SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

AM Plenary Session

Sally Choe, PhD
Director
Office of Generics Drugs (OGD)
CDER | US FDA

Sally Choe, PhD, serves as the director of the Office of Generic Drugs (OGD), where she is the principal authority on all matters related to generic drug review, and scientific advisor to the Commissioner and other agency officials. Previously, Dr. Choe served as deputy director of the Office of Study Integrity and Surveillance (OSIS) in CDER's Office of translational Sciences (OTS). With more than 18 years of experience in global drug development, Dr. Choe is an accomplished leader in both government and the private sector. She is a recognized expert in drug review, clinical pharmacology, biopharmaceutics, and pharmacokinetics. Dr. Choe was senior director at PAREXEL International Corporation, overseeing the Asia-Pacific region and Japan offices, as well as managing the global Vice President Technical consultant group. From 2006 - 2011, Dr. Choe was leader of the metabolism and endocrinology team in FDA's Office of Clinical Pharmacology, OTS. She supervised scientists in clinical and pharmacology review and evaluation of New Drug Applications (NDAs), Biologics License Application (BLAs), and investigational new drug applications (INDs), including original submissions and amendments. Prior to FDA, she also was a clinical pharmacology manager at Pfizer Global Research and a research investigator at Bristol-Myers Squibb. Dr. Choe earned her master's and doctoral degrees in pharmaceutics from the University of Michigan and her bachelor's degree in electrical engineering from Virginia Polytechnic Institute and State University.

Janet Woodcock, MD
Acting Commissioner
US FDA

Janet Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021.

As Acting Commissioner, Dr. Woodcock oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Woodcock began her FDA career in 1986, joining the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs, as well as serving as CBER's Acting Deputy Director for a period of time. She later became Director of the Office of Therapeutics Research and Review in CBER, which included the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. There she led many of the FDA's drug initiatives, including introducing the concept of risk management as a new approach to drug safety; modernizing drug

manufacturing and regulation through the Pharmaceutical Quality for the 21st Century Initiative; advancing medical discoveries from the laboratory to consumers more efficiently under the Critical Path Initiative; and launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively.

In 2004, Dr. Woodcock became Deputy Commissioner and Chief Medical Officer in the Office of the Commissioner. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer.

In 2007, Dr. Woodcock returned as Director of CDER until she was asked to lend her expertise to "Operation Warp Speed" for developing therapeutics during the COVID-19 pandemic, such as evaluating the potential benefits of monoclonal antibody treatments for certain COVID-19 patients. From late 2020, she split her time advising "Operation Warp Speed" on advancing COVID-19 therapeutics while also serving as the Principal Medical Advisor to the Commissioner on key priorities on behalf of the Office of the Commissioner.

Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She also completed further training and a fellowship in rheumatology, as well as held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She is board certified in internal medicine.

Dr. Woodcock has been bestowed numerous honors over her distinguished public health career, most notably: a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Ellen V. Sigal Advocacy Leadership Award in 2016 from Friends of Cancer Research; the Florence Kelley Consumer Leadership Award in 2017 from the National Consumers League; and the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute.

Source: https://www.fda.gov/about-fda/fda-organization/janet-woodcock

Robert Lionberger, PhD
Director
Office of Research & Standards (ORS)
OGD | CDER | US 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 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 18 years ago, he was an Assistant Professor of Chemical Engineering at the University of Michigan.

James Polli, PhD
Co-Director
Center for Research on Complex Generics
CDER | US FDA
And
Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics
University of Maryland

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 MS in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

Anna Schwendeman, PhD
Co-Director
Center for Research on Complex Generics
CDER | US FDA
And
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 BS from Moscow Institute of Physics and Technology and PhD in Pharmaceutics from The Ohio State University. Prior to starting her academic career in 2012, Dr. Schwendeman spent 12 years in 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.

Generic Industry Challenges #1: Model-Integrated Evidence for Generic Drug Development

Amin Rostami, PhD
Professor of Systems Pharmacology
University of Manchester

The scientific work of Professor Rostami covers wide areas of drug development over last 30 years, ranging from pharmaceutics (e.g. bioequivalence) to clinical pharmacology (e.g. mixture pharmacology of drug/metabolites) and beyond (e.g. provision of drug-independent system parameters for scaling from in vitro to in vivo studies).
As a leader in the field of physiologically-based pharmacokinetics (PBPK) and quantitative systems pharmacology, Amin is internationally recognized for his expertise in the use of in vitro information to predict the behaviour of drugs in human body and associated inter-individual variabilities under the so called "bottom up" modelling.
Amin is a Professor of Systems Pharmacology and the Director of the Centre for Applied Pharmacokinetic Research (CAPKR) at the University of Manchester. In addition, he is the Senior Vice President of Research & Development and Chief Scientific Officer at Certara. He facilitates the incorporation of the latest advances in translational modelling to biosimulation platforms offered by Certara to its pharmaceutical clients to accelerate regulatory approvals and bring safer drug products to the patients faster.

More than 280 highly cited articles have been authored by Amin (>17,000 citations, H-Factor = 70). In 2017 ISI listed him as one of the world's most highly cited researchers (under 'Pharmacology & Toxicology'). He was a founding editor of Pharmacometrics and System Pharmacology and serves on the Editorial Boards of several other journals.

Liang Zhao, PhD
Director
Division of Quantitative Methods and Modeling

Office of Research and Standards (ORS)
OGD | CDER | U.S. 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 backgrounds in Pharmaceutical Sciences, Applied Statistics, and Business Administration.

Generic Industry Challenges #2: Complex Product Characterization/Analysis

Zdenko Casar, PhD
Head Early Stage Development Slovenia
Lek Pharm. d.d.
Sandoz Pharmaceuticals

Dr. Zdenko Casar received his PhD in organic chemistry from the Université de Rennes 1, France. He has 17 years of experience in the generic pharmaceutical industry. His experience spans from product pre-development phase to scale-up to industrial scale activities and includes classical as well as complex generic products. The main areas of his research and development work are linked to the synthesis of active pharmaceutical ingredients, drug analytics and drug stability. During his career at Novartis/Sandoz, Zdenko was heading Organic Synthesis Department and Analytics Department at the Sandoz Development Center Slovenia. In addition, he was also Sandoz's Head of Global Portfolio Management API, where he led Sandoz's Global Polymorphism Competence Center and API Portfolio Management Team. Currently, at Sandoz he is Head of Early Stage Development Department Slovenia. Zdenko is also a full professor of Medicinal Chemistry at the Faculty of Pharmacy, University of Ljubljana, Slovenia. He published 55 articles in peer-reviewed journals.

Rachel Dunn, PhD
Director
Division of Pharmaceutical Analysis
Office of Testing & Research (OTR)
OPQ | CDER | US FDA

Rachel Dunn joined the FDA in 2020 as the Director of the Division of Pharmaceutical Analysis. Dr. Dunn earned a PhD in Chemistry from the University of Illinois at Urbana-Champaign. She held positions both in the lab and in management at Chemir Analytical Services (now EAG), including Associate Scientist and Director of Technical Services. Prior to joining the FDA, Dr. Dunn supervised the operations and staff of the Chemistry Department at Washington University in St. Louis.

Generic Industry Challenges #3: In Vitro & In Vivo BE Approaches: Challenges & Opportunities

Beatriz North, MPH
Senior Director
Global Clinical Affairs
Perrigo Pharmaceuticals

Beatriz North, MPH, is the Sr. Director of Global Clinical Affairs with PERRIGO, world's largest producer of store brand products whom over the last 130+ years has more than 400 private label product formulations manufactured and sent to more than 130 U.S. customers. Her responsibilities include global management of clinical functions in the continuing

development of Perrigo's generic Rx products, and support of nutritional infant formulas and over the counter self-care products. Ms. North has over 25 years of extensive hands-on experience in clinical program design and execution of both NDA and ANDA Phase I-IV clinical trials in various therapeutic areas. An accomplished clinical researcher and operations leader with expertise in the areas of clinical trial design and management, strategic planning & execution, Regulatory Compliance, policy development & risk mitigation, quality data collection & analysis and drug product research & development.

Prior to joining Perrigo, Ms. North led the development and management of the Clinical Affairs function as Head of Clinical Operations for Altana, Inc.'s (Fougera) pipeline of generic drug products for nearly 5 years. Her experience also includes serving as an Outsourcing Manager at Purdue Pharma, Sr. Clinical Trials Manager at Forest Laboratories, Lead Program Manager/Clinical Research Associate for Quintiles and study manager with St. Luke's/Roosevelt Hospital, Division of Endocrinology, Diabetes and Nutrition. Ms. North has earned a Master's degree of Public Health from New York Medical College, Valhalla, NY and her undergraduate degree from SUNY at Stony Brook, NY.

Partha Roy, PhD
Director
Office of Bioequivalence (OB)
OGD | CDER | US FDA

Dr. Partha Roy is recognized senior clinical / regulatory strategist and a proven business leader with 21 years of drug development experience in both US FDA and industry involving new drugs, novel biologics, generics and biosimilars.

Currently leads an FDA/CDER Office that oversees the thorough assessment of bioequivalence data required to support Abbreviated New Drug Application (ANDAs). Manages a multi-disciplinary program, providing leadership and management oversight to OB Division Management and primary and secondary assessors. Partha plans, manages, organizes, and directs all the regulatory review operations, program segment(s), functions, and activities of OB. OB establishes bioequivalence specifications for drug products and develops guidelines for bioequivalence reviews, industry protocols, and studies. Prior to his current role, Partha was Vice President in PAREXEL's Regulatory and Access Consulting Global Business Unit, possessing a unique blend of executive management, regulatory strategy and thought leadership focused on driving corporate growth / delivery. In his previous FDA role from 2006-2012, Partha supported US FDA Division of Pulmonary, Allergy and Rheumatology (DPARP) and Office of Non-Prescription Products (ONP) as part of the clinical pharmacology review team.

EDUCATION
Postdoctoral Fellowship, Drug Metabolism and PK, Boston University, Boston, MA
Ph.D., Biochemical Toxicology, University of South Florida, Tampa, FL
B.S. Pharmacy, Jadavpur University, Kolkata, India

Prepared Public Comments

Raja Velagapudi, PhD
Head
Clinical Development
Sandoz Pharmaceuticals

Raja Velagapudi is currently Executive Director, Clinical Development, Sandoz Inc., US. Raja has 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, Chair-elect for Regulatory Sciences section. He has been active participant of the FDA GDUFA Generic Drug Sciences and Research Workshops over the years and served as a panelist for the Modeling and Simulation session in 2020.

Janet Vaughn
Vice President
Regulatory Affairs
Teva Pharmaceuticals

Janet Vaughn is Vice President North America Generics Regulatory Affairs at Teva Pharmaceuticals USA. Janet has been in pharmaceutical regulatory affairs for nearly 30 years. In her current role she provides regulatory guidance, manages and leads teams in strategic decision making, ensuring quality submissions to the Food and Drug Administration. She is intimately involved with all of the respective R&D formulation development, clinical, quality and other functions that have resulted in securing FDA approvals for various products. Janet has held positions in quality control/analytical research, quality assurance and regulatory affairs at various companies with a combined experience of more than 30 years in the pharmaceutical industry.

Martin Ehlert, PhD
Vice President
R & D – Global API & Procurement
Apotex Inc.

Dr. Martin Ehlert obtained a B.Sc. in Applied Chemistry at McMaster University in 1987. He subsequently obtained a Ph.D. in Chemistry at the University of British Columbia in 1992. In 1994, Dr. Ehlert commenced his career in the pharmaceutical industry as an industrial postdoctoral fellow at Phytogen Life Sciences and continued with the company for the next four years working in the areas of API process development, engineering and production operations. In 1998, he joined Apotex Pharmachem Inc., serving in various capacities within API R&D and Operations. In 2015, Dr. Ehlert moved to Apotex Inc. and currently holds the role of Vice President, Global API R&D.

Aloka Srinivasan, PhD
Principal and Managing Partner
Raaha LLC Pharmaceutical Regulatory Consulting

Dr. Aloka Srinivasan is current a Principal and Managing Partner of Raaha LLC, who brings more than two decades of experience in the pharmaceutical industry, including nine years of progressive experience with the U.S. FDA in the Office of Generic Drugs and seven years at National Cancer Institute. Dr. Srinivasan was the Vice President of Regulatory in Lupin Pharmaceutical Inc. and Lachman Consultants Services and Principal at Parexel. Dr. Srinivasan received her Ph.D. at University of Missouri, Columbia working on nitrosamines in cosmetics, tobacco under Dr. Richard N. Loeppky of nitrosamine fame. As a senior scientist at National Cancer Institute, she evaluated nitrosamines in potential drug candidates under Larry K. Keefer, also well known in the field of nitrosamines and nitric oxide. At FDA, Dr. Srinivasan played a significant role in development of the Question Based Review and also spearheaded the establishment of a review division for APIs referenced in Type II DMFs.

AM Plenary Panel

Moderator:
Robert Lionberger, PhD
Director
Office of Research & Standards (ORS)
OGD | CDER | US FDA

(See biography above)

Panelists:
James Polli, PhD
Co-Director
Center for Research on Complex Generics
CDER | US FDA
And
Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics
University of Maryland

(See biography above)

Anna Schwendeman, PhD
Co-Director
Center for Research on Complex Generics (CRCG)
CDER | US FDA
And
William I Higuchi Collegiate Professor of Pharmacy | Associate Professor of Pharmaceutical Sciences
Biointerfaces Institute
College of Pharmacy
University of Michigan

(See biography above)

Amin Rostami, PhD
Professor of Systems Pharmacology
University of Manchester

(See biography above)

Pradeep Bhadauria, MPharm
President and Global Chief Science Officer
Cipla Pharmaceuticals

Pradeep Bhadauria is the President and Global Chief Scientific Officer (CSO) at Cipla.
In his current role, Pradeep leads Cipla's Global Integrated Product Development (IPD) organization to strengthen the company's position as an innovation driven generic and specialty pharmaceutical organization. Pradeep is also a member of the Management Council of Cipla. He joined the organization in Feb 2020.

Prior to joining Cipla he served as Chief Scientific Officer and member of the Executive Committee at Amneal Pharmaceutical Inc. Pradeep also served as Executive Vice President, Global R&D for Apotex Inc. Prior to joining Apotex, he served as Vice President - Generic R&D for Allergan/Actavis. Pradeep has also held leadership positions with increasing responsibilities with Watson Pharmaceuticals Inc, Sandoz Inc and Cardinal Health (now Catalent).

With more than two decades of experience, Pradeep is an industry veteran with expertise in building the industry's largest pipelines for several leading generic and specialty pharmaceutical companies. Throughout his career, his leadership has resulted in the development and filing of more than 250 products, including numerous first-to-file and first-to-market opportunities. He has deep R&D expertise across nearly all dosage form, and has extensive experience on complex generics, 505(B)2, specialty, Biosimilars and other difficult-to-formulate products.
Pradeep holds a Master of Pharmacy (M. Pharm) from the Birla Institute of Technology in India and a Bachelor of Pharmacy from SGSITS, Devi Ahilya University in India. He also holds several patents and has published research in various publications.

Molly Ventrelli, PhD
Senior Vice President
Regulatory Affairs
Fresenius Kabi

Dr. Molly Ventrelli has over 25 years of pharmaceutical experience with an emphasis on regulatory affairs and the ANDA/505b2 generic space. Additional experience in pharmacovigilance, quality compliance, quality control laboratories and product development.

Source: Linkedin and GRx+Biosimis 2020 Conference

Janet Vaughn
Vice President
Regulatory Affairs
Teva Pharmaceuticals

(See biography above - AM Prepared Public Comments)

Rosario LoBrutto, PhD
Executive Director, Head of Scientific Affairs
Sandoz Pharmaceuticals

(See biography above - PM Breakout Session 2)

Karthik Balasubramanian, PhD
Director
Generic Combination Product Development
Teva Pharmaceuticals

Dr. Karthik Balasubramanian, Ph.D. is a director of Generic Combination Product Development at Teva Pharmaceuticals, currently working in biosimilar and semisolid and liquid combination product development. He has over 15 years of experience in all phases of medical device and combination product development, from R&D to Technical Operations. Prior to joining Teva, he has worked in numerous device areas in roles of increasing responsibility, from syringes to large scale diagnostic systems, as well as in sterile injectables and radioactive contrast imaging devices. He has a bachelor's degree in biomedical engineering from Columbia University, and a Ph.D. in Mechanical Engineering from Drexel University.

Kiran Krishnan, PhD
Senior Vice President
Regulatory and Medical Affairs
Apotex Corp.

Kiran joined Apotex in 2006, holding roles of increasing responsibility within Global Regulatory Affairs. Today, he is responsible for overseeing the global regulatory function for Apotex. In addition to creating and executing the company's global regulatory strategy, he also manages a worldwide team of regulatory professionals.
Dr. Krishnan has more than 18 years of regulatory experience in the generic pharmaceutical industry, integrating regulatory strategy into drug development. He was part of the American Association for Accessible Medicines (AAM) team that actively engaged with the US FDA to develop the commitment letter to support the second authorization of Generic Drug User Fee Act. Dr. Krishnan has a Master's degree in Pharmacy with a specialization in Industrial Pharmacy and a PhD in Pharmacy.

Beatriz North, MPH
Senior Director
Global Clinical Affairs
Perrigo Pharmaceuticals

(See biography above)

Zdenko Casar, PhD
Head Early Stage Development Slovenia
Lek Pharm. d.d.
Sandoz Pharmaceuticals

(See biography above)

BREAKOUT SESSIONS

PM Breakout Session 1A

Danny Brinkley, BSc
Director
Global Inhalation, R&D
Teva Pharmaceuticals

Danny Brinkley is a director of Teva Pharmaceutical's global inhalation R&D department performing the role of project lead for product development. He began his career at GlaxoSmithKline and spent 10 years working in respiratory R&D while also earning a B.Sc. in Pharmaceutical Sciences at London Metropolitan University. He then spent 4 years working in early phase respiratory R&D at Novartis before joining Teva in 2012. He has a passion for understanding the intricacies of IVIVC and how this can be applied to improve the efficiency of respiratory product development.

Andrzej Przekwas, PhD
Director
Chief Technical Officer
CFD Research Corporation

Dr. Andrzej Przekwas, CTO and Sr. VP for Research at CFD Research Corp., Huntsville AL, received his education at Wroclaw Institute of Technology in Poland and at Imperial College of Science and Technology in London, England. He is heading the Computational Medicine and Biology (CMB) Div. developing of multi-bio-physics tools, CoBi, for computational pharmacology in military and civilian applications. He has been the PI on several projects with DARPA, DoD, FDA, NIH, CDC and US Pharma in collaboration with US Academia. Dr. Przekwas has published over 290 papers, three book chapters, and currently serves in the Technical Advisory Committee for the US Dep. of Commerce Bureau of Industry and Security.

PM Breakout Session 1A Panel

Moderator:
Andrew Babiskin, PhD
Team Lead
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Andrew Babiskin, Ph.D., currently holds the position of Team Leader for the locally-acting Physiologically Based Pharmacokinetic modeling team in the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards (ORS), Office of Generic Drugs, CDER. His current work focuses on advancing mechanistic-based absorption modeling of local-acting complex products to develop/support novel in vitro and in vivo pharmacokinetic-based methods to establish bioequivalence in lieu of a bioequivalence study with clinical endpoints. Dr. Babiskin received his B.S. degree from the University of Maryland (College Park) in Chemical Engineering and his M.S. and Ph.D. degrees from the California Institute of Technology in Chemical Engineering. He joined the FDA in 2012 as an ORISE postdoctoral fellow in the OGD Science Staff (now ORS) and became an employee within DQMM in 2014.

Panelists:
Andrzej Przekwas, PhD
Director
Chief Technical Officer
CFD Research Corporation

(See biography above)

Guenther Hochhaus, PhD
Professor
Department of Pharmaceutics
University of Florida

Dr. Hochhaus received his Ph.D. in 1984 at the Institute of Pharmaceutical Chemistry, Westf. Wilhems University (Münster, Germany). He completed a postdoctoral fellowship at the University of California-San Francisco and subsequently joined the University of Florida's College of Pharmacy as an Assistant Professor in 1987, where he continues to serve today as a Professor of Pharmaceutics. Dr. Hochhaus' research is interested in evaluating inhalation drugs through in vitro and pharmacokinetic/dynamic approaches. He collaborates with regulatory authorities to improve methodology for drug approval of generic inhalation drugs.

Dr. Hochhaus is a Fellow of AAPS and the American College of Clinical Pharmacology (ACCP). In 1998, he was recipient of the young investigator award of the German Airway and Lung Research Society and received ACCP's Tanabe Young Investigator Award. He was awarded the University of Florida Foundation Research Professorship in 2015-2018; 2019-2022, American College of Clinical Pharmacology's Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award (2019) and is Honorary Regent of ACCP. He has published more than 220 research papers.

Ross Walenga, PhD
Reviewer
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US FDA

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

Danny Brinkley, BSc
Director
Global Inhalation, R&D
Teva Pharmaceuticals

(See biography above)

Andrew Cooper, PhD
Head of Analytical Control & Development
Viatris Global Respiratory Group
Viatris Pharmaceuticals

Dr. Andrew Cooper joined Mylan Global Respiratory Group (now within Viatris) as Head of Analytical & Materials Sciences in 2012, based in Sandwich (UK) and responsible for CMC strategies across Viatris' global portfolio of innovative and generic respiratory products. Andrew earned his B.Sc. in Chemistry and Ph.D. in Pharmaceutical Analysis from Bath University. He began his career working in bioanalysis at Upjohn and drug residue analysis for a UK government agency before spending 14 years with Pfizer Global R&D, where he gained broad experience of API and complex dosage form development. His current interests include understanding the relevance of in-vitro tests for in-vivo product performance and bioequivalence strategies.

PM Breakout Session 1B

Andrew Hooker, PhD
Professor of Pharmacometrics
Uppsala University

Andrew Hooker is a Professor of Pharmacometrics at Uppsala University, Sweden. Andrew received a BS in Physics with a Mathematics Minor at the University of Colorado and received a Master's and then a PhD 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 original research articles, supervised 12 students to their PhD degree and mentored 11 post-docs.

Joga Gobburu, PhD
Professor
School of Pharmacy and Medicine
University of Maryland

Dr. Gobburu is a 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 1999 and 2011. Under his leadership, a Division of Pharmacometrics was formed at the FDA and several policies were established. He is a world-recognized scientific leader in the area of quantitative disease models and their application to decisions. Dr. Gobburu is best known for transforming the field of Pharmacometrics across the world into a decision-supporting science. He also established a Pharmacometrics Fellowship program at the FDA. He received numerous FDA awards such as the Outstanding Achievement Award. 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 (ACCP) (2008) and the Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics in 2019. Dr. Gobburu is on the Editorial Boards of several journals and a Fellow of ACCP, AAPS and International Society of Pharmacometrics. He has published over 100 papers and book chapters.

PM Breakout Session 1B Panel

Moderator:
Lanyan (Lucy) Fang, PhD
Deputy Director
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US 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). 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).

Panelists:

Andrew Hooker, PhD
Professor of Pharmacometrics
Uppsala University

(See biography above)

Joga Gobburu, PhD
Professor
School of Pharmacy and Medicine
University of Maryland

(See biography above)

Liang Zhao, PhD
Director
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US FDA

(See biography above)

Keith Gallicano, PhD
Pharmaceutical Consultant

Keith Gallicano, Ph.D. (Chemistry) is a consultant in clinical pharmacology and biopharmaceutics with expertise in the areas of bioequivalence, drug-drug interactions, and pharmacokinetic, pharmacodynamic and clinical endpoint trial design and data analysis/interpretation. He has 33 years of diverse experience working in the pharmaceutical field, including various positions in government (Senior Research Scientist, Health Canada), academia (Assistant Professor of Medicine, University of Ottawa; Adjunct Professor of Pharmacology and Therapeutics, University of British Columbia), the pharmaceutical manufacturing industry (Head, Clinical and Regulatory Affairs, Axar Laboratories, Inc.; Director, Biopharmaceutics, Watson Laboratories, Inc.) and the CRO service industry (Chief Scientific Officer, Novum Pharmaceutical Research Services; Vice President, Research and Development, Axelson Biopharma Research, Inc.). Dr. Gallicano has co-authored 78 publications, including research papers, reviews, and book chapters. He was a member of the Editorial Board of the Journal of Chromatography and the British Journal of Clinical Pharmacology. Dr. Gallicano has given numerous invited lectures on bioanalytical, pharmacokinetic, clinical and pharmacostatistical aspects of drug interaction and bioequivalence studies, as well as chaired or co-chaired international meetings on these topics. He is a Founder and Trustee of Scientists Advancing Affordable Medicines (SAAMnow), which is a non-profit organization founded in 2018 that provides a dedicated platform for scientists to share cutting-edge research that facilitates the development of high-quality affordable medicines (https://saamnow.com/).

Xiaoming Xu, PhD
Lab Chief, Branch III
Division of Product Quality Research
Office of Testing & Research (OTR)
OPQ | CDER | US FDA

Dr. Xiaoming Xu serves as the Lab Chief of the Branch 3 in Division of Product Quality Research in Office of Testing and Research, where he leads multiple research areas including complex formulations and advanced manufacturing. Dr. Xu is a member of the FDA Nanotechnology Task Force and CDER Nanotechnology Working Group. As the FDA representative, Dr. Xu also participates in various international collaborations in areas relating to nanotechnologies, including standard development and International Pharmaceutical Regulator's Program.

PM Breakout Session 1C

Charlie DiLiberti, MS
President
Montclair Bioequivalence Services, LLC

Charles DiLiberti has over 30 years' experience in the pharmaceutical industry, the majority of which (17 years) were at Barr Laboratories (later acquired by Teva Pharmaceuticals). Charlie built and oversaw Barr's cutting-edge bioequivalence and pharmacokinetics program for generic drugs, small molecule proprietary drugs, and biologics. Charlie left his position as Vice President of Biopharmaceutics at Teva Women's Health Research in 2010 to start his own firm, Montclair Bioequivalence Services, LLC, which provides strategic consulting services around the world in generic, innovative, and biological drug development, biostudy planning/risk management, formulation development guidance, and advanced troubleshooting methods, with a focus on difficult/complex products. Charlie has given numerous public presentations, in the US and internationally, on a wide variety of topics, including pharmacokinetics, bioequivalence, BCS waivers, biosimilars, highly variable drugs, narrow therapeutic index drugs, complex drugs, locally-acting drugs, adaptive sequential bioequivalence designs, analytical chemistry, physicochemical characterization of biological products, generic drug development, etc. In 2018, along with several colleagues, Charlie co-founded Scientists Advancing Affordable Medicines, Inc. (SAAMnow). Charlie holds a BA in Biochemical Sciences from Princeton University and an MS in Chemistry from Stevens Institute of Technology.

Defang Ouyang, PhD
Assistant Professor
University of Macau

Dr. Ouyang has a multidisciplinary background in pharmaceutics & computer modelling, with experience in academia and industry. He obtained his bachelor (2000) and master (2005) in pharmaceutics from Shenyang Pharmaceutical University, China. He completed his PhD in pharmacy at The University of Queensland, Australia, in 2010 and progressed directly to his faculty position (Lecturer in Pharmaceutics, PI) at Aston University (UK). From the end of 2014, he moved to the University of Macau as an assistant professor.

Since 2011, he has pioneered the integration of multi-scale modeling, artificial intelligence and big data techniques in the field of drug delivery – "computational pharmaceutics". He has published 2 books, 5 book chapters and over 70 refereed SCI journal papers. He held 5 approved patents, which had been used in medicinal products. He edited the first book <Computational Pharmaceutics - the application of molecular modeling in drug delivery> (John Wiley & Sons Inc., 2015) in this research area. He is invited to be the Editors-in-Chief of <In Silico Pharmacology> (Springer Nature) and associate editor of <Drug Delivery and Translational Research>. He also serves as the editorial board or scientific advisor of <Asian Journal of Pharmaceutical Sciences>, <Pharmaceutical Research>, <Pharmaceutics> and <Journal of Pharmaceutical Sciences>. He is establishing the first global artificial intelligence (AI)-based formulation platform. He successfully trained 4 PhD and 25 master. Currently his group includes 1 postdoctoral, 3 PhD students and 4 master students.

His research focused on computational pharmaceutics, including:

- Artificial intelligence (AI) of pharmaceutical formulations: to build the database of pharmaceutical formulations and predict pharmaceutical formulations by machine learning approaches.
- Multi-scale modeling in drug delivery: to integrate quantum mechanics (QM), molecular dynamics (MD) and physiologically based pharmacokinetic (PBPK) modeling into drug delivery systems.
- Pharmacoinformatics: big data analysis of pharmaceutical information from the literature, patent, clinical trial and marketed products.

Jerneja Opara, PhD
Leading Scientist
Sandoz Pharmaceuticals

Dr. Opara is a Leading Scientist Analytical Development, SANDOZ Development Center Ljubljana, Slovenia. Jerneja has expertise in modeling and simulation in generic drug development. Among other modeling approaches she uses artificial intelligence based systems, which have been successfully applied to the evaluation of the risk of bioequivalence studies. Jerneja's artificial intelligence modeling in pharmacokinetics started with neural networks and continued with hybrid-artificial intelligence systems: neuro-genetic and neuro-fuzzy systems. Research articles were published and her work was presented at the international conference.

PM Breakout Session 1C Panel

Moderator:
Meng Hu, PhD
Team Lead
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Dr. Hu received both his Bachelor of Engineering in Biomedical Engineering and Ph.D. in Physics from the Zhejiang University, China. He conducted his post-doctoral training at Drexel University, Philadelphia. He joined the FDA's Center for Drug Evaluation & Research as a staff fellow in 2015 and currently serves as a scientific lead in the Division of Quantitative Methods and Modeling under the Office of Research and Standards in the Office of Generic Drugs. His main research interests include the development and application of advanced data analytics tools to promote business intelligence in government, big data management, generation of real-world evidence, and quantitative methods to facilitate assessment for in-vitro bioequivalence study.

His published works include: machine learning (ML) based time-to-event analysis, predictive analysis of first abbreviated new drug application (ANDA) submission for new chemical entities based on ML methodologies, equivalence assessment of complex particle size distribution, quantitative method to facilitate active pharmaceutical ingredient (API) sameness assessment for complex peptide products, and analysis of dissolution failure of solid oral drug products in field alert reports.

Panelists:
Charlie DiLiberti, MS
President
Montclair Bioequivalence Services, LLC

(See biography above)

Defang Ouyang, PhD
Assistant Professor
University of Macau

(See biography above)

Jerneja Opara, PhD
Leading Scientist
Sandoz Pharmaceuticals

(See biography above)

Stella Grosser, PhD
Director
Division of Biostatistics VIII
Office of Biostatistics
OTS | CDER | US FDA

Dr. Grosser is Director, Division of Biometrics 8 in the Office of Biostatistics, CDER. This division provides statistical support to the Office of Generic Drugs. She has been at the FDA for 21 years, beginning as a statistical reviewer for new drug products and serving as a team leader before assuming her current position. Dr. Grosser received her PhD in biostatistics from UCLA and spent several years there afterwards as an assistant professor in the School of Public Health.

Liang Zhao, PhD
Director
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US FDA

(See biography above - AM Plenary Session

Robert Lionberger, PhD
Director
Office of Research and Standards (ORS)
OGD | CDER | US FDA

(See biography above - AM Plenary Session)

Donald Mager, PhD
Professor and Vice Chair
Department of Pharmaceutical Science
University at Buffalo, State University of New York

Dr. Mager is Professor and Vice Chair of Pharmaceutical Sciences at the University at Buffalo, State University of New York. He is also President and CEO of Enhanced Pharmacodynamics, LLC. He has served previously on the Pharmaceutical Sciences and Clinical Pharmacology Advisory Committee to the FDA and as an Associate Editor at CPT:Pharmacometrics & Systems Pharmacology and Pharmacology. He is a Fellow and the current President of the American College of Clinical Pharmacology and is a Fellow and former President of the International Society of Pharmacometrics. Dr. Mager received the ASCPT Malle Jurima–Romet Mid-Career Leadership Award and is also a Fellow of AAPS and AAAS. In addition, he is an expert member of the Board of Pharmaceutical Sciences at FIP and serves on the Scientific Advisory Board to Simcyp. His research focuses on identifying molecular and physiological factors that control the pharmacological properties of drugs by combining experimental data with pharmacometrics and systems pharmacology, with a focus on anti-cancer and immunomodulatory agents. Current efforts seek to combine network-based analysis with empirical and systems models to explore combinatorial anti-cancer drug regimens, heterogeneity in cancer responses, and chemotherapy-induced adverse drug reactions. He served as a Co-Editor of the book Systems Pharmacology and Pharmacodynamics and has contributed to 150+ peer-reviewed publications.

Robert Bies, PhD
Associate Professor
Department of Pharmaceutical Science
University at Buffalo, State University of New York

Dr. Bies is an Associate Professor of Pharmaceutical Sciences at the School of Pharmacy and Pharmaceutical Sciences as well as a member of the Institute for Computational Data Science (ICDS) at the State University of New York at Buffalo.

Prior to this, he served as Associate Professor of Medicine and Medical and Molecular Genetics at the Indiana University School of Medicine and Director of the Disease and Therapeutic Response Modeling program for the Indiana CTSI. He is a consulting scientist at the Centre for Addiction and Mental Health, University of Toronto; North American senior and executive editor for the British Journal of Clinical Pharmacology; and on the editorial boards of the Journal of Pharmacokinetics and Pharmacodynamics, Clinical Pharmacology and Therapeutics, Pharmacometrics and Systems Pharmacology, and Biopharmaceutics and Drug Disposition. He is a member of AAPS, ISoP, ACCP, and ASCPT and served as a board member of ISoP until December 2017. Dr. Bies was elected a Fellow in ISoP in 2020.
Dr. Bies received a BSc degree in Pharmacy from the University of Toronto (1991), a Pharm.D. from the UTHSCSA and the UT Austin (1994), and a Ph.D. Pharmacology from Georgetown University in 1998. This was followed by postdoctoral training at the Center for Drug Development Sciences at Georgetown University. His research has two main tracks: an applied track focuses on the application of pharmacometric approaches in psychiatry, oncology, neurology, and cardiovascular disease; and a novel methods development track, including machine learning approaches to model selection and optimization methods for parameter estimation in dynamic systems.

PM Breakout Session 2

Rosario LoBrutto, PhD
Executive Director, Head of Scientific Affairs
Sandoz Pharmaceuticals

Dr. Rosario LoBrutto has 25+ years of experience in driving R&D, commercial, and operational excellence in development, scale-up and launch preparation of generic/branded products at Merck, Novartis, TEVA and Sandoz. This includes development of APIs/drug products containing small molecules, synthetic polypeptides and proteins and drug-device combination products. Currently at Sandoz he is Head of Scientific Affairs responsible for external partnership product development and oversees due diligence evaluating CMC/bio-analytical aspects of new product opportunities amenable to co-development, in-licensing or acquisition. Moreover, he advances pipeline strategy and leads team for identification, evaluation and prioritization of internal/external assets.

Darby Kozak, PhD
Deputy Director
Division of Therapeutic Performance I
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Dr. Darby Kozak is the Deputy Division Director for the Division of Therapeutic Performance I in the FDA's Office of Generic Drugs. Dr. Kozak leads a group of interdisciplinary scientists on the development of new analytical methods and equivalence evaluation methodologies for complex drug substances and parenteral, ophthalmic, and otic formulations. Prior to joining the FDA, Dr. Kozak was Chief Scientist for Izon Science and Research Fellow at the Australian Institute for Bioengineering and Nanotechnology. Dr. Kozak has a B.Sc. in Chemical Engineering from the University of Washington (Seattle, WA) and Ph.D. in Chemistry from the University of Bristol (United Kingdom).

A Malleswara Reddy, PhD
Head Analytical R&D
Dr. Reddy's Laboratories Limited

Dr Malleswara Reddy Annarapu is having 25 years of experience in Analytical Research and Development and is associated with Dr Reddy's Laboratories Ltd since 1996. He is currently working as Head Analytical Research and development. His expertise includes characterization of natural products, peptides, Glycosaminoglycans, Cross linked Polymers as drug substances, Peptide polymers, PLGA based depot formulations, Liposomes and ophthalmic emulsions using various advanced integrated analytical technologies. He has worked on more than 400 drug products for ANDAs and dossiers catering to various geographies, such as North America, South America, Europe, Russia, China, Japan and

India. He served as USP expert committee member for the Chemical Medicines Monographs 4 Expert Committee (CHM4 EC) for 2015-2020 cycle.

He is an author or co-author of more than 15 scientific papers. He received his masters and M.Phil degree in Analytical chemistry from University of Gulbarga, Karnataka and Doctorate in analytical chemistry from Sri Krishnadevaraya University, Ananthapur, A.P. He received his MBA degree from Narsee Monjee Institute of Management Studies (NMIMS), Mumbai.

PM Breakout Session 2 Panel

Moderator:
Markham Luke, MD, PhD
Director
Division of Therapeutic Performance I
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Markham C. Luke, MD, PhD serves as FDA Supervisory Physician (Dermatology) and Director of the Division of Therapeutic Performance (DTP1) in the Office of Research and Standards, Office of Generic Drugs at FDA. DTP1 is responsible for facilitating pre-application development of complex generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new complex generic drug products. Markham has been at FDA since 1998 serving various roles, including as the Lead Medical Officer for dermatology drugs in the Office of New Drugs at CDER, Chief Medical Officer and Deputy Director for the Office of Device Evaluation in CDRH, and as Acting Director for Cosmetics in CFSAN. Markham has an MD degree and a PhD in Pharmacology from Johns Hopkins University, internal medicine training at Johns Hopkins Bayview Medical Center, and dermatology residency and fellowship at Washington University, St. Louis, MO and at NCI/NIH, Bethesda, MD. Markham is an Associate Professor in Dermatology at the Uniformed Services University of the Health Sciences, Bethesda, MD. Markham has research interests in dermato-pharmacology, clinical pharmacology, product innovation and design – especially for combination drug-device products, clinical study design and endpoints assessment (including patient-reported outcomes) for medical, surgical, and aesthetic products and serves as consultant dermatologist to various parts of FDA.

Panelists:
Rosario LoBrutto, PhD
Executive Director, Head of Scientific Affairs
Sandoz Pharmaceuticals

(See biography above)

Darby Kozak, PhD
Deputy Director
Division of Therapeutic Performance I
Office of Research and Standards (ORS)
OGD | CDER | US FDA

(See biography above)

A Malleswara Reddy, PhD
Head Analytical R&D
Dr. Reddy's Laboratories Limited

(See biography above)

Pahala Simamora, PhD
Director
Division of Liquid Based Products II
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | US FDA

Dr. Pahala Simamora is the Division Director for the Division of Liquid Based Products II in CDER/OPQ/OLDP at the FDA. His division is responsible for collaborative evaluation and assessment of Abbreviated New Drug Applications (ANDAs) for topical/dermatological products, injectables, ophthalmics, otics, oral liquids, nasal and inhalation drug products and making risk-informed recommendations on their approvability. He joined the FDA in 2010 as a Chemistry Reviewer in OGD. Since that time, Pahala has held additional positions with increasing responsibilities including acting Team Leader and Branch Chief in OLDP. Prior to joining the FDA, Dr. Simamora spent 14 years in pharmaceutical industry with experience in product development, process development, scale-up and validation. He received his Ph.D. in Pharmaceutical Sciences from the University of Arizona, his M.S. in Chemistry from Pittsburg State University, and his Chemistry Diploma from the Academy for Chemical Analyses in Bogor, Indonesia.

Ravi Patel, MS
Assistant Vice President and Head of R&D
Cosette Pharmaceuticals

Ravi has 12+ years' experience in pharmaceutical industry for the development and approval of 50+ ANDAs for varies dosage forms. Ravi is currently working as Assistant Vice President and Head of R&D at Cosette Pharmaceuticals. Ravi received his M.S. in Pharmaceutical Manufacturing from the Stevens Institute of Technology, NJ, USA and Bachelor's degree in Pharmacy from K.B Institute of Technology, India.

Dama Venugopala Rao, PhD
Analytical Exert
Dr. Reddy's Laboratories Limited

Dr. Venugopal Rao Dama is having 20 years of experience in Analytical Research and Development and is associated with Dr Reddy's Laboratories Ltd since 2001. He is currently working as Characterization Lead in Analytical Research and development. His expertise includes characterization of natural products, peptides, glycosaminoglycans, cross linked polymers as drug substances, random poly peptides, PLGA based depot formulations, Liposomes and ophthalmic emulsions using various advanced integrated analytical technologies. He has worked on more than 300 drug products for ANDAs and dossiers catering to various geographies, such as North America, South America, Europe, Russia, China, Japan and India. He is an author or co-author of more than 15 scientific papers. He is currently serving as USP-Expert committee member (BIO3 - Complex Biologics & Vaccines) 2020-2025 cycle.

He received masters in Organic chemistry from Sri Krishnadevaraya University, Ananthapur, Anadhrapradesh and Doctorate in analytical chemistry from Sri Krishnadevaraya University, Ananthapur. He received his MBA degree from Narsee Monjee Institute of Management Studies (NMIMS), Mumbai. He is a certified six sigma black belt from American Society for Quality (ASQ)

Ramnarayan Randad, PhD
Branch Chief, Branch II
Division of Lifecycle Active Pharmaceutical Ingredients
Office of New Drug Products (ONDP)
OPQ | CDER | US FDA

Ramnarayan (Ram) Randad Ph.D. is a Branch chief in the Division of Lifecycle API. He joined FDA in 2002 as a review chemist. He has served on number of working group such as Post approval drug substance guidance, Complex Drug Substance, Risk-Based Review, QbR, DMF Completeness assessment team, and US Pharmacopeia monograph development committees. He has frequently represented Agency on CMC and regulatory science issues at various

conferences. He has published 28 research papers and has 14 patents and has authored chapter on “FDA Drug Review and Regulation” in the “Burger's Medicinal Chemistry, Drug Discovery and Development”. Prior to joining FDA he worked in a various research positions at National Cancer Institute, Tibotec, and Neogenesis.

Kevin Hawkins, PhD
Senior Director and Head of Development
Drug Development R&D Operations (Steriles)
Teva Pharmaceuticals

Kevin is a pharmaceutical executive with 25+ years’ experience and knowledge in drug product development and leadership of R&D organisations. Kevin studied Chemistry & Toxicology at the University of Hull, and completed his post-graduate studies at John Moore’s University in Liverpool.
Kevin worked in several analytical laboratories in both the chemical and pharmaceutical industry before joining Teva where he held several positions of increasing seniority for the past 20 years. Kevin’s experience includes roles in Regulatory Affairs as well as Process Development and Analytical Development. Kevin is currently responsible for the development and launch of complex generic products across several platforms including inhalation, ophthalmic and parenteral.

PM Breakout Session 3A

Talia Flanagan, PhD
Head of Biopharmaceutics
UCB

Dr. Talia Flanagan is currently Head of Biopharmaceutics at UCB Pharma in Belgium, accountable for biopharmaceutics strategies on projects across the portfolio from preclinical to commercial phases. Previously, Talia was a Principal Scientist at UCB Pharma, with a focus on strengthening collaboration between the Pharma Sciences, Clinical Pharmacology and DMPK functions to drive integrated risk assessment and cross-functional product development strategies. Before this, Talia worked at AstraZeneca for 12 years, most recently as an Associate Principal Scientist in Biopharmaceutics. During her time at Astrazeneca, she leads the UK late stage biopharmaceutics group and the Global Biopharmaceutics Network for several years. Talia also chaired AstraZeneca’s global cross-functional Bioequivalence Expert Panel, which had oversight of all bridging and bioequivalence strategies within the company. She has extensive and diverse experience of developing and overseeing biopharmaceutics and clinically relevant dissolution strategies on drug projects, with particular focus on oral products Phase 2 to post-launch. Her research interests include clinically relevant dissolution tests and specifications, IVIVC/IVIVR, biowaivers, and biopharmaceutics in patients and special populations. Talia was EFPIA Deputy Topic Lead on the ICH M9 (BCS-based biowaivers) Expert Working Group, and is currently representing EFPIA as Deputy Topic Lead on the ICH M13 (bioequivalence studies) Expert Working Group. She has been an invited speaker at several national and international conferences/workshops in the field of biopharmaceutics and clinically relevant specifications, and has authored/co-authored 40 manuscripts and 3 book chapters in these fields. Talia received a Master of Pharmacy with honors (2002) and Doctor of Philosophy (2007) degrees from the Welsh School of Pharmacy, Cardiff University.

Igor Legen, PhD
Head of Clinical Development
Sandoz Pharmaceuticals

Igor Legen is Head Clinical development at Sandoz development center, Slovenia. He has a PhD in Pharmacy, specializing in the absorption of active substances from the gastrointestinal tract. Throughout his professional career he has been involved in bioequivalence risk management including permeability studies across model intestinal epithelia, development of innovative dissolution apparatus (i.e. artificial stomach and intestine) and PBPK modelling. He has experience with more than 300 bioequivalence studies as well as BCS based biowaivers. He was a Member of the Expert Working Group for preparation of ICH guideline M9 on biopharmaceutics classification system based biowaivers. He is

an author of 20+ original scientific articles and 12 granted patents from pharmaceutical technology and biopharmaceutics fields and also gives lectures to pharmacy students at Faculty of pharmacy, University of Ljubljana.

PM Breakout Session 3A Panel

Moderator:
Heather Boyce, PhD
Active Team Lead
Division of Therapeutic Performance II
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Dr. Heather Boyce works for the Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research at the Food and Drug Administration in White Oak, MD. Heather has over 10 years of experience in the pharmaceutical industry including high level expertise in good manufacturing processes (GMP), pharmaceutical product development, bioequivalence trial design and analysis, and generic drug regulation.
In her current role, Heather proposes and manages the technical aspects of intramural and extramural research contracts and grants that help support and guide generic drug policy, regulation and decision making. Heather also reviews and provides product specific guidance recommendations for the generic industry.
Heather's current topics of interest and research are focused on clinical study design, clinical pharmacology and generic equivalency of abuse deterrent formulations.

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.
Heather can be reached at heather.boyce@fda.hhs.gov

Panelists:
Talia Flanagan, PhD
Head of Biopharmaceutics
UCB

(See biography above)

Igor Legen, PhD
Head of Clinical Development
Sandoz Pharmaceuticals

(See biography above)

Paul Seo, PhD
Director
Division of Biopharmaceutics
Office of New Drug Products (ONDP)
OPQ | CDER | US FDA

Paul received his BS in Biochemistry from the University of Maryland at College Park in 1999. Shortly thereafter, he received his Ph.D. in Pharmaceutical Sciences in 2004, from the University of Maryland, Baltimore, focusing in the area of biopharmaceutics and pre-formulation. Paul has worked for the FDA for over 15 years, and has gained experience in the Office of Generic Drugs, Office of Pharmaceutical Science, and Office of New Drug Quality Assessment. He currently oversees the direction and review processes of the Division of Biopharmaceutics in the Office of New Drug Products, as

they pertain to NDA and ANDA related Biopharmaceutics issues. Additionally, his professional experience included time at the National Institute of Standards and Technology, Shire Labs, Inc., and the Walter Reed Army Institute of Research.

Bing Cai, PhD
Director
Division of Liquid Based Products I
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER | US FDA

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

Sid Bhoopathy, PhD
Senior Vice President of Operations
Absorption Systems

Dr. Sid Bhoopathy is Senior Vice President of Operations at Absorption Systems, a Pharmaron Company. In this capacity, Dr. Bhoopathy's primary responsibility is to execute the scientific and strategic growth of Absorption Systems. He possesses a thorough understanding of the processes that support lead optimization, candidate selection, and preclinical drug development. His in-depth appreciation of the nuances of the Biopharmaceutics Classification Systems (BCS) as it relates to biowaivers, drug formulation, and drug development in general, have made him a highly sought-after speaker and a strong advocate for use of BCS. In addition, he has led the commercialization of Absorption Systems' portfolio of cell-based transporter assay systems. Prior to joining Absorption Systems, Dr. Bhoopathy received his Bachelor's degree in Pharmacy from Kakatiya University and a PhD in Pharmaceutics from Virginia Commonwealth University. His current research interests are in the areas of complex drug product development, expanding BCS based biowaivers, and improving in vitro procedures and outcomes for drug transporter assays.

Fang Wu, PhD
Scientific Lead
Division of Quantitative Methods and Modeling
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Dr. Fang Wu is a senior pharmacologist reviewer and scientific lead for oral Physiologically-based Pharmacokinetic modeling in Division of Quantitative Methods and Modeling. Dr. Wu has been with FDA for more than 9 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 biopharmaceutics 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.

Tausif Ahmed, PhD
Director
Global Clinical Management
Dr. Reddy's Laboratories

Tausif Ahmed is currently working as Head-Bioanalytical & Biopharmaceutics in the Global Clinical Management group, IPDO at Dr. Reddy's Laboratories Limited (DRL), Hyderabad. He is responsible for managing the Bioanalysis of all Bio studies and preclinical studies supporting global complex generic products at DRL. He is also involved in PK/Modeling and Simulation activities supporting global generic development. Prior to joining DRL, he was Associate Director and Head-DMPK (preclin discovery, Clinical dev. and Generic) & Dy. Test Facility Mgt. GLP toxicology dept. at Piramal Enterprises Limited, Mumbai. He 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 past. He obtained MS in Pharmaceutics from NIPER and Ph.D. in Pharmaceutical Medicine (specialization: Biopharmaceutics and PK/PD) from Hamdard University (Ranbaxy Sponsored). He has been working in the field of drug discovery, development and generic BA-BE studies for more than 16 years. His area of specialization includes DMPK, metabolite-ID, population PK, PK-PD modelling and simulation, generic BA-BE studies and GLP bioanalysis. He also has experience in designing and conducting generic BA/BE studies, facing regulatory audits (GLP certification at Ranbaxy and Piramal), Phase I & Phase II studies. He has extensive experience in outsourcing preclinical and clinical studies to CROs both in India and outside. Dr. Tausif has contributed to > 12 IND filings, ~300 ANDAs and multiple Phase II/III regulatory submissions, nationally and globally. He has co-authored 2 book chapters and over 40 papers and presentations. He is a reviewer for many international journals and is on the Editorial board of Int. J. Pharma Research. He is a guest faculty at Hamdard University, NMIMS (Mumbai), NIPER and various other universities in India. He has also supervised many Master's and Ph.D. students.

Sandra Suarez-Sharp, PhD
Vice President
Regulatory Affairs
Simulations Plus Inc.

Dr. Sandra Suarez Sharp obtained her bachelor's degree in Industrial Pharmaceutical Chemistry in 1989 from National School of Biological Sciences, IPN, Mexico. She worked for Johnson and Johnson Mexico for 5 years as a research and development engineer. In 1994, she joined the Department of Pharmaceutics, School of Pharmacy, University of Florida, Gainesville, FL, USA as a graduate student and obtained a Ph.D. in Pharmaceutical Sciences in 1997. She spent two years at UNC Chapel Hill as a postdoctoral fellow. She worked at the US FDA for more than 20 years supporting the offices of clinical pharmacology and the division of biopharmaceutics. She joined Simulations Plus in March 2020 as the vice president of regulatory affairs. Dr. Suarez-Sharp has a large number of publications related to the areas of dissolution, in vitro-in vivo correlation, establishment of specifications with clinical relevance, and physiology-based biopharmaceutics modeling (PBBM)

PM Breakout Session 3B

Nageshwar Thudi, PhD
Senior Director
Global Generic/Biosimilar Clinical Development & Operations
Teva Pharmaceuticals

Dr. Nagesh Thudi is currently working as Senior Director-Global Generics and Biosimilar Clinical Development and Operations at Teva Pharmaceuticals, Parsippany, NJ, USA. Prior to Teva, he worked at Allergan, Actavis, Watson, Ranbaxy, Pharmamedica, Chembiotek and VIMTA Labs.
Dr. Thudi has 22 years of Generic as well as CRO experience in the field of Bioequivalence and Clinical efficacy trials. Dr. Thudi got his Ph.D., degree in pharmacy from university of Jadavpur, India. Dr. Thudi has 25 publications in international peer reviewed journals and also presented at various conferences. His interest is to harmonize various regulatory requirements in the field of Bioequivalence and Efficacy trials.

Bill Brashier, MBBS & DTCD
Group Head
Respiratory Clinical Development
Sandoz Pharmaceuticals

Bill Brashier Medical Doctor (MBBS), Diploma in Chest diseases, Fellow of European Respiratory Society (2009) Currently Head of Respiratory Clinical development at Sandoz, India. Bill has been trained at National Heart and Lung Institute (NHLI), Imperial College, London UK. He has significantly contributed to respiratory research, including drug development since last 18 years particularly inhaled drugs in Asthma and COPD. Bill has several research papers published in high impact peer reviewed journals. He is also reviewer of several premier respiratory journals.

PM Breakout Session 3B Panel

Moderator:
Mitchell Frost, MD
Deputy Director
Division of Therapeutic Performance II
Office of Research and Standards (ORS)
OGD | CDER | US FDA

Dr. Mitchell Frost serves as Acting Deputy Director of the Division of Therapeutic Performance II, Office of Research and Standards, Office of Generic Drugs, CDER/FDA. Since his joining the Office of Research and Standards in 2016, Dr. Frost has been helping to oversee GDUFA-funded clinical research and to manage clinical issues related to product-specific guidance development and pre-application support. One of Dr. Frost's main focuses is on the protection of the human subject participants of clinical studies. He has served on FDA's Institutional Review Board (IRB) and currently serves as a Human Subject Protection Liaison to the FDA IRB and the Office of the Chief Scientist.

Panelists:
Nageshwar Thudi, PhD
Senior Director
Global Generic/Biosimilar Clinical Development & Operations
Teva Pharmaceuticals

(See biography above)

Siddharth Chachad, MBBS, MS
Executive Vice President and Head
Global Clinical Management
Dr. Reddy's Laboratories Limited

Dr. Siddharth Chachad is a clinical pharmacologist with 19 years of experience in global clinical development strategy for registration of new drugs, complex generics, orphan medicines, biosimilars and even vaccines:

- Strategic leader with success history of marketing authorizations granted worldwide for medicinal products across dosage forms and therapeutic segments
- Medical Safety Leadership with comprehensive theoretical and practical knowledge of the legal and regulatory requirements surrounding global pharmacovigilance
- Preclinical and Clinical regulatory consultancy and expert representation at the Scientific Advice Meetings with the heath authorities including EMA, MHRA, USFDA, TGA and WHO
- Preclinical and Clinical Strategy Design for registration of conventional vaccines, multivalent "universal" vaccine and Covid products including Sputnik
- Internationally acclaimed speaker at various seminars and conferences on clinical research and pharmacovigilance

- Expert faculty in the functional areas of clinical development and pharmacovigilance at the teaching and training institutes, India, Czech Republic and Netherlands
- Audit experience of over 100 audits including Clinical, BE and Pharmacovigilance audits
- Author of 25+ publications in scientific journals & congress presentations, and expert signatory for 1000+ clinical and nonclinical dossier modules

Yu Chung Tsang, PhD
Chief Scientific Officer
Biopharmaceutics & Biostatistics
Apotex Inc.

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 advices in preparing protocol and study report 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 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.

William Chong, MD
Associate Director for Clinical Affairs
OGD | CDER | US FDA

Dr. William Chong is an Internist and Endocrinologist who has worked at FDA since 2012. Dr. Chong started his FDA career in the Office of New Drugs before joining the Office of Generic Drugs in 2019 where he is currently the Associate Director for Clinical Affairs. In his current role, Dr. Chong lends support to the generic drugs program across an array of activities in order to provide safe, effective, and high quality generic drugs.

Raja Velagapudi, PhD
Head
Clinical Development
Sandoz Pharmaceuticals

(See biography above - AM Prepared Public Comments)

Bill Brashier, MBBS & DTCD
Group Head
Respiratory Clinical Development
Sandoz Pharmaceuticals

(See biography above)

Beatriz North, MPH
Senior Director
Global Clinical Affairs
Perrigo Pharmaceuticals

(See biography above - AM Plenary Session)

Kachikwu Illoh, MD

Director
Division of Clinical Review
Office of Safety and Clinical Evaluation (OSCE)
OGD | CDER | US FDA

Kachi Illoh serves as the Director of the Division Clinical Review, Office of Safety and Clinical Evaluation, Office of Generic Drugs, in the Center for Drug Evaluation and Research (CDER). He oversees staff involved in the assessment of bioequivalence trials with clinical endpoints, submitted to the Food and Drug Administration (FDA) to support Abbreviated New Drug Applications (ANDAs). He has led a team in CDER's Office of Compliance, which evaluates compliance with Good Clinical Practice (GCP) regulations and implements compliance and enforcement actions under the Bioresearch Monitoring (BIMO) program. In 2019, he served as a reviewer on the Grant Application Review Panel for FDA's Office of Orphan Products Development. Previously, he served as a medical officer with the Office of New Drugs (OND) Immediate Office and the Division of Neurology Products. Before joining the FDA in 2008, he held academic appointments at medical schools in the University of Texas Health System, where he served as an attending stroke neurologist. He completed his neurology training at Howard University Hospital, Washington, DC; vascular neurology fellowship training at the National Institutes of Health (NIH), Bethesda, MD. Also, he received an MPH degree from the George Washington University, Washington, DC. He is board certified in neurology and vascular neurology.