Drug Dissolution in Oral Drug Absorption

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration

Public In-Person Workshop
May 23-24, 2023 | 8:20 AM – 4:30 PM Eastern Time

Biographies

Lynne S. Taylor, PhD
Retter Distinguished Professor of Pharmacy
Department of Industrial and Physical Pharmacy
Purdue University

Dr. Lynne S. Taylor is the Retter Distinguished Professor of Pharmacy in the Department of Industrial and Physical Pharmacy, Purdue University. Prior to moving to academia, she spent several years working at AstraZeneca in Sweden developing new drugs. Lynne received a Bachelor of Pharmacy degree with First Class Honors from the University of Bath in the UK. Her PhD was undertaken at the University of Bradford, UK, in the area of Pharmaceutical Technology. After her PhD, Lynne was a postdoctoral researcher at the University of Wisconsin-Madison. Research in Lynne's group is directed toward exploring the science underlying the preformulation, formulation, and manufacturing of drugs and other bioactive substances, with a particular focus on poorly water soluble compounds. She has published more than 350 peer reviewed articles. Lynne has received a number of awards including the Coblentz Society Craver Award in Applied Vibrational Spectroscopy (2014), the Journal of Pharmaceutical and Biomedical Analysis Outstanding Manuscript award (2007), the Ebert prize for the best manuscript in the Journal of Pharmaceutical Sciences (2012), and the Pharmaceutical Research meritorious manuscript award (2012), the Provost's Award for Outstanding Graduate Student mentor (2019), and the Dale E. Wurster Research Award (2020). Lynne is a Fellow of the Royal Society of Chemistry and the American Association of Pharmaceutical Scientists, and is editor-in-chief of the ACS journal, *Molecular Pharmaceutics*. In her spare time, she enjoys running, swimming, biking, and cooking.

Martin Brandl, PhD, Dr. habil
Full Professor
Department of Physics, Chemistry & Pharmacy
University of Southern Denmark

Dr. Martin Brandl received his PhD ("summa cum laude") in 1990 and Dr. habil. degree in 1998, both from Albert-Ludwigs-University, Freiburg, Germany.

Since 2009, he is serving as a full professor of Pharmaceutics at Department of Physics, Chemistry & Pharmacy, University of Southern Denmark (SDU), Odense DK. Prior positions include: Arctic University, Tromsø Norway (UiT, full professor 1998-2008), Albert-Ludwigs-University (lecturer 1992-98), School of Pharmacy, Univ. London (PostDoc 1991-92), and Scientific officer/head of pharmaceutical affairs & registration Gry-Pharma GmbH, Kirchzarten (now part of Teva; 1986-91). His management experience comprises functions as head of department (UiT), (founding) director of the pharmacy bachelor-& master-program (SDU), management team of COST-action (UNGAP), and PI of approx. 10 research projects and consortia.

Currently, Martin serves as Editor in chief (*European Journal of Pharmaceutical Sciences*, Elsevier (since 2012) and leads (together with prof Annette Bauer-Brandl) a team of ten PostDocs, guest-researchers, and PhD-students. Earlier he has mentored/(co-)supervised approx.10 PostDocs, 30 PhD- and 50 bachelor- /master-students.

His research is focusing on oral delivery of poorly soluble drugs, especially the mechanistic understanding of candidate-enabling formulations and in vitro tools for predictive performance ranking (artificial biomimetic barriers, combined dissolution/permeation, microdialysis sampling); Another focus is on the elucidation of colloidal and micro-particulate structures relevant for oral drug absorption.

https://portal.findresearcher.sdu.dk/en/persons/mmb
https://orcid.org/0000-0003-3561-5016

Werner Weitschies, PhD
Professor of Biopharmaceutics
Center of Drug Absorption and Transport
University of Greifswald, Germany

Dr. Werner Weitschies is Professor of Biopharmaceutics at the University of Greifswald, Germany. He studied Pharmacy at the Free University of Berlin (1983-1987) and received his PhD in Pharmaceutical Technology in 1990. From 1990 to 1995, he worked at Schering AG in Berlin in the field of injectable contrast agents. From 1996 to 1998, he was head of a research department in the field of medical applications of magnetic nanoparticles at the Free University of Berlin. In 1998, he was appointed Professor at the University of Greifswald. His main research areas are the investigation of the interplay between physiology and drug delivery systems with focus on the gastrointestinal tract. He is the author or co-author of more than 300 scientific articles and 31 patents.

Christos Reppas, PharmD, PhD
Professor in Pharmaceutics
Department of Pharmacy
National and Kapodistrian University of Athens, Greece

Dr. Christos Reppas' research interests focus to the effects of dosage form characteristics, gastrointestinal physiology on intraluminal performance of xenobiotics, and the development of in vitro tests that are predictive of the intraluminal dosage form and drug performance. He has supervised 13 completed PhD Theses. He is co-author of more than 160 peer reviewed papers and chapters in international journals and books, two books on Biopharmaceutics and Drug Disposition, and one patent. He is a member of the editorial board of *The AAPS Journal*, *European Journal of Pharmaceutical Sciences*, *Journal of Pharmacy and Pharmacology*, and *Journal of Drug Delivery Science and Technology*. He is/has been PI in several EU funded training and research programs (OrBiTo, PEARRL, COLOTAN, InPharma, AGePOP) and one COST action (UNGAP, vice-chair). Dr. Reppas is currently Chair of the Department of Pharmacy at NKUA (2022-2024).

Zongming Gao, PhD
Research Chemist
DCDA | OTR | OPQ | CDER | FDA

Dr. Zongming Gao is a Research Chemist in the Office of Testing and Research (OTR) within the Office of Pharmaceutical Quality (OPQ) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) where he has worked after he received his doctorate degree from the Department of Chemistry, University of Cincinnati in 2004. His work focuses on in vitro dissolution testing of oral solid dosage formulations to support regulatory review and surveillance. As a principal investigator, Dr. Gao made a great effort to enhance robust dissolution methods, and some of his results have become requirements or recommendations in the FDA guidance for industry. His research on development of state-of-the art technology for biorelevant in vitro testing methods provides another approach on agency's consideration of biowaiver extension and BE for generic drug products. Being a subject matter expert (SME) in dissolution testing, Dr. Gao has been actively participating in providing consults and training to support regulatory review, respond citizen petitions, and assess FDA external funding applications. He also frequently consults for the PFs and stimuli articles for Compendial Operations and Standards, and serves as the Government Liaison to the USP expert panel for drug dissolution. Dr. Gao has published more than 40 peer reviewed articles and co-authored 2 book chapters. He has been on two doctoral dissertation oral defense committees, and mentored five postdoctoral fellows (ORISE). Since joining FDA, he has received a Critical Path funding award, outstanding poster award, and numerous group honor awards for outstanding team efforts on meeting organizing committee, product review/recall, ICH harmonization, ADF research, nitrosamines study, and others.

Patrick Augustijns, PhD
Full Professor
University of Leuven

Dr. Patrick Augustijns has a Pharmacy degree, a Master in Medical Sciences, and a PhD in Pharmaceutical Sciences. Prior to becoming a professor at the University of Leuven (Belgium), he performed postdoctoral research at the University of Kansas and at GSK (North Carolina). In 2003, Patrick Augustijns became chairman of Drug Delivery and Disposition.

The laboratory has a strong track record in the biorelevant profiling of intestinal drug absorption, covering all underlying processes including dissolution, precipitation, degradation, and permeation. For this purpose, a wide range of simulation models is available, including the in vitro Caco-2 cell culture system, the Ussing chambers system, and the in situ intestinal perfusion system. In addition, Drug Delivery and Disposition is able and licensed to perform whole animal absorption and pharmacokinetic experiments. Physiology-based pharmacokinetic modelling is available to extrapolate experimental data to human pharmacokinetics.

One of the lab's major research topics involves the aspiration and in-depth characterization of gastrointestinal fluids, including the evaluation of intraluminal drug and formulation behavior in humans. The latter involves the bio-relevant and predictive evaluation of absorption-enabling strategies, including solubilization and supersaturation of poorly soluble drugs.

As age or disease may add an additional layer of (patho)physiological variability, dedicated projects have also been initiated to profile gastrointestinal fluid variability in children, elderly, and patients with Parkinson's disease.

All aspiration and absorption studies are supported by well-developed analytical equipment (LC-UV, -fluo, -MS/MS) to assess the concentrations of endogenous compounds found in the intestinal fluids, as well as of drugs and excipients in biological matrices.

Patrick Augustijns is (co)author of ± 380 (peer reviewed) papers in international journals and more than 350 presentations at scientific meetings.

Since 2008, Patrick Augustijns is an AAPS-fellow. In January 2019, he was awarded an honorary doctorate from Uppsala University.

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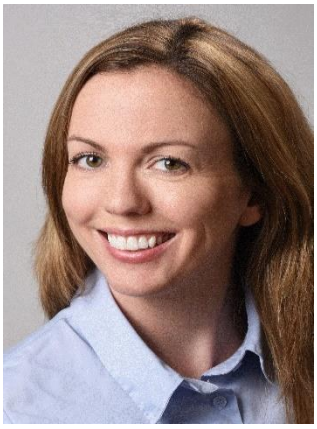
Kerstin Julia Schaefer, PhD
Senior Associate Director
Material and Analytical Sciences Department
Boehringer-Ingelheim Pharmaceuticals Inc.



Dr. Kerstin Schaefer is currently heading the *Patient Centric Drug Delivery* team within the *Advanced Therapeutics Medicinal Products (ATMP)* section of the Material and Analytical Sciences Department of Boehringer-Ingelheim in Ridgefield, CT. Prior to her expat assignment into the US, she has worked for 10 years in different positions in the Pharmaceutical Development of Boehringer-Ingelheim in Biberach, Germany. Positions covered early and late stage drug product development, including clinical trial manufacturing and external collaborations. She started at BI as a postdoc and scientific champion for the IMI project OrBiTo in 2012. Dr. Schaefer is a pharmacist by training and completed her PhD in Pharmaceutical Technology and Biopharmaceutics at the University of Southern Denmark, focusing on predictive in vitro tools and advanced analytics for amorphous solid dispersions. Her passion is non-conventional formulations for all kinds of APIs, their scientific understanding, and investigation of their in vivo performance.

Corinne Jankovsky, PhD
Senior Scientist
Material and Analytical Sciences Department
Boehringer-Ingelheim Pharmaceuticals Inc.

Dr. Corinne Jankovsky is currently working in the *Drug Delivery and Material Sciences* section of the Material and Analytical Sciences Department of Boehringer-Ingelheim in Ridgefield, CT. She is a Physical-Chemist by training and received her PhD at Université Bordeaux I, France. She has over 15 years of experience at Boehringer-Ingelheim as a Preformulation scientist, focusing on oral drug absorption through investigating the impact of physicochemical properties of drug substance, as well as formulation design of drug product on their performance during different development stages. Her areas of expertise are drug dissolution/diffusion, precipitation/supersaturation, amorphous solid dispersion, and predictive bio-relevant in vitro dissolution method development to understand in vivo performance of oral formulations. Currently she is supporting Harmonizing biopredictive methodologies through Product Quality Research Institute (PQRI) working Group as an effort to understand in vivo behavior of oral dosage forms. She has made numerous presentations at various scientific meetings/conferences such as AAPS in her expertise areas.

Shinji Yamashita, PhD
Visiting Professor of College of Pharmaceutical Sciences
Ritsumeikan University

Dr. Shinji Yamashita is a Visiting Professor of College of Pharmaceutical Sciences at Ritsumeikan University, Japan. After receiving a master's degree of Pharmaceutical Science in 1982 from Kyoto University, he started his carrier as an academic scientist in Jyosai University, then, he moved to Setsunan University and was promoted to Assistant Professor (1989), Associate Professor (1995), and full Professor (2001-2023). He received his PhD degree in 1987 from Kyoto University supervised by Prof. Hitoshi Sezaki. From 1992 to 1993, he worked at the University of Michigan, College of Pharmacy, as a post-doctoral research fellow under Prof. Gordon L. Amidon.

His research interests include drug absorption, oral formulation technology, drug delivery and PK/PD analysis. Especially, he has been focusing on the prediction and improvement of intestinal drug absorption and has developed various methodologies to evaluate oral drug absorption. He has published over 160 original research articles and book chapters. In 2014, he was designated as a president of The Academy of Pharmaceutical Science and Technology Japan (APSTJ). He has received the JSSX Award (The Japanese Society for the Study of Xenobiotics) (2011), The Minister Prize of Economic, Trade and Industry (2013), The Distinguished Science Award from International Pharmaceutical Federation (FIP) (2016), and APSTJ Award (2018).

Annette Bauer-Brandl, PhD
Full Professor
Department of Physics, Chemistry & Pharmacy
University of Southern Denmark

Dr. Annette Bauer-Brandl is a full Professor in Pharmaceutical Technology at the University of Odense in Denmark.

She is a licensed pharmacist, earned a dr.rer.nat. degree with her work on mathematical description of physical processes during tablet compression. Her prize-winning Handbook on Formulation, Manufacturing and Quality Assurance of Solid Dosage Forms ("Die Tablette") is now available in 4th ed.. With well over 100 published research papers, she is among the top-cited authors in Pharmaceutical Sciences at her university. Currently she serves as an expert at the EDQM (European Directorate for Quality of Medicines) in Group 12 (Dosage Forms and Methods) and the Danish Medicines Agency.

At the University of Odense, she played a key role in building the curriculum for pharmacy students. She mentored/supervised 16 postdocs and PhD students, several of whom entered academic careers and are now holding (associate) professor positions. She is a co-inventor of the biomimetic artificial barrier PermeaPad®, which has been patented and out-licensed by her university.

Her research focus in Drug Transport & Delivery is the solid state of drug substances, the dissolution process and solvation of drug molecules in different solvents, and prediction of oral bioavailability of drugs.

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Leah W. Falade, PhD
Pharmacologist
Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Leah W. Falade has over 15 years of regulatory experience. She is a pharmacologist in the Division of Biopharmaceutics within the Office of Pharmaceutical Quality (OPQ) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). Dr. Falade assesses biopharmaceutics data contained in New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Investigational New Drug Applications (INDs) across a wide range of therapeutic areas. She previously served as a Team Leader in the Division of Bioequivalence I (DBI) within the Office of Generic Drugs (OGD).

Dr. Falade obtained her BS in Chemistry from the University of North Carolina at Greensboro, MS in Chemical Engineering from North Carolina Agricultural and Technical State University, and PhD in Pharmaceutical and Biomedical Sciences from the University of Georgia.

Okpo Eradiri, PhD
Branch Chief in the Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Okpo Eradiri obtained his PhD in Pharmaceutical Sciences from the University of Alberta, Canada. He joined FDA in 2012 and is currently a Branch Chief in the Division of Biopharmaceutics, Office of New Drug Products, Office of Pharmaceutical Quality. Prior to his FDA career, Okpo was in academia and later worked in the pharmaceutical industry within the clinical pharmacology space for more than 20 years, principally in Biovail corporation, Valeant Pharmaceuticals, and Parexel Consulting. While in industry, he made significant contributions to the regulatory filings and approval of several flagship products. Okpo continues to leverage his industry experience in the assessment of a variety of submissions in FDA.

Jennifer Dressman, PhD
Group Leader
Pharmaceutical Technology
Fraunhofer Institute of Translational Pharmacology and Medicine

Dr. Jennifer Dressman, who retired as Professor of Pharmaceutical Technology at the Goethe University in 2021, now leads a formulation group at the Fraunhofer Institute of Translation Medicine and Pharmacology in Frankfurt am Main, Germany.

Prof. Dressman's research interests focus principally on predicting the in vivo performance of drugs and dosage forms after oral administration. She is best known for pioneering the use of Biorelevant dissolution testing and her contributions to combining dissolution testing with physiologically based pharmacokinetic modelling, in order to achieve quantitative predictions of oral drug absorption.

In recognition of her research excellence, she has been made a Fellow of the AAPS, the CRS, AJPST, and the FIP. In 2008, she was awarded the Distinguished Scientist Award of the FIP and in 2017 was named the International Woman Pharmaceutical Scientist of the Year by the APSTJ. In 2022, a special issue of the Journal of Pharmaceutical Sciences was dedicated to her contributions to the Pharmaceutical Sciences.

Haritha Mandula, PhD
Senior Pharmaceutical Quality Assessor
BB3 | DB | ONDP | OPQ | CDER | FDA

Dr. Haritha Mandula is a Senior Pharmaceutical Quality Assessor in the Division of Biopharmaceutics, ONDP, OPQ in the FDA's Center for Drug Evaluation and Research. She received a PhD in Pharmaceutical Sciences from Texas Tech University, Health Sciences Center in 2005. Haritha has experience supporting review of the biopharmaceutical aspects of new and generic drug product review submissions across a wide range of therapeutic areas. Haritha also serves on several review committees at the FDA including the Biopharmaceutical Classification System (BCS) committee, In Vitro In Vivo Correlations (IVIVC) committee and Physiologic Based Biopharmaceutics Modeling Committee (PBBM). She has been the recipient of several awards at FDA including CDER Regulatory Science Excellence Awards, CDER Special Recognition Awards and FDA Commissioner's Special Citation Awards.

Abu Serajuddin, PhD
Professor of Industrial Pharmacy
St. John's University

Dr. Abu Serajuddin is Professor of Industrial Pharmacy at College of Pharmacy and Health Sciences, St. John's University, Queens, New York. Prior to joining academia in 2008, he worked in the pharmaceutical industry for 32 years in scientific and managerial positions. In his latest positions in the industry, he was Executive Director and the US Head of Pharmaceutical R&D at Novartis. He published over 130 scientific papers and book chapters, and he is a co-inventor in 13 issued patents. He also made over 150 invited presentations at national and international conferences. He served in many leadership positions in the AAPS and received several of its major awards, including AAPS Fellow (1998), AAPS Research Achievement Award in Formulation Design & Development (2010), AAPS Research Achievement Award in Manufacturing Science & Engineering (2014), and AAPS Lipid-based Drug Delivery Outstanding Research Award (2015). He is also the recipient of the IPEC Ralph Shangraw Memorial Award, the highest scientific recognition given by the International Pharmaceutical Excipients Council (IPEC). For his achievements and academic excellence, St. John's University bestowed him the College of Pharmacy and Health Sciences Distinguished Alumni Award (2018) and the University President's Medal for Outstanding Achievement (2019).

Kevin Wei, PhD
Pharmacologist, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Kevin Wei is a Biopharmaceutics reviewer at the Division of Biopharmaceutics, Office of New Drug Products, Office of Pharmaceutical Quality (OPQ), Center of Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Wei has been conducting Biopharmaceutics assessment for a wide variety of drug products submitted under Investigational New Drugs (INDs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and supplements. Dr. Wei started his career at Novartis. Prior to joining FDA in 2017, he had over 10 years of experience in the pharmaceutical industry working on drug development programs from proof of concept to regulatory approval. Dr. Wei received his Ph.D. in Pharmaceutical Sciences from the University of North Carolina at Chapel Hill.

Kimberly Raines, PhD
Branch Chief, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

Dr. Kimberly Raines is a Supervisory Pharmacologist at the FDA. Dr. Raines and her team lead efforts in establishing in vitro dissolution/release specifications and assessing biopharmaceutics topics (e.g., biowaiver, bridging, IVIVC, etc.) in regulatory submissions. Additionally, Dr. Raines develops CDER biopharmaceutic guidances, leads research projects within her division, and provides subject matter expertise to FDA policy initiatives. She has co-authored original research articles and presented on bioequivalence, biowaivers, in vitro dissolution, and physiologically based model informed quality risk assessment. Her tenure at the Agency began in the Office of Generic Drugs 15 years ago as a bioequivalence reviewer and controlled correspondence team lead. Prior to joining the FDA, Dr. Raines received post-doctoral training at the University of North Carolina Lineberger Comprehensive Cancer Center where she was an UNCF-Merck Fellow. In 2006 she received her PhD in Pharmaceutical Sciences from the University of Maryland School of Pharmacy and a BS in Chemistry with a concentration in pharmacology from Duke University.

Bhagwant Rege, PhD
Division Director, Division of Biopharmaceutics
ONDP | OPQ | CDER | FDA

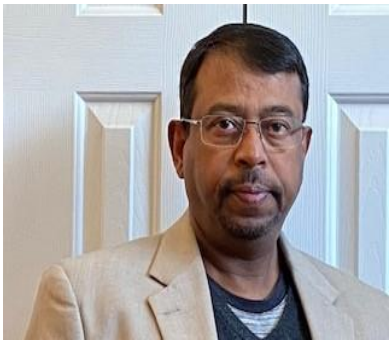
Dr. Bhagwant Rege is the Division Director for the Division of Biopharmaceutics in CDER/OPQ/Office of New Drug Products at the FDA. His division at FDA is responsible for assessment of clinically relevant in vitro release specifications for drug products, in vitro-in vivo correlations (IVIVC), physiologically-based biopharmaceutics models (PBBM), scientific bridging strategies, biowaivers, and BCS classification requests. Most recently he served as a division director for CDER/OPQ/OLDP/ Division of Immediate and Modified Release Products III. Prior to joining FDA in 2010, he worked in industry for many years in oral biopharmaceutics and formulation development groups. Bhagwant has served as a team leader and review chemist in the Office of Generic Drugs where he was part of the team that developed the QbD examples for the generic industry. He is a member of the FDA Emerging Technology Team (ETT) and ICH Q12 Expert/Implementation Working Group. He served as FDA liaison on the USP expert committee on dosage forms general chapter (2015-2020). Bhagwant received his BS and MS in Pharmacy from the University of Mumbai, India and a PhD in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Anette Müllertz, PhD
Professor in Oral Drug Delivery and Industrial Relations
University of Copenhagen, Denmark

Dr. Anette Müllertz is professor in oral drug delivery and industrial relations at the University of Copenhagen, Denmark (UCPH) and head of Bioneer:FARMA, a business unit of Bioneer A/S, which is a research-based, non-for-profit service provider within the area of biomedicine and pharmaceutical development. She is heading the Physiological Pharmaceutics Research Group at UCPH, focusing on developing oral lipid-based drug delivery systems and predictive biopharmaceutics tools. She has >250 publications in international, peer-reviewed journals (h-index: 67, 13604 citations, I10 index: 213 (Google Scholar 5/4-23). She is/has been supervising 12 post docs, 53 PhD students and numerous master students, primarily at the University of Copenhagen, but also at other universities. She is/has been involved in multiple national and international research consortia, e.g. the EU sponsored Innovative Medicines Initiative Consortium Oral Biopharmaceutics Tools (OrBiTo; http://www.orbitoproject.eu) and Horizon 2020 MSCA training network COLOTAN.

She is a fellow at the American Association of Pharmaceutical Scientists (AAPS) and recipient of the AAPS Lipid Based Drug Delivery Award. She is editor of Journal of Drug Delivery Science and Technology (IF 5.06).
Email: anette.mullertz@sund.ku.dk

Tapash Ghosh, PhD
Senior Pharmaceutical Quality Assessor and Master Reviewer
ONDP | OPQ | CDER | FDA



Dr. Tapash Ghosh is a Senior Pharmaceutical Quality Assessor (SPQA) and a Master Reviewer of the Biopharmaceutics Division at the Office of New Drug Products (ONDP) under the new Office of Product Quality (OPQ) at CDER/FDA supporting Gastroenterology, Hepatology & Nutrition and Dermatology and Dentistry therapeutic areas for both new and generic drug applications. At his current position, he oversees review activities of various dosage forms and participates in various key regulatory decision-making processes. He is a member of various working groups within CDER/FDA including the Transdermal Working Group. He is also an FDA-USP liaison of the Dosage Form Expert Committee. He is an avid speaker and coordinated short courses/symposiums in various national and international meetings on the regulatory aspects of different dosage forms. Beside several publications in different peer reviewed scientific journals, he is also the principal editor of four scientific books in the Marcel and Dekker series.

Hanlin Li, PhD
Senior Director
Vertex Pharmaceuticals

Dr. Hanlin Li is a Senior Director at Vertex Pharmaceuticals, located in Boston, MA. Hanlin has a PhD degree in Analytical Chemistry from Iowa State University, and is currently the head of the Technical Operations Analytical – Drug Product group, leading commercial projects. Prior to joining Vertex, Hanlin had worked at Pfizer Global R&D, and together has more than 15 years of pharmaceutical industry experience in analytical development and product life cycle management.

Dr. Li has worked on numerous Marketing Applications with QbD filing and is a member of multiple IQ consortium groups, ISPE group, and a USP expert panelist. Dr. Li has publications, book chapters, and conference presentations in the subjects of continuous manufacturing, dissolution, and predictive stability.

Parnali Chatterjee, PhD, RPh
Pharmacologist
DB | ONDP | OPQ | CDER | FDA

Dr. Parnali Chatterjee is a Biopharmaceutics assessor within the Division of Biopharmaceutics at the FDA who is involved in the evaluation of in vitro, in vivo, and in-silico absorption, metabolism, distribution, and elimination (ADME) data in support of dissolution methods, clinically relevant dissolution specifications, biowaivers, animal and clinical studies, in vitro-in vivo relation/correlation (IVIVR/IVIVC) to support regulatory approvals.

Dr. Chatterjee received her doctoral degree in Pharmaceutical Sciences from the University of Louisiana, LA, following which she pursued a post-doctoral training in Pharmacology/Toxicology at the University of Utah, UT. Dr. Chatterjee has worked in the pharmaceutical industry supporting drug discovery and development activities. She held a faculty position at St. John's University, NY. Her research interests include formulation development, cell culture, animal and clinical studies, and analytical/bioanalytical chemistry to support in vitro, in vivo, and in-silico ADME.

Anitha Govada, PhD
Biopharmaceutics Team Lead, Senior Pharmaceutical Quality Assessor
DB | ONDP | CDER | FDA

Dr. Anitha Govada is a Biopharmaceutics Team Lead serving as a Senior Pharmaceutical Quality Assessor (SPQA) in the Division of Biopharmaceutics/Office of New Drug Products at CDER/FDA. In this position, she provides leadership and oversight for the biopharmaceutics assessments of investigational, new, and generic drug product submissions in Oncology and Hematologic Malignancy therapeutic areas. She serves as an Application Technical Lead (ATL) for NDAs including priority Breakthrough Therapy Fast Track submissions supporting the Oncology Center of Excellence's initiatives such as Project Orbis, Real-Time Oncology Review (RTOR) program. She began her FDA career in 2007, joining CDER's Office of Generic Drugs as a Bioequivalence Reviewer and later transitioned to Office of Pharmaceutical Quality (OPQ) as a CMC, biopharmaceutics reviewer and manufacturing facility investigator. In her 16 years of multidisciplinary experience spanning the entire product lifecycle from pre-IND to NDA, pre-ANDA to ANDA and post marketing supplements, she was involved in aspects related to research, review and guidance development. She led multiple internal and external committees, working groups and cross-center collaborations as a subject matter expert (SME) for complex drug products. She received several awards and honors at FDA including CDER Regulatory Science Excellence Awards and CDER Center Director's Special Recognition Award. Prior to joining the FDA, Anitha worked in the pharmaceutical industry as a senior formulation scientist and as a pharmacist. She received her Bachelor of Pharmacy from Kakatiya University and a PhD in Pharmaceutical Sciences from Texas Tech University School of Biomedical Sciences.

Rajesh Savkur, PhD
Biopharmaceutics Reviewer
DB | ONDP | OPQ | CDER | FDA

Dr. Rajesh Savkur is a Biopharmaceutics Reviewer in the Division of Biopharmaceutics (DB) in the Office of New Drug Products/Office of Pharmaceutical Quality at the U.S. Food and Drug Administration (FDA). Dr. Savkur received a Bachelor and Master of Science in Chemistry and Biochemistry, respectively from the University of Mumbai, India, and a PhD in Biochemistry/Pharmacology from the University of Mississippi Medical Center, Jackson, Mississippi. During his PhD, he designed novel anti-cancer chemotherapeutic drugs (Daunorubicin derivatives) that exhibited increased specificity to the target DNA. During his stint in the pharmaceutical industry, he identified novel targets for the development of NME drugs for the treatment of cardio-endocrine-metabolic diseases, including atherosclerosis, dyslipidemia, type 2 diabetes, and heart failure. He has extensive experience in pharmacogenomics, proteomics, biomarker validation and pharmacokinetic/pharmacodynamic (PK/PD) modeling approaches for pre-clinical and clinical studies. Dr. Savkur has authored and co-authored several peer-reviewed journal articles, invited review articles and book chapters, and serves as an editorial consultant for several journals including *Biochemical Pharmacology*, *PPAR Research*, *Endocrinology*, and *Expert Opinion in Therapeutic Targets*. In his current role in the DB at the FDA, he evaluates the pharmacological and biopharmaceutical studies associated with drug and drug-device-combination applications that are submitted to the Agency.

Yi Gao, PhD
Research Fellow of Formulation Sciences, Development Sciences, R&D
AbbVie, Inc.

Dr. Yi Gao leads a group of formulation scientists at AbbVie focusing on developing clinical formulations for small molecular drug candidates. Yi Gao earned her BS and MS in Pharmacy from China Pharmaceutical University and her PhD in Chemistry from Loyola University Chicago. She joined Abbott/AbbVie in 1992. During her 31-year tenure with Abbott/AbbVie, Yi has pursued her interests in research frontiers of improving solubility, dissolution, and bioavailability of drug products, in particular by applying amorphous solid dispersions and lipid-based drug delivery systems. She is an inventor and co-inventor of over 50 granted patents and patent applications; has authored and co-authored 43 research papers and book chapters; and given 20 invited speeches and graduate course lectures. Yi currently serves as Editorial Advisory Board for *Molecular Pharmaceutics*. A paper she co-authored won the 2012 AAPS Pharmaceutical Research Meritorious Manuscript Award. In 2015 and 2018, three of her publications were honored by the *Journal of Pharmaceutical Sciences* as the "Most Original and Most Significant Scientific Findings." In 2023, a paper of hers was selected as Featured Articles in the Raj Suryanarayanan Dedicated Issue of *Journal of Pharmaceutical Sciences*.

Rohit Jaini, PhD
Principal Scientist
Global Biopharmaceutics Team – Drug Product Design
Pfizer Inc.

Dr. Rohit Jaini is a Principal Scientist in the Global Biopharmaceutics Team under the Small Molecule Drug Product Design organization at Pfizer. Dr. Jaini received his PhD in Chemical Engineering from Purdue University where his work primarily focused on developing mathematical models to understand complex biochemical reactions in plant metabolism. Since joining Pfizer in 2017, Dr. Jaini has worked on developing biopharmaceutic models for oral, parenteral, and transdermal drug delivery spanning a wide array of formulation technologies. In his current role, Dr. Jaini enables formulation design, provides guidance and recommendations on biopharmaceutics aspects with the use of Physiology Based Pharmacokinetic (PBPK) modeling for drug products during their entire lifecycle from early development to post marketing changes. In addition, he is responsible for developing and advancing new mathematical models and progressing translational biopharmaceutics with a focus on improving predictive capabilities of in vitro methods.

David Curran, BS
Principal Investigator, Analytical Development
GSK

Dave Curran is an analytical scientist and GSK Fellow with 25 years of experience in the pharmaceutical industry. He is one of GSK's experts in dissolution method development and is the key expert on the flow through cell. For the past 10 years, he has been primarily focused on in-vitro release methods for long acting parenteral products, including aqueous milled nanosuspensions, matrix implants, ionic liquids, and in-situ-forming implants.

Dave serves on the core team of the AAPS In-Vitro Release and Dissolution Testing Community (IVRDTc), and the IQ Consortium's Dissolution Working Group, co-leading the LAI subteam.

Dave is a co-author of USP <1001> In-Vitro Release Test Methods for Parenteral Drug Preparations, as well as co-author of six manuscripts and one book chapter.

Debasis Ghosh, PhD
Biopharmaceutics Reviewer
B3 | DB | ONDP | OPQ | CDER | FDA

Dr. Debasis Ghosh joined the Agency in 2008 as a CMC reviewer in ONDQA (currently ONDP) serving the Oncology Clinical division. Prior to joining the Division of Biopharmaceutics, he held the position of Quality Assessment Lead in the Division of New Drug API. During his tenure at the Agency, he served as the Quality by Design (QbD) Liaison, DP-CMC Lead (DHP-Oncology), DS-CMC Lead (GI, Pain, Pulmonary, Dermal, and Repro.), Application Technical Lead (DAAAP), and consultant for USP, CDRH and CBER. He also served as the Subject Matter Expert for the development of Review Templates, and Guidances. As a biopharmaceutics reviewer, Dr. Ghosh has been involved in the review of biopharmaceutics issues of various products including complex formulations (e.g., drug-device combination products, ophthalmic implants) and emerging technologies (e.g., continuous manufacturing). Before joining the Agency, Dr. Ghosh garnered significant professional experience both in industry and in academia. He taught Medicinal Chemistry and Pharmacology as an Associate Professor of Pharmacy at the School of Pharmacy, South University, Georgia. He co-founded Cognitive Pharmaceuticals in Toledo, Ohio to develop a treatment for Alzheimer's disease. His industrial work experience ranges in diverse areas of discovery research (Anti-sense, Anti-cancer, and Anti-bacterial). Dr. Ghosh received his PhD from the School of Pharmacy, University of Louisiana at Monroe and conducted post-doctoral studies at the School of Pharmacy at Purdue University. Dr. Ghosh obtained his BS and MS in Pharmacy from India. Dr. Ghosh's research work has been published in several peer-reviewed journals. He has several US and International patents.

Dana E. Moseson, PhD
Senior Principal Scientist, Drug Product Design
Pfizer

Dr. Dana Moseson is currently working in the Formulation and Process Design group of the Drug Product Design department at Pfizer in Groton, CT, where she specializes in the formulation design, characterization, and manufacturing of early-stage clinical drug products using amorphous solid dispersion (ASD) technology. She has over 10 years of industry experience developing formulations for early phase NCEs. Dana received a PhD in Industrial and Physical Pharmacy from Purdue University, where her research under Professor Lynne Taylor focused on the thermodynamic and kinetic aspects of hot melt extrusion processing to produce ASDs, as well as investigating the in vitro biopharmaceutics implications of residual crystallinity in ASDs. During her postdoctoral research, she investigated the physical stability and dissolution performance implications of atomic layer coating on amorphous solid dispersion particles. Dana has received several research awards including the PhRMA Foundation Postdoctoral Fellowship in Drug Delivery (2021-2022), National Institute for Pharmaceutical Technology & Education Outstanding Student Research Award (2020), Jenkins/Knevel Award for Excellence in Research (2020), International Pharmaceutical Excipients Council of the Americas (IPEC) Foundation Graduate Student Award (2019), and the National Science Foundation Graduate Research Fellowship (2018-2020). She has 20 publications on amorphous solid dispersion formulation design, hot melt extrusion processing design, particle engineering, and in vitro dissolution performance of supersaturating formulations, and has presented at numerous scientific meetings and conferences.

Andre Hermans, PhD
Executive Director, Small Molecule Analytical R&D
Merck & Co, Inc.

Dr. Andre Hermans is an Executive Director in Small Molecule Analytical Research and Development at Merck & Co., Inc. in Rahway, NJ. He received his PhD in Analytical Chemistry from the University of North Carolina in Chapel Hill before joining Merck in 2007. During his time at Merck, Andre supported analytical method development and process development in the small molecule solid oral dosage area throughout all phases of drug development. In this function, he authored several IND and NDA applications mainly for oral formulations containing amorphous solid dispersions. Additionally, he is co-leading Merck's efforts around in-vivo predictive technologies, dissolution innovations, and clinically relevant dissolution specifications. Andre is former chair of the AAPS in-vitro release and dissolution testing (IVRDT) community, leader of the IQ sub team for dissolution of amorphous solid dispersions, and member of the USP expert panel for "New Advancements in Performance Testing". He is the author of multiple publications in the field of dissolution testing and clinical relevance.

Hansong Chen, PharmD, PhD
Senior Interdisciplinary Scientist
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Dr. Hansong Chen is a senior interdisciplinary scientist, the Division of Biopharmaceutics/ONDP/OPQ/CDER. He initially joined the Office of Study Integrity and Surveillance in 2013, where he conducted two years of BA/BE inspection. In 2015, he joined the Division of Biopharmaceutics. Before joining FDA, he worked at a biopharmaceutics company as a chemist.

Alaadin Alayoubi, PhD
Biopharmaceutics Reviewer
DB | ONDP | OPQ | CDER | FDA

Dr. Alaadin Alayoubi is a Biopharmaceutics Reviewer in the Office of New Drug Products (ONDP) at FDA. He serves to establish in vitro dissolution/release specification and help assessing biopharmaceutics topics (e.g., biowaiver, bridging, IVIVC, etc.) in regulatory submissions. He received his PhD in Pharmaceutical Sciences from University of Louisiana at Monroe with two years of post-doctoral training at University of Tennessee Health Science Center. Dr. Alayoubi has extensive experience in development process of solid dosage forms in terms of material characterization, formulation & process development using risk based and Quality by Design (QbD) principles, from laboratory to pilot scale manufacturing. He is an expert in the development process of multiple drug delivery systems including immediate release, controlled release & delayed release formulations of small molecules employing conventional & novel techniques. Dr. Alayoubi authored more than 40 peer-reviewed papers, 2 book chapters and got several awards for his professional accomplishments.

James Polli, PhD

Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics
University of Maryland School of Pharmacy

Dr. James 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. His two main research interests are 1) maximizing oral bioavailability through formulation and chemical approaches and 2) developing public quality standards for oral dosage forms. He has served as advisor to 24 PhD graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; www.cersi.umd.edu) and the Center for Research on Complex Generics (CRCG; www.complexgenerics.org), each 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).

He is a fellow of the American Association for Pharmaceutical Scientists and until recently served as an editor of its flagship journal Pharmaceutical Research for 12 years. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB). He is a member of the Scientific Advisory Board of Simulations Plus.