








<p>Organized By:</p>  	 <p>PQRI/EUFEPS Global Bioequivalence Harmonisation Initiative</p> <p>6th International Workshop – GBHI 2024 April 16-17, 2024 - Rockville, MD</p>	<p>In Collaboration with:</p>  <p>Hosted by</p> 
--	---	--

Speaker/Moderator/Panelist Bios

<p>Susana Almeida, Ph.D. Secretary General, International Generic and Biosimilar medicines Association (IGBA) salmeida@igbamedicines.org</p> 	<p>Dr. Susana Almeida was nominated Secretary General of the International Generic and Biosimilar medicines Association (IGBA) in January 2024.</p> <p>With over 20 years of substantial contribution to the role of the European and international generic and biosimilar medicines industry’s trade bodies and companies, Susana brings significant experience in the process of international harmonisation of standards through the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), as former topic leader of ICH M9 (BCS Based Biowaivers), member of the ICH Generic Discussion Group and deputy topic leader in the ICH M13 Expert Working Group. Before joining the IGBA, Susana was Clinical Development and Safety Director at Medicines for Europe. She has also worked in clinical trials and pharmacovigilance in Europe and in North America, and her experience includes the pharmaceutical industry and clinical research organizations.</p> <p>Susana is a firm believer that the generic and biosimilar medicines industries play a vital role in fostering worldwide patient access to quality-assured medicines and that a strong off patent sector is essential to a healthy medicines ecosystem</p> <p>She holds a PhD in Clinical Pharmacology from the Faculty of Medicine, Universidad Autònoma de Barcelona (UAB), Spain (2011) and has authored several scientific papers and patents.</p>
<p>Alfredo García Arieta, Ph.D. Head of Area on Pharmacokinetics and Generic Medicines Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) agarciaa@aemps.es</p> 	<p>Dr. García Arieta is Head of Area on Pharmacokinetics and Generic Medicines of the Division of Pharmacology and Clinical Evaluation in the Spanish Agency for Medicines and Health Care Products and member of the Methodology Working Party at the European Medicines Agency as well as the drafting groups on the Guideline on Quality and Equivalence of Topical Products and the Guideline on Orally Inhaled Products. He holds a Bachelor’s degree in Pharmacy (1993), a Master’s degree in Pharmaceutics and Industrial Pharmacy (1996) and a PhD in Pharmaceutical Technology (1999), all from Universidad Complutense, Madrid, Spain. Dr. García Arieta also holds a Master’s degree in Statistics in Health Sciences (2001) from the Universidad Autónoma de Barcelona, Spain. Other affiliations include civil servant of the Body of Pharmacist of the National Health of Spain (2001), Consultant on Bioequivalence in the WHO Prequalification of Medicines Team, observer as WHO representative in the Bioequivalence Working Group for Generics of the International Pharmaceutical Regulators Programme, member of the Expert Advisory Panel on International Pharmacopoeia and Pharmaceutical Preparations (WHO), and EC (European Union) member of ICH M10 EWG.</p>

Gerald Beuerle, Ph.D.

Senior Director

Teva

gerald.beuerle@ratiopharm.de



Gerald Beuerle studied pharmacy at the Julius-Maximilians-University in Würzburg, Germany and got his PhD at the Eberhard-Karls-University of Tübingen. He has been working for ratiopharm GmbH since 1996. After ratiopharm's acquisition by Teva in 2010 he became responsible for Teva Europe as Regional Manager in the Generics Global Biopharmaceutics group. After two years working in early clinical development for New Therapeutic Entities, he is now Senior Director Pharmacokinetics & Regional Clinical Operations Europe / International Markets in the Teva R&D organisation. Being the chair of the Bioequivalence and Clinical Development Working Group of Medicines for Europe and a member of the Steering Committee of the European Federation for Pharmaceutical Sciences (EUFEPS) Network "Bioavailability and Biopharmaceutics" he is involved considerably in discussions related to harmonization and on new bioequivalence guidelines. He was speaker at several Medicines for Europe / EGA, EUFEPS and other meetings and a member of Organizing Committees, e.g. in all six conferences related to the Global Bioequivalence Harmonization Initiative.

Elizabeth Bielski, M.S., Ph.D.

Senior Pharmacologist

DTP-I | ORS | OGD | CDER | FDA

elizabeth.bielski@fda.hhs.gov



Elizabeth Bielski, M.S., Ph.D. is a Senior Pharmacologist working at Division of Therapeutic Performance-I (DTP-I), Office of Research and Standards (ORS), Office of Generic Drugs (OGD), Center of Drug Evaluation and Research (CDER) at the FDA. Prior to her role as a Senior Pharmacologist, she served as a Pharmacologist (2020-2022), a Chemist (2020), and ORISE Fellow (2018-2020) within DTP. Her areas of expertise involve orally inhaled and nasal drug products (OINDPs) and drug-device combination products (DDCPs). She is actively involved in regulatory guidance development and research initiatives to promote generic drug development of OINDPs and DDCPs. Elizabeth completed her Ph.D. in Chemical Engineering from Wayne State University (Detroit, MI, USA) in 2018. She also received her Master of Science in Biomedical Engineering in 2012 and her Bachelor of Science in Biomedical Physics Honors with University Honors in 2011 from Wayne State University.

Heather J. Boyce, Ph.D
Lead Pharmacokineticist
DTP II | ORS | OGD | CDER | US 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.

Rodrigo Cristofolletti, Ph.D.
Assistant Professor
University of Florida
rcristofolletti@cop.ufl.edu



Rodrigo Cristofolletti, Ph.D., joined the University of Florida in 2019 as research assistant professor in the Center for Pharmacometrics and Systems Pharmacology (Orlando) in the Department of Pharmaceutics. He received his B.S. in Pharmaceutical Sciences from the University of Sao Paulo, Brazil in 2004. Dr. Cristofolletti received his Ph.D. summa cum laude from the Johann Wolfgang Goethe University (Frankfurt am Main, Germany) under the supervision of Dr. Jennifer Dressman in 2017. The Clinical Pharmacology & Biopharmaceutics Office of the Brazilian Drug Regulatory Agency (ANVISA) has been Dr. Cristofolletti's place of employment for the last 15 years. While there, his research on oral drug absorption has helped in building scientific foundations for generic policies within Brazilian jurisdiction.

Dr. Cristofolletti received the Simcyp Academic Most Informative and Scientific Report 2017 and 2020 Award for his research on translational modeling strategies to establishing an in vitro-in vivo link. He serves as a member of the Special Interest Group on BCS and Biowaiver of the International Pharmaceutical Federation (FIP) and a member of the Brazilian Pharmacopoeia.

Jack Cook, Ph.D.
Senior Vice President
A2-Ai, LLC
jack@a2-ai.com



Jack Cook, Ph.D. joined A2-Ai in June of 2023 and is a Senior Vice President in the Clinical Pharmacology Department. Prior to that, Jack spent 33 years at Pfizer, Inc. where he worked in a multitude of therapeutic areas. Dr. Cook holds an adjunct faculty position at the University of Michigan College of Pharmacy. He received B.S. degrees in Applied Mathematics and Pharmacy from Ferris State College, and his Ph.D. in Pharmaceutics from the University of Michigan. He has authored/co-authored over 80 peer-reviewed publications. He served as an industrial representative for the United States Food and Drug Administration’s Pharmaceutical Science and Clinical Pharmacology Advisory Committees from 2012 to 2019. He is a fellow of the AAPS. His current interests include improving therapy by optimizing drug delivery and the use of modeling and simulation to make rational decisions in the development of drugs.

Lanyan “Lucy” Fang, Ph.D.
Deputy Director
DQMM | ORS | OGD | CDER | US FDA
Lanyan.fang@fda.hhs.gov



Dr. Lanyan (Lucy) Fang serves as Deputy Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, Office of Generic Drugs (OGD), CDER/FDA. Since her joining OGD in 2014, Lucy has held roles of increased responsibilities, Team Lead of the Quantitative Clinical Pharmacology team, Associate Director, and Deputy Director within DQMM. She has established herself as the FDA expert in the use of quantitative clinical pharmacology approaches in the review and regulation of generic drugs. She co-leads CDER work group tasked with the use of partial area under the curve for the bioequivalence assessment. Prior to her OGD career, Lucy worked as senior clinical pharmacology reviewer in the FDA’s Office of Clinical Pharmacology and senior pharmacokineticist in Merck. Lucy obtained her PhD in Pharmaceutical Sciences from The Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Eduardo Agostinho Freitas Fernandes, MSc.

Therapeutic Equivalence Coordinator
Brazilian Health Regulatory Agency – ANVISA

eduardo.fernandes@anvisa.gov.br

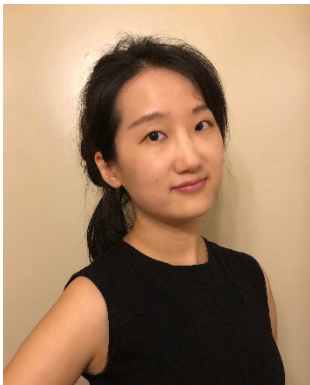


Mr. Fernandes is the Therapeutic Equivalence Coordinator at the Brazilian Health Regulatory Agency (ANVISA). He joined ANVISA in 2005 as a specialist in regulation.

He received his B.S. in Pharmaceutical Sciences from the University of Minas Gerais, Brazil in 2004. Mr Fernandes received his MSc. from the University of Brasilia in 2012. The Clinical Pharmacology Office of the Brazilian Drug Regulatory Agency (ANVISA) is Mr. Fernandes’s place of employment for the last 17 years. During this period, he has been working on topics related to pharmacokinetic as well as building the regulatory policies within Brazilian jurisdiction. He is the representative of Anvisa in forums related to bioequivalence and pharmacokinetics such as ICH.

Yuqing Gong, Ph.D.

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

Anthony J. Hickey, Ph.D.
CEO
Astartein, LLC
ahickey@astartein.com



Dr. Hickey is Professor Emeritus of Pharmacoengineering and Molecular Pharmaceutics of the Eshelman School of Pharmacy, and Adjunct Professor of Biomedical Engineering of the School of Medicine at the University of North Carolina at Chapel Hill. He is a Fellow of the American Association for the Advancement of Science, the American Association of Pharmaceutical Scientists, the Royal Society of Biology, the Royal Society of Medicine and the National Academy of Inventors. He received the Research Achievement Award of the Particulate Presentations and Design Division of the Powder Technology Society of Japan, the David W Grant Award in Physical Pharmacy of the American Association of Pharmaceutical Scientists; Thomas T Mercer Joint Prize for Excellence in Inhaled Medicines and Pharmaceutical Aerosols of the American Association for Aerosol Research and the International Society for Aerosols in Medicine, the Ralph Shangraw Memorial Award for Excipient and Excipient Technology of the International Pharmaceutical Excipient Consortium Foundation. He is founder (and formerly President and CEO) of Cirrus Pharmaceuticals, Inc.; founder (formerly CSO) of Oriel Therapeutics, Inc.; CEO of Astartein, LLC. and; Scientific Advisor to TFF Pharmaceuticals Inc.; Chair of the USP Joint Sub-Committee on Nanotechnology, Member of the USP Pharmaceutical Dosage Forms Expert Committee (DFEC) and Aerosols Sub-Committee of the DFEC of the United States Pharmacopeia. He conducts multidisciplinary research programs in the field of pulmonary drug and vaccine delivery for the treatment and prevention of a variety of diseases.

Rebeka Jereb, Ph.D.
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, Ph.D.

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.

Filippos Kesisoglou, Ph.D.

Distinguished Scientist

Merck & Co., Inc.

filippos_kesisoglou@merck.com



Filippos Kesisoglou is a Distinguished Scientist at Merck & Co., Inc., (Rahway, NJ) where he is currently leading the Biopharmaceutics efforts in the Pharmaceutical Sciences department. Filippos has more than 18 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 across modalities. He has been a key contributor to several new drug applications. He has authored/co-authored 90 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 over the years in several cross-industry and academia consortia and since 2023 has joined the ICH M13 Expert Working Group. He is currently serving as an Editor for Journal of Pharmaceutical Sciences and on the Editorial Advisory Board for the AAPS Journal and Pharmaceutical Research. In 2017 he was elected a Fellow of the American Association of Pharmaceutical Scientists (AAPS).

Chaitanya Koduri

Director for International Government
and Regulatory Engagement

United States Pharmacopeia (USP)

ckk@usp.org



Dr. Chaitanya Koduri is the Director for International Government and Regulatory Engagement for US Pharmacopeia’s Global External Affairs department. In his role, Dr. Koduri handles external regulatory collaboration for the US Pharmacopeia with global regulatory authorities, pharmacopeias and other government stakeholders involved in health and pharmaceutical regulatory policies. He has more than 15 years of experience in multidisciplinary areas including clinical, regulatory toxicology, nanotechnology, pharmaceutical, regulatory, and public health policy. He has held various positions with several clinical and nonprofit organizations in public policy and regulatory affairs where his scientific research; advocacy and policy efforts have focused primarily on strengthening regulatory policy and laboratory practices. Dr. Koduri holds a bachelors degree in Clinical Dentistry from Dr NTR University of Health Science and Masters degree in Nanotechnology from Amrita University in India.

Mark Liu, M.S.

Head of Statistics and Data Management
Viatriis Inc.

Shiyao.liu@viatriis.com



Mark Liu, originally from northeastern China, embarked on his academic journey by earning a B.S. degree in Applied Mathematics from Northeastern University, Shenyang, in 1985. Subsequently, he pursued a passion for Mathematical Statistics, achieving an M.S. degree from Beijing Normal University in 1988.

Transitioning into academia, Mark began his professional career as a Lecturer in the Mathematics Department at Northeastern University. In pursuit of further academic and career growth, he relocated to the United States in 1992. There, he attained an additional M.S. degree in Biometry from The University of Nebraska-Lincoln in 1995.

Mark's professional trajectory led him to roles at Clinical CRO MDS in Lincoln, NE, and Glaxo Wellcome in Raleigh, NC, where he served as a SAS programmer/Biostatistician specializing in clinical pharmacology data science for approximately three years.

Since May 1998, Mark has been an integral part of Viatriis Inc.'s Global Pharmacology Department. Initially joining as a research scientist in statistics, he progressed to become the Head of Statistics and Data Management for early-phase in 2019. Presently, Mark leads the Clinical Data Management and Statistical Science function for all earlier phase programs.

Throughout his career, Mark's expertise has contributed to the successful submission of numerous ANDAs, NDAs, and Biosimilars in various regions including the US, EU, Japan, Canada, China, New Zealand, and Australia.

Junya Makino, Ph.D.

Reviewer
Pharmaceuticals and Medical Devices
Agency (PMDA)

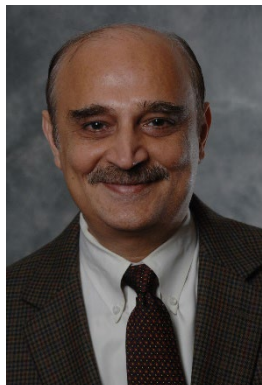
makino-junya@pmda.go.jp



Junya Makino is a reviewer at the office of generic drugs in PMDA/Japan, belonging to this office for about 5 years. He generally reviews new generic drugs and deals with some consultations. He earned his Ph.D. in 2016 before entering PMDA. He has reviewed new drugs at another department and learned drug safety at the Minister of Health and Labor Welfare (MHLW) before he assigned at the office of generic drugs. Usually, he participates in Japanese bioequivalence research group and discusses to revise existing guidelines or publishing new guidance or guidelines for some dosage forms.

Mehul U. Mehta, Ph.D.

Director, Division of Neuropsychiatric
Pharmacology (DNP)
OCP | CDER | US FDA
mehul.mehta@fda.hhs.gov



Dr. Mehta is the Director, DNP (Division of Neuropsychiatric Pharmacology), OCP (Office of Clinical Pharmacology), in CDER (Center for Drug Evaluation and Research), FDA. With a current staff of about 30 PhDs, his division is responsible for reviewing the clinical pharmacology aspects of the Neurological, Psychiatric, Analgesic, Anesthetic, and Addiction drug products from pre-IND (Investigational New Drug) to post-NDA (New Drug Application) stages. He obtained his M.Sc. from University of Bombay in Synthetic Organic Chemistry in 1979, M.S. from University of Houston in Medicinal Chemistry in 1981, and his Ph.D. in Pharmacokinetics from the University of Pittsburgh in 1986 and joined FDA as a reviewer the same year. He has been in his current position for last 23 years over which period he has contributed significantly to the approval of hundreds of NDAs. In addition to his review oversight, administrative, and management responsibilities, he continues to play a significant role in broad based regulatory needs. For example, he represented the agency as the FDA Lead Expert on the ICH M9 EWG for BCS (Biopharmaceutics Classification System) based biowaivers guideline that was finalized in 2021; co-chair of the CDER NTI (Narrow Therapeutic Index) WG; founding co-chair and current member of the CDER BCS Committee; member of the CDER Lifecycle Management Board; co-chair of the FDA-EUFEPS-AAPS sponsored GBHI (Global Bioequivalence Harmonization Initiative) workshop; member of the FIP BCS SIG, etc. Current regulatory research interests include potential of biomarkers as confirmatory efficacy evidence for therapeutics to treat major unmet needs like Alzheimer’s disease, ALS, etc.; therapeutic equivalence of complex modified release products; NTI designation of drug products; adult to pediatric efficacy extrapolation in various indications; possible extension of BCS based biowaivers, and the CDER MIDD (Model Informed Drug Development) initiative. He has authored numerous publications and book chapters, has led WGs for the FDA ‘Hepatic Impairment’ guidance and ‘SUPAC MR’ guidance, and has been a key member for several more guidance WGs. He is a charter member of AAPS and was recognized as AAPS Fellow in 2012.

Paulo Paixão, Ph.D.
Clinical Pharmacology Assessor
INFARMED
Methodological Working Party Member,
EMA
paulo.paixao@infarmed.pt



Paulo Paixão, is an Assistant Professor in Pharmacokinetics and Biopharmaceutics at the Pharmacy Faculty of Lisbon University since 2012. He is also a Clinical Pharmacology assessor at INFARMED (Portuguese Regulatory Agency) since 2003 and a member of the former Pharmacokinetics Working Party (PKWP) from EMA and a current member of the Methodological Working Party MWP, also from EMA. In his regulatory work, he has been involved in the assessment of bioequivalence and general clinical pharmacokinetics in Centralized, Decentralized, Mutual recognition and National Procedures. He has also been Involved in Scientific Advices Procedures both at the National and European level.

Regarding research, his main topics of interest has been related to pharmacokinetics and Therapeutic Drug Monitoring. In particular, he has been involved on creating and optimizing drug development tools, namely, on the use of QSAR and data integration procedures with PBPK models. He has been mainly focused in modelling and simulation on oral drug absorption with several papers with direct implication on bioavailability/bioequivalence regulatory sciences, namely on the establishment of pharmacokinetic metrics for bioequivalence of modified release formulations, and on the evaluation of similarity metrics for dissolution profiles. Latter research interests are related to the better understanding of the physiology of the GI tract and its consequences in clinical variability for oral drug products.

Vivek S. Purohit, Ph.D.
Senior Director
Pfizer
vivek.s.purohit@pfizer.com



Vivek Purohit received his Ph.D. degree in Pharmaceutical Sciences from the University at Buffalo, State University of New York, Buffalo in 2005. He has over 19 years of experience in clinical pharmacology/pharmacometrics in various disease areas such as infectious diseases, cardiovascular, rare diseases and inflammation/immunology. He is deeply committed to the application of quantitative approaches to decision making and answer key development questions for efficient drug development. He has extensive experience in the areas of Inflammation & Immunology with a special focus on dermatology indications. He has consistently applied MIDD principles in areas of infectious diseases, inflammation and topical dermatological agents with high impact on development decisions. He is recognized as an SME for topical dermatological agents where he has championed the development and use of innovative MIDD approaches to design patient PK trials and analysis of PK data. He has developed MIDD approaches for efficient conduct of organ impairment trials and conduct of virtual bioequivalence trials using PBPK models. Vivek has authored/co-authored several peer-reviewed publications, book chapters and holds 4 patents.

Yihong Qiu, Ph.D.

Founder

QPD Solutions LLC

qiu.yihong@qpd-solutions.com

qiu.yihong@outlook.com



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.

Ke Ren, Ph.D.

Deputy Division Director

Division of Bioequivalence III /Office of Bioequivalence/OGD/CDER/FDA

ke.ren@fda.hhs.gov



Dr. Ke Ren is the Deputy Division Director for the Division of Bioequivalence III (DBIII) in the Office of Bioequivalence of Office of Generic Drugs, CDER, FDA. In this role, she leads a team of scientists responsible for the assessment of the bioequivalence section of Abbreviated New Drug Applications. During her time in DBIII, Dr. Ke Ren has developed extensive expertise in generic drug development in various therapeutic areas, including orally inhaled and nasal drug products. She has participated in the drafting of numerous Agency guidances pertaining to bioequivalence. Dr. Ren received her Ph.D. in Pharmaceutical Science from the University of Florida in 2005 and then undertook post-doctoral training at the University of Florida before joining OGD in 2008.

Barbara Schug, Ph.D.

Managing Director

SocraTec R&D GmbH

barbara.schug@socratec-pharma.de



¹ German Pharmaceutical Society

¹ Association for Applied Human Pharmacology

¹ German Society for Pharmaceutical Medicine

¹ Society for Dermopharmacy

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

Helmut Schütz B.Eng.

Owner/Lecturer, BEBAC Vienna/Center for Medical Data Science of the Medical University of Vienna

helmut.schuetz@bebac.at



Helmut Schütz is a chemical engineer by training and worked in the generic industry as well as for twenty years in Austria's first Contract Research Organization, where he established a Laboratory Information Management System certified according to the rules of Good Automated Laboratory Practices, holding senior management positions, most recently as head of the biostatistical department. Since 2004 he is an independent consultant in the domain of comparative bioavailability studies and since 2022 he is a lecturer at the Center for Medical Data Science of the Medical University of Vienna.

He has extensive experience with GCP/GLP, bioanalytics, pharmacokinetics, and biostatistics. His professional career spans 43 years and more than six hundred bioavailability studies. He participated in the BioInternational conferences (1989 – 2005) and the GBHI workshops (2015 – 2022), is a co-organizer of the BioBridges conferences (since 2016), and maintains the global BEBA Internet Forum (since 2004). He gave more than 300 presentations on topics related to bioequivalence.

Amongst others, he is a member of the Austrian Pharmaceutical Society (ÖPhG), the European Federation for Pharmaceutical Sciences (EUFEPS), the American Association of Pharmaceutical Scientists (AAPS), the International Pharmaceutical Federation (FIP), the International Biometric Society (IBS), the International Society for Clinical Biostatistics (ISCB), and the Association for Applied Human Pharmacology (AGAH). Since 2015 he is a member of the editorial board of »Drugs in R&D«.

Gur Jai Pal Singh, Ph.D.
Chief Scientific Advisor
BBSG Pharm Associates
gjps@bbsgpharm.com



Dr. Gur Jai Pal Singh is the Chief Scientific Advisor at the BBSG Pharm Associates since June 2023. Before that he served as a Senior VP and headed the Cipla Respiratory Centre of Excellence - providing end-to-end hand-on leadership for state-of-the-art development of inhalation drug products. Under his leadership, a number of orally inhaled products have been successfully developed for the US, EU, and other geographies. Earlier, he had spent many years of his professional life at the US FDA, where he was also the designated expert on respiratory drug products in the Office of Generic Drugs.

Dr. Singh strongly believes in continued innovations relevant to reduction of product development expenditures, particularly through explorations for cost-effective alternatives to the resource-intensive clinical studies to support bioequivalence (BE) of drugs. While at the FDA, Dr Singh played a lead role in establishing BE of nasal solution sprays and aerosols and, also spearheaded the effort to provide allowance for BE documentation of an inhaled suspension based solely on in vitro testing. Numerous ANDAs have been approved utilizing these approaches.

Dr. Singh commands international recognition and respect for his expertise. He has participated by invitation in a number of expert panels debating regulatory and product development issues related to respiratory drug products, given invited lectures at lead international forums including, but not limited to, RDD, ISAM, PDD and IPAC-RS conferences. He has chaired symposia and co-chaired committees for organization of several international conferences.

With a pioneering mind set Dr. Singh continues to expand his horizon, currently focusing on Inhaled Biologics, Challenges in development of MDIs to accommodate the imminent shift to the low global warming potential propellants, resolution of bioequivalence complexities, and drug repurposing.

Wanjie Sun, Ph.D.
Master Scientist
DBVIII | OB | OTS | CDER | US FDA
wanjie.sun@fda.hhs.gov



Wanjie Sun is a Master Scientist at CDER/OTS/OB/DBVIII supporting review for generic and biosimilar drugs. She is currently the President of the FDA Statistical Association. Wanjie joined the FDA in 2013. Prior to joining the FDA, she worked in industry for a couple of years and at GWU as a PI/Co-PI/Research Scientist for twelve years. Wanjie received her PhD in Biostatistics from George Washington University. She is an active member of multiple international and FDA general guidance WGs such as the ICH M13 and the Statistical Approaches to Establishing Bioequivalence. Wanjie has received numerous awards for her contributions to regulatory research, such as FDA, CDER, and OTS Regulatory Science Excellence Awards. Wanjie is active in organizing scientific sessions and serves as an invited speaker, speaker, discussant, and panelist at various international, national, and internal statistical and regulatory meetings. Wanjie has authored and co-authored over fifty publications with 5000+ citations. She is also a referee for multiple statistical journals.

Duxin Sun, PhD.

Associate Dean for Research, College of Pharmacy

Charles Walgreen Jr. Professor of Pharmacy
Professor of Pharmaceutical Sciences

The University of Michigan

<https://pharmacy.umich.edu/sun-lab>
duxins@med.umich.edu



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.

Nilufer Tampal, Ph.D.

Associate Director for Scientific Quality
Office of Bioequivalence (OB)

OGD | CDER | FDA

nilufer.tampal@fda.hhs.gov



Dr. Nilufer Tampal is the Associate Director for Scientific Quality in OB within OGD. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). Dr. Tampal serves as the FDA Topic Lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. She is an active committee member of the GBHI since 2019. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky and an M.S. in Chemistry from Bombay University, India. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance and has held various leadership positions in OB for the last 15 years. Prior to her FDA career, she gained years of experience in synthesis and analysis of small molecules working as chemist at a multinational pharmaceutical company in India.

Yu Chung Tsang, B.Sc., Ph.M., Ph.D.

President

YCT Scientific Inc.

yuchung.tsang@outlook.com



Dr. Yu Chung Tsang is a consultant in pharmacokinetics, biopharmaceutics and biostatistics, with specialty in the areas of PK bioequivalence and clinical endpoint study design and data analysis/interpretation. He obtained his Bachelor's degree in Pharmacy in 1984 and PhD degree in Pharmacokinetics in 1990 from the University of Toronto. Prior to starting his consulting business, he worked for Apotex Inc. for over 33 years, with his last position being the Chief Scientific Officer, Biopharmaceutics and Biostatistics. His main responsibilities were to provide pharmacokinetic and statistical advice in preparing protocol and study reports for pharmacokinetic/pharmacodynamic and clinical studies of complex drug and biosimilar products, and in the design of bioequivalence/clinical endpoint studies and the analysis of data for the development of traditional generic drug products in the Apotex group of companies. In his career, he was involved with the design and data analysis of over one thousand bioequivalence/clinical studies for the registration of complex drug and biosimilar products and over 300 traditional generic drugs in Canada, US, EU, and many other international marketplaces. He also provided statistical support in clinical trials of new chemical entities at ApoPharma. Dr. Tsang was the Past Chair of the Bioequivalence Committee in the Canadian Generic Pharmaceutical Association, and the Past Chair of the Generic Pharmaceuticals Focus Group of the American Association of Pharmaceutical Scientists. He was also a member of the Bioequivalence Working Group of the Medicines for Europe. Aside from his industrial experience, he also holds an appointment (status only) at the Leslie Dan Faculty of Pharmacy, University of Toronto.

Susanne Urach, Ph.D.



Statistical Assessor

Austrian Medicines and Medical Devices Agency (AGES)

susanne.urach@ages.at



Susanne Urach is currently a statistical assessor at the Austrian Medicines and Medical Devices Agency and part of the Biostatistical Operational Expert Group and ESEC Member of the Methodological Working Party at EMA. She has supported the methodological development in various areas of drug development including group sequential designs, adaptive designs, multi-arm multi-stage designs and multiple comparison procedures.

