentary standards (monographs) for small molecular weight medicines intended for the United States Pharmacopeia. She provides support to the Small Molecules Expert Committees.

Prior to Joining USP, Dr. Shivaprasad was a Principal Scientist at Lancaster Laboratories, Lancaster PA, with responsibility for analytical method development, method validation, documenting work required for GMP compliance, writing/reviewing reports and collaboration with Lancaster Laboratories clients. Shankari played a key role in establishing the mass spectrometry facility for bio-analytical method development and validation of large molecules (biologics), under cGMP regulation.

Dr. Shivaprasad also held various positions at other biotech companies in the areas of research and development, mainly on peptide antibiotics and protein aggregation related to Alzheimer's disease.

Dr. Shivaprasad received her Ph.D. in Organic Chemistry from Bangalore University, India, and had subsequent postdoctoral appointments at the University of Zurich, Switzerland, and the University of Tennessee, Knoxville, USA. She has more than 20 publications including review articles in peer-reviewed journals and has also written book chapters.

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Dr. Duxin Sun is the Associate Dean for Research in the College of Pharmacy at the University of Michigan. He is the Charles Walgreen Jr. Professor of Pharmacy and Professor of Pharmaceutical Sciences, and serves as the Director of the Pharmacokinetics (PK) Core. Dr. Sun also has a 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 direct measurement of drug dissolution in human GI tract, drug development, cancer nanomedicine, cancer vaccine, and pharmacokinetics. Dr. Sun developed the STAR system (Structure-Tissue/Cell Selectivity-Activity-Relationship) to address the 90% failure rate in drug development and to enhance its success. He also proposed a drug/nanocarrier-specific anticancer nanomedicine design strategy to enhance clinical efficacy and improve clinical success rates.

Dr. Sun earned his BS in Pharmacy, MS in Pharmacology, and PhD in Pharmaceutical Sciences, and has also received training in Molecular Biology as a visiting scientist. With research experience in both academia and the pharmaceutical industry, Dr. Sun has published over 260 papers (H-index 71) and has mentored 40 PhD students and 75 postdoctoral fellows/visiting scientists.

Dr. Sun is an elected Fellow of both the American Association for the Advancement of Science (AAAS) and the American Association of Pharmaceutical Scientists (AAPS). He has served on the FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee and participated in study sections for the NIH and FDA.

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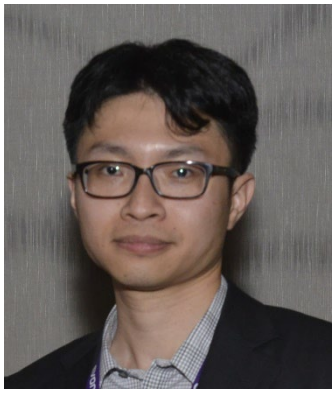

Dr. Wei-Jhe Sun is a senior pharmacologist in Office of Research and Standards at the Office of Generic Drugs. He has been working on projects to improve generic drug quality and provides new standards for FDA. Prior to joining FDA, he worked in the pharmaceutical industry as a formulator. Dr. Sun received his Ph.D. in Pharmaceutics from the University of Minnesota. He has a variety of research interests, including the abuse-deterrent formulation, formulation design, drug delivery, manufacturing sciences and solid-state pharmaceutics.

Nitin K. Swarnakar, PhD
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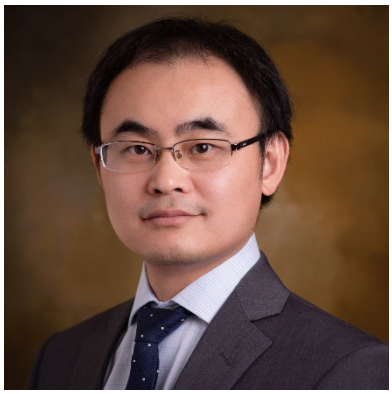
Dr. Nitin Kumar Swarnakar is a seasoned professional with over 15 years of experience in oral and parenteral drug product development. He currently holds the position of North America Application Lab Manager at BASF Corporation, USA. Dr. Swarnakar earned his Ph.D. in Pharmaceutical Science from the National Institute of Pharmaceutical Research and Education in Mohali, India, and also holds B.Pharm. and M.Pharm. degrees in Pharmaceutical Sciences from Dr. H.S. Gour University, Sagar, India.

Dr. Swarnakar joined BASF in 2019 and currently providing leadership, direction, and technical oversight for North America technical service lab (Pharma solution). He is responsible for developing innovative products development strategies by leading/managing people (direct report/junior scientists) and projects, working with CMO, external industry and academic partners, and interfacing with various cross-functional teams.
Before joining BASF, Dr. Swarnakar served as a Senior Scientist at TesoRx Pharma, USA, where he was responsible for developing oral and parenteral formulations. He has also held Post-Doctoral positions at the University of Connecticut, the University of Cincinnati, and Western University of Health Science, where he worked on the development of sustained release, controlled release, and enabled drug products. Additionally, he has two years of experience working in the generic pharmaceutical industry (Ajanta Pharma and Macleods Pharma), where he developed instant release formulations based on 505(j) and 505 (b)(2) strategies.

Dr. Swarnakar is a co-inventor of 11 patents and has authored over 35 publications. He has also presented his research at various national and international conferences. His research interests include enhancing the safety and efficacy of difficult-to-deliver drugs, formulation development for bioavailability enhancement, melt extrusion process development for pharmaceutical manufacturing, and continuous manufacturing of lipid-based drug products.

Fang Wu, PhD Senior Pharmacologist DQMM | ORS | OGD | CDER | FDA fang.wu@fda.hhs.gov 	**Dr. Fang Wu** is a senior pharmacologist reviewer and scientific lead for oral Physiologically-based Pharmacokinetic modeling in Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs (OGD) in FDA. Dr. Wu has been with FDA for more than 12 years. She is responsible for using modeling and simulations tools for reviewing pre-abbreviated new drug applications (pre-ANDA) meeting packages, ANDA consults and controlled correspondences. Prior to joining DQMM, Dr. Fang Wu was a biopharmaceutics reviewer for more than 4 years and responsible for NDA and ANDA reviews. She has been a principal and co-principal investigator for multiple FDA research projects and involved in several guidance working groups and grant review panels.
Rama Yarasani, PhD Chief Scientific Officer Alvogen rama.yarasani@alvogen.com 	**Rama Yarasani, PhD** is the Chief Scientific Officer in Alvogen. In this role Rama is responsible for all aspects of Generics and Brand R&D, including CMC, clinical development, project management, product transfers and commercial validation at all internal and external sites. Rama has more than 25 years of pharmaceutical industry experience, with diverse development experience in complex generics and 505(b)(2) products. Most recently he was the Vice President and Generic R&D Site Head for the Teva Pharmaceuticals Elizabeth, New Jersey. There he managed a R&D team involved in the development of complex generic products including first to file and first to market as well as some brand products for US market. He also oversaw the development of generic products for European, Mexican and Canadian markets. Rama also has post-doctoral research experience on improving the oral bioavailability of macromolecules at Kyoto Pharmaceutical University in Kyoto, Japan. In addition, he is the recipient of numerous awards for his work, as well as published several scientific research articles in peer reviewed journals. Rama holds a BS in Pharmaceutical Sciences, MS in Pharmaceutics and PhD in Pharmaceutics all from Andhra University in India.
Hongling Zhang, PhD Division Director DB II | OB | OGD | CDER | FDA hongling.zhang@fda.hhs.gov 	**Dr. Hongling Zhang** is the director of the Division of Bioequivalence II in the Office of Bioequivalence of OGD, FDA. Since joining OGD in 2008, she has been involved in developing bioequivalence (BE) recommendations and evaluating BE studies in ANDAs for many complex drug products. She is an expert in resolving complex scientific and/or regulatory issues related to BE. In her current role, she provides scientific advice on BE standards through guidances, meetings and controlled correspondences. Dr. Zhang received her Ph.D. degree in Pharmacology from the University of South Florida and completed a post-doctoral training at the Moffitt Cancer Institute.

Zhen Zhang, PhD Master Pharmacologist DB I | OB | OGD | CDER | FDA zhen.zhang@fda.hhs.gov 	**Dr. Zhen Zhang** is a Master Pharmacologist at FDA's Office of Generic Drugs (OGD), Office of Bioequivalence. His expertise encompasses a broad range of areas including data analysis, modeling and simulation, dissolution studies, and topical product evaluations. He co-leads the OGD's Oral PBPK Expert Committee and spearheads the efforts to modernize SAS programs, thereby enhancing the efficiency of the bioequivalence review process. With a rich background in addressing complex bioequivalence challenges, Dr. Zhang has contributed to the development of multiple FDA guidances and the Manual of Policies and Procedures (MAPP). Prior to joining the FDA in 2014, he obtained his Ph.D. in Pharmacology from the University of Wisconsin-Madison and completed his postdoctoral training at the National Institutes of Health.
Liang Zhao, PhD Division Director DQMM | ORS | OGD | CDER | FDA liang.zhao@fda.hhs.gov 	**Dr. Liang Zhao** has been serving as the Director of Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs, CDER/FDA since 2015. He has demonstrated excellence and leadership in drug development and regulatory science in regulatory and industrial settings for new and generic drugs during his 18+ professional tenue including in Pharsight as an associate consultant, BMS as a research investigator, MedImmune as an Associate Director, FDA as Clinical Pharmacology reviewer and Pharmacometrics team leader. He has started several regulatory initiatives including concepting model master files for model sharing and implemented model integrated evidence for generic product development and approval. Dr. Zhao has introduced a broad array of innovative tools in the realm of Machine Learning (ML)/Large language models, drug deliveries and bioequivalence assessment. He has published 110+ peer reviewed articles including 12 papers in ML/AI tools and 8 book chapters. He received the 2023 Gary Neil Prize for Innovation in Drug Development from ASCPT as a recognition to his contribution to clinical pharmacology and pharmacometrics.

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Dr. Zhou is a Senior Pharmacologist in the Division of Bioequivalence III (DBIII), Office of Bioequivalence (OB), Office of Generic Drugs (OGD), Center for Drugs Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Zhou received his Ph.D. in Toxicology from University of Colorado and has a diversified educational background in Computer Science and Microbiology. He joined the OGD in 2014 as a bioequivalence assessor and has been actively involving in multiple scientific and regulatory working groups. He is experienced in assessing the in vivo and in vitro bioequivalence of various dosage forms of complex generic drug products.