Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products

Virtual Public Workshop
November 30th
2021

Speaker Biographies

Géraldine Cellière (Ayral), Ph.D.
VP Application
Simulations Plus, Lixoft Division

Dr. Géraldine Cellière (Ayral) joined Lixoft in 2016 as VP Application. She leads the team in charge of all pre- and post-sales activities (demonstrations, trainings, technical support), research activities (improvement and development of new methods, application to case studies, publications), as well as the MonolixSuite development (product specification and testing). She also leads the consulting services, focused on technical aspects of population PK/PD modeling and simulation. Geraldine holds an engineering degree from Ecole Polytechnique (Paris, France) and a Master in Computational Biology from ETH Zürich (Switzerland), obtained in 2012. After an experience as assistant project manager at SoBios, a start-up developing software for modeling and in silico simulation, she started a Ph.D. in systems biology and multi-scale modeling at INRIA Paris. She received her doctoral degree in 2016.

Murray Ducharme, Pharm.D., F.C.C.P., F.C.P.
President and CEO, Learn and Confirm Inc., Montreal, Canada

Professor Ducharme has thirty years of academic, clinical, and industrial experience in pharmacometrics, infectious diseases, drug metabolism, and clinical drug and biological development. Murray has an undergraduate Pharmacy degree and a graduate diploma in Hospital Pharmacy from the University of Montreal, Canada, and a graduate Pharm.D. degree from the College of Pharmacy and Allied Health Professions of Wayne State University in Michigan, USA. He has presented more than 300 seminars and posters internationally and published more than 150 abstracts, manuscripts, and book chapters in clinical pharmacology. He has been involved in thousands of clinical trials as a PI or sub-PI, and has served as an expert consultant in the drug development field for dozens of pharmaceutical companies located in the USA, Europe, Middle East, Africa, Asia, or Canada. Murray has directed the work of 8 Ph.D. candidates, 6 post-doctoral fellows, and 11 MSc candidates at the University of Montreal. He has trained thousands of pharmacy students in PK/PD and infectious diseases, and has given special workshops and training sessions to regulatory agencies and pharmaceutical companies in Canada, USA, Asia, Middle East, Africa,

and Europe. Murray was elected as a Fellow of the American College of Clinical Pharmacy in 2000 and nominated as a Fellow of the American College of Clinical Pharmacology in 2001. Since 2012, Murray also serves as a Core Member of the Health Canada Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology.

Lanyan (Lucy) Fang, Ph.D.
Deputy Director
DQMM | ORS | OGD | CDER | FDA

Dr. Lanyan (Lucy) Fang currently serves as acting Deputy Director and has served as Associate Director of the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards, since February 2019. Prior to that, she served as Team Lead of the Quantitative Clinical Pharmacology team within DQMM for 5 years. 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. Dr. Fang also served as the co-chair of Generic Drug Science Committee in 2018 and moderated the 2018 Generic Drug Science Day. Prior to her current position, Dr. Fang worked as senior clinical pharmacology reviewer in the FDA's Office of Clinical Pharmacology (2009 – 2014) and senior pharmacokinetist in Merck (2007 – 2009). Dr. Fang obtained her Ph.D. in Pharmaceutical Sciences from The Ohio State University and is a graduate of the Excellence in Government Fellows program (2014-2015).

Michael Fitzgerald, Ph.D.
Head of Injectable Formulation Development
Viatris

Michael Fitzgerald is currently working as Head of Formulation R&D for Injectable products at Viatris, with over 26 years of experience in the Pharmaceutical sector.

He joined Viatris in 2011 and had previously worked for Pfizer in Drug Product development roles supporting early to late stage clinical development. Michael gained a wide range of experience with complex dosage forms (Injectables/Orals/Transdermals) for both generic and innovator products. He led CMC development progression for both ANDAs and NDAs with focus on development approaches supporting clinical equivalence as a drug product progresses from early to late-stage pivotal clinical studies. Michael has a Ph.D. in Physical Chemistry and Surface Science from the University of Reading (UK).

Parmesh Gajjar, Ph.D.
Principal Scientist
Seda Pharmaceutical Services

Dr. Parmesh Gajjar is a principal scientist at Seda Pharmaceutical Services, with responsibility for pharmacokinetic and pharmacodynamic modelling. Dr. Gajjar has a strong mathematical background with a BA (Hons) & MMath from the University of Cambridge (UK) and a Ph.D. in Applied Mathematics from the University of Manchester (UK). Prior to his current role at Seda Pharmaceutical Development Services, Dr. Gajjar built significant experience working on the physical characterisation and development of inhalation medicines, and is known as a renowned speaker at international conferences such as Respiratory Drug Delivery along with having an extensive publication record.

Joga Gobburu, Ph.D.
Professor
School of Pharmacy and School of Medicine, University of Maryland

Dr. Gobburu is Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at the US FDA between 1998 and 2011. He has experience with overseeing the review of 1000s of Investigational New Drug Applications (INDs), over 250 New Drug and Biological Licensing Applications, numerous FDA Guidances and policies pertaining to drug approval and labeling. At the FDA, he was part of the committee responsible for 21st Review Process and provided input into PDUFA planning. He received numerous FDA awards such as the Outstanding Achievement Award and recognized with the Senior Biomedical Research Scientist appointment. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (2008) and Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics (2019). He is also a Fellow of AAPS and ACCP. Dr. Gobburu is on the Editorial Boards of several journals. He has published over 100 papers and book chapters.

Andrew Hooker, Ph.D.
Professor of Pharmacometrics
Department of Pharmacy, Uppsala University

Andrew Hooker is a Professor of Pharmacometrics at Uppsala University, Sweden. Andrew received a B.S. in Physics with a Mathematics Minor at the University of Colorado and received a Masters and then a Ph.D. in Bioengineering from the University of Washington, Seattle. Andrew joined the faculty at Uppsala University in 2006. His research ranges between methodological and applied pharmacometrics, including: optimal (adaptive) experimental design,

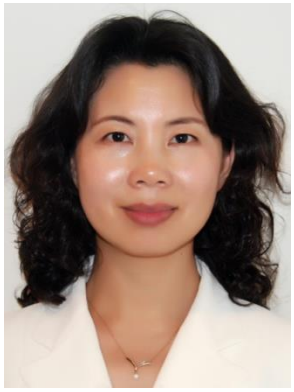
methodological problems associated with building and evaluating pharmacometric models (including using models for bioequivalence evaluation) and the development and use of PKPD models in a range of therapeutic areas and drug classes such as cancer, addiction, PET and biologics. Andrew is a co-developer of a number of software programs including Xpose, PsN and the optimal design program PopED. Andrew has published over 70 papers in peer reviewed journals, supervised 12 students to their Ph.D. degree and mentored 11 post-docs.

Ameya Kohojkar, M.S., R.A.C.
Associate Director, Regulatory Affairs
Teva Pharmaceuticals

Ameya Kohojkar currently serves as an Associate Director, Regulatory Affairs within the sterile and biosimilars organization at Teva Pharmaceuticals. He is responsible for all co-development sterile portfolio comprising several complex products. In the 10 plus years of experience, he has worked on combination products and a variety of dosage forms including topical, transdermal, buccal, injectable, ophthalmic and otic. Prior to Teva, Ameya had primarily worked on generics at Alvogen, Dr. Reddy's Laboratories, Pfizer and Sandoz.

Ameya received his undergraduate degree in Pharmacy from Mumbai University in 2010 and M.S. in Regulatory Affairs for Drugs, Biologics and Medical Devices from Northeastern University in 2012, MA. He received and maintains a Regulatory Affairs Certification from RAPS since 2013.

Bing Li, Ph.D.
Associate Director for Scientific Innovation
OBE | OGD | FDA



Dr. Bing V. Li serves as Associate Director for Scientific Innovation for Office of Bioequivalence within the Office of Generic Drugs. In this role, she provides scientific leadership and expertise for the assessment of the bioequivalence studies submitted by pharmaceutical industry through Abbreviated New Drug Applications (ANDAs), and oversees the scientific programs including guidance development and implementation in Office of Bioequivalence. Dr. Li is an Expert Pharmacologist at the FDA in the area of bioequivalence of aerosolized drug products. Prior to joining FDA in 2004, she was a Research Investigator at Bristol-Myer-Squibb where her responsibilities included formulation identification, development and optimization for oral solid dosage form formulations. Dr. Bing V. Li received her Ph.D. in Pharmaceutical Sciences from University of Wisconsin at Madison in 2001, and a bachelor's degree in Medicinal Chemistry in 1990 in Beijing University, China.

Robert Lionberger, Ph.D.
Director
ORS | OGD | CDER | FDA

Robert Lionberger, Ph.D. 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 Ph.D. 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 18 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

James Polli, Ph.D.
Co-Director of CRCG
Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics University of Maryland
Simcyp

Dr. James E. Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption and formulation, involving laboratory and clinical research. He has served as advisor to 21 Ph.D. graduates. He is co-Director of the recently initiated Center for Research on Complex Generics, an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

Anna Schwendeman, Ph.D.
Co-Director of CRCG
William I Higuchi Collegiate Professor of Pharmacy
Associate Professor of Pharmaceutical Sciences
Biointerfaces Institute
College of Pharmacy
University of Michigan

Anna Schwendeman is William I Higuchi Collegiate Professor of Pharmacy and Associate Professor of Pharmaceutical Sciences at the University of Michigan. Her research focus is on optimization high-density lipoprotein (HDL) nanoparticles for treatment of atherosclerosis, sepsis and drug delivery purposes. In 2016, she co-founded a company EVOQ Therapeutics (www.evoqtherapeutics.com) focused on the use of HDL nanodiscs for delivery of personalized neoantigen cancer vaccines. Dr. Schwendeman received her B.S. from Moscow Institute of Physics and Technology and Ph.D. in Pharmaceutics from The Ohio State University. Prior to starting her academic career in 2012, Dr. Schwendeman spent 12 years in the pharmaceutical industry at Cerenis Therapeutics, Pfizer and Esperion Therapeutics. She was involved in discovery and translation HDL drugs to clinical trials. She successfully submitted FDA INDs for seven different products including nanoparticles, liposome, recombinant proteins, peptides and small molecules. Her laboratory's research in regulatory sciences is focused on analytical characterization of liposomes, polymer microspheres, peptides and biosimilar products. She is co-director of FDA sponsored Center for Research in Complex Generics (http://www.complexgenerics.org). Dr. Schwendeman is an Associate Editor for *Nanomedicine NBM* and *Eur. J. Pharm and Biopharm*.

Yu Chung Tsang, B. Sc., Phm., Ph.D.
Chief Scientific Officer, Biopharmaceutics-Biostatistics
Global Regulatory Affairs

Dr. Yu Chung Tsang is currently working at Apotex Inc. as Chief Scientific Officer, Biopharmaceutics and Biostatistics. He obtained his bachelor's degree (1984) in Pharmacy and Ph.D. degree in the area of Pharmacokinetics in 1990 from the University of Toronto. He has been with Apotex since then. His main responsibilities are 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 analysis of data for the development of traditional drug products in the Apotex group of companies. To date, he has been involved with the design and data analysis of over a thousand bioequivalence/clinical studies for the registration of complex drug and biosimilar products and over 300 traditional drugs in Canada, US, EU and many other international marketplaces. Dr. Tsang is currently the 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. Aside from his industrial experience, he also holds an appointment (status only) at the Leslie Dan Faculty of Pharmacy, University of Toronto.

Raja Velagapudi, M. Pharm., M.S., Ph.D.
Sandoz Inc., a Novartis Company

Raja Velagapudi is currently Executive Director, Clinical Development, at Sandoz Inc., US. Raja received his Master of Pharmacy (1976) from Andhra University (India), Masters in Pharmaceutics (1978) from Duquesne University, and his doctorate in Biopharmaceutics (1983) from University of Texas at Austin. He worked at the FDA as a reviewer for 9 years in different capacities in the Division of Biopharmaceutics (now Office of Clinical Pharmacology). He worked in the brand pharmaceuticals (Ciba-Geigy/Knoll Pharmaceuticals/Abbott) for 13 years in clinical pharmacology and pharmacokinetics. At Barr Laboratories/Teva, he worked on the clinical development of generics drugs and biosimilars for 7 years. Now at Sandoz, he works in clinical development of small molecules through business development and in licensing for the last 9 years. He has over 20 publications and presented numerous abstracts at scientific meetings.

Raja is active in AAPS and served over the years as Chairs of Nutraceuticals focus group, Membership Strategic Oversight Committee, Generic Pharmaceuticals focus group, and Chair-elect for Regulatory Sciences section. He has been an active participant of the FDA GDUFA Generic Drug Sciences and Research Workshops over the years and served as a panelist and speaker for the Modeling and Simulation sessions.

Miyoung Yoon, Ph.D.
Team Lead
Quantitative Clinical Pharmacology Team
DQMM | ORS | OGD | CDER | FDA

Dr. Miyoung Yoon currently serves as the acting Team Lead for the quantitative clinical pharmacology team in the Division of Quantitative Methods and Modeling, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Since her joining the team in 2019, Miyoung has been leading the team's efforts to conduct regulatory and research activities leveraging clinical pharmacology tools and expertise and actively developing collaborations with multiple stakeholders. In addition, she is contributing to applying mechanistical modeling approaches such as physiologically based pharmacokinetic models to support generic drug assessment. Miyoung received her Ph.D. degree in Pharmacology/Toxicology from the School of Pharmacy at Seoul National University in South Korea and completed her post-doctoral training at the U.S. Environmental Protection Agency through the National Research Council of the National Academies of Sciences, Engineering, and Medicine's Research Associateship program.

Liang Zhao, Ph.D.
Director
DQMM | ORS | OGD | CDER | FDA

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. Dr. Zhao has a broad spectrum of scientific and management experience from industry and the regulatory agency. Through his 16-year professional career, he has established his leadership in industrial R&D, quantitative methods and modeling, and model based strategic decision makings in regulatory and industrial settings for generic and new drugs. He initially joined the FDA as a clinical pharmacology reviewer in the Office of Clinical Pharmacology in 2009 and worked as a team leader in the Division of Pharmacometrics in 2013-2015. Prior to joining FDA, he worked at Medimmune for biotech products, BMS for small molecule drug development, and Pharsight as an associate consultant for new drug R&D. Dr. Zhao has a diversified educational background in Pharmaceutical Sciences, Applied Statistics, and Business Administration.

Hao Zhu, Ph.D.
Deputy Director
DPM | OCP | OTS | CDER | FDA

Dr. Hao Zhu is the Deputy 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's in Statistics from the University of Florida. He started his career in modeling and simulation teams at 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 pharmacometrics related submissions and supports pharmacometrics - related policy development across CDER.