<p>Carolien Versantvoort, Ph.D. Senior Clinical Pharmacokinetic Assessor Medicines Evaluation Board (MEB) The Netherlands c.versantvoort@cbg-meb.nl</p> 	<p>Dr. Versantvoort has over 20 years experience as senior clinical pharmacology assessor and scientific expert at Medicines Evaluation Board in the Netherlands for new medicines and generics. Since 2014, I am a member of the Pharmacokinetic Working Party / Product Specific Bioequivalence Guidance Drafting Group at EMA, currently as Chair. Further, I am part of the ICH-M12 team as EU expert on the harmonisation of the drug drug interaction guidelines.</p> <p>In the past, experience as scientist in transporter mediated multidrug resistance in oncology at the Free University in Amsterdam The Netherlands, and at University of Cambridge United Kingdom and as Senior scientist in the field of bioavailability of toxicants and risk assessment in children; development of in vitro models to estimate in vivo exposure.</p>
<p>Rong Wang, PharmD, PhD Associate Director Division of Bioequivalence I (DB I) OB OGD CDER FDA rong.wang@fda.hhs.gov</p> 	<p>Dr. Rong Wang is currently the Associate Director in Division of Bioequivalence I (DBI), Office of Bioequivalence (OB), Office of Generic Drugs (OGD). Dr. Wang embarked on her regulatory science career at Food and Drug Administration (FDA) in 2010 and has since gained over 13 years of extensive experience within OGD. Throughout her tenure, Dr. Wang has served as a primary, secondary and tertiary assessor of abbreviated new drug applications (ANDAs), Control Correspondences (CCs), Protocols and various other generic drug related regulatory submissions. Dr. Wang has played an active role in various working groups within the Agency where she has contributed her expertise and experience in revising or developing general guidance for ANDAs and establishing work process for ANDA assessment. Dr. Wang received her undergraduate degree in pharmacy from Shanghai Medical University and her Ph.D. in Microbial and Biochemical Pharmaceutical Science from the Institute of Medicinal Biotechnology, Chinese Academy of Medical Science & Peking Union Medical College. Dr. Wang also holds a Pharm.D. degree from the University of Florida.</p>

Jan Welink, Ph.D.
(Senior) Clinical Assessor
Medicines Evaluation Board (MEB)
j.welink@cbg-meb.nl



Drs. Jan Welink works since 1997 as a (senior) clinical assessor at the Dutch Medicines Evaluation Board (MEB). He was chair of Pharmacokinetic Working Party of the European Medicines Agency (EMA) till September 2019 and thereafter as an expert member of this group till 2022. Currently he is expert member of EMA's Product Specific Bioequivalence Guidelines Drafting Group. Specialist areas of interest are bioavailability, bioequivalence and the BCS. Joined the EUFEPS Steering Committee on Bioavailability and Biopharmaceutics in 2012. He is involved in the WHO Prequalification program, an approval procedure for products (mainly generics) within areas such as HIV/AIDS, tuberculosis and malaria. He is participating in the ICH Generics Discussion Group (IGDG) as Regulatory Chair and has been involved in the ICH harmonization process M09 on BCS-based biowaivers as Rapporteur and in ICH M10 on Bioanalytical method validation as Deputy Topic Leader. Currently he is involved in ICH M13 on Bioequivalence for immediate-release solid oral dosage forms as Regulatory Chair and Topic Leader.

Fang Wu, Ph.D.
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.

Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
OGD | CDER | FDA
leik.zhang@fda.hhs.gov



Dr. Lei Zhang serves as the Deputy Director of Office of Research and Standards within Office of Generic Drugs at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Zhang oversees the implementation of the Generic Drug User Fee Amendments (GDUFA) science and research program to ensure the therapeutic equivalence of generic drug products. Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology at CDER, FDA. Dr. Zhang is an accomplished professional with more than 25 years of combined experiences in the areas of drug research, development and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on science-based regulatory decision making. Before joining FDA in 2002, she worked at Bristol Meyers Squibb as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is currently the Rapporteur for the ICH M13 Expert Working Group that is developing harmonized guidelines on bioequivalence (BE) for immediate-release oral dosage form drugs. She was a member of the ICH Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Lead. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013. She has published more than 130 peer-reviewed papers and book chapters.

Hao Zhu, Ph.D.
Division Director, Division of
Pharmacometrics
OCP | CDER | FDA
hao.zhu@fda.hhs.gov



Dr. Hao Zhu is the director of the Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Science, 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 17 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. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.