Shaping the Future of Pediatric Formulation Development

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

Public In-Person Workshop
June 24-25, 2026 | 8:00 AM – 5:00 PM Eastern Time

Biographies

LCDR Jibril Abdus-Samad, PharmD
Compendial Operations and Standards Staff
OPPQ, OPQ, CDER, FDA

Lieutenant Commander (LCDR) Jibril Abdus-Samad is a U.S. Public Health Service officer and pharmacist with more than 20 years of experience in regulatory policy, pharmaceutical quality, and medication safety.

At FDA's Center for Drug Evaluation and Research (CDER), LCDR Abdus-Samad serves as the Nomenclature and Labeling Policy Lead within the Office of Policy for Pharmaceutical Quality. As an FDA Government Liaison on multiple United States Pharmacopeia expert committees, he plays a direct role in developing the compendial standards that define drug naming and labeling at the national level. His previous FDA roles include Labeling Reviewer for CDER-regulated biological products and Safety Evaluator in the Division of Medication Error Prevention and Analysis.

LCDR Abdus-Samad's career began in clinical pharmacy practice across Veterans Affairs and private sector settings. He holds a PharmD from the University of the Sciences, a Graduate Certificate in Patient and Product Safety from the University of Southern California, and ASHP professional certificates in Pharmacy Informatics and Medication Safety.

Anjali Agrawal, PhD
Executive Director, Global Manufacturing and Supply
Nova Nordisk, Inc.

Dr. Anjali Agrawal is a strategic Pharmaceutical Executive with more than 25 years' experience in leading global product development functions, diverse portfolio, and project teams. She has deep technical, strategic and operational leadership expertise in development and commercialization of oral and parenteral product portfolio consisting of NCE's, product line extensions, and in-licensed assets for adult and pediatric patients in several disease areas.

She successfully established global DP group, facilities, structure, operating models, business processes, and CRO/CDMO network at Novo Nordisk, Forma Therapeutics, BMS, Celgene, Boehringer Ingelheim, Pfizer, and Wyeth. Anjali broadened her impact on drug development through leadership roles in global project management, CMC project management, commercial supply management, and alliance management. She is an innovative thought leader with a proven track record in designing novel processes, platform formulations, and material sparing predictive methodologies that streamlined DP development and accelerated commercialization of innovative medicines. She has a passion to develop palatable pediatric dosage form and established enterprise strategy for oral and parenteral pediatric products at several companies. She is an active member of AAPS, IQ Pediatric, and EuPFI consortia.

John Alexander, PhD, MPH
Supervisory Physician
DPMH, ORDPURM, OND, CDER, FDA

Dr. John Alexander is Deputy Director of the Division of Pediatrics and Maternal Health in the Center for Drug Evaluation and Research at FDA. Dr. Alexander is a pediatrician who joined the US Food and Drug Administration in 1995 as part of a joint fellowship in pediatric infectious diseases with FDA and Children's National Medical Center. After completion of his fellowship, he became a full-time medical officer, and subsequently a team leader, in the Division of Anti-Infective Products. Dr. Alexander also obtained a Masters degree in Public Health (MPH) from the George Washington University School of Public Health in 2001. He has been involved in drug regulation and pediatric drug development for more than 30 years.

Adrie Bekker, PhD, Cert (Neo), MMed (PAED), FCPAED, DCH, MD
Professor, Neonatologist: Department of Paediatrics and Child Health
Stellenbosch University, Cape Town, South Africa

Dr. Adrie Bekker is a Professor of Paediatrics in the Division of Neonatology at Stellenbosch University, South Africa, with 17 years of experience as a neonatologist. Her research focuses on neonatal infectious diseases and the pharmacology and safety of anti-infective medicines in this population. She has been an active investigator in the NIH-funded IMPAACT Network, serving as vice-chair of P1106 (pharmacokinetics of antiretroviral and tuberculosis drugs in low-birth-weight infants), national PI for P2023 (dolutegravir pharmacokinetics and safety in term neonates), and currently vice-chair of P2050 (long-acting cabotegravir/rilpivirine in pregnant women). Of note, she also leads other neonatal pharmacokinetic studies at our site evaluating cefiderocol, colistin, fosfomycin, and flomoxef. Dr. Bekker contributes to global policy through the WHO Pediatric AIDS Working Group (member since 2021; co-chair in 2025) and the PENTA Clinical Pharmacology working group. In collaboration with Dr. Tim R. Cressey (MPI), she has co-led the PETITE Research Platform for over five years, generating pivotal data on the pharmacokinetics and safety of antiretrovirals in neonates. The PETITE-DTG trial, which included the evaluation of a novel pediatric dolutegravir dispersible film, established the first dolutegravir dosing guidance for term neonates and directly informed the July 2025 WHO guidelines recommending dolutegravir from birth.

April C. Braddy, PhD, RAC, SEP
Division Director
DB III, OB, OGD, CDER, FDA

Dr. April Braddy serves as Director of the Division of Bioequivalence III in the Office of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research at the Food and Drug Administration. With over 19 years of regulatory experience since joining FDA in 2006, she has advanced through progressively senior roles from primary assessor to her current directorship.

Dr. Braddy has led center-level scientific committees and initiatives while representing the Agency in global regulatory collaborations, demonstrating her commitment to international scientific cooperation, harmonization of bioequivalence standards, and maintaining FDA as the scientific gold standard. She is actively involved in Agency efforts for pediatric formulation development and evaluation, advancing safe and effective generic medications for children.

A recognized expert in regulatory science, Dr. Braddy has authored over 20 publications and presented at major national and international conferences, workshops and symposiums. She holds a PhD in Pharmaceutical Sciences from the University of Florida and a BSc in Microbiology with a minor in Chemistry from Clemson University. Her professional achievements are further distinguished by her recognition as an Excellence in Government Fellow and her membership in Rho Chi, the international honor society for pharmaceutical sciences.

Stuart Charlton, BPharm, PhD
Director, Oral Product Development
Bristol Myers Squibb

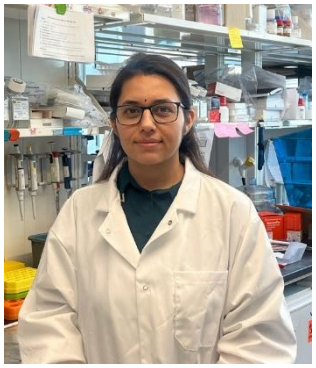
Dr. Stuart Charlton is a Director at Bristol Myers Squibb, where he leads Oral Product Development in the UK. He has over a decade of experience in paediatric drug product development, leading and supporting formulation development and regulatory filings across the development lifecycle.

Stuart is an active member of the IQ Consortium Pediatric Working Group and the BMS Pediatric Centre of Excellence. He has presented at international paediatric conferences and has led the organisation of several internal paediatric symposia.

In 2019, he received the Bristol Myers Squibb James B. D. Palmer Award for Excellence in Drug Development for establishing mini-tablets as a paediatric platform. His technical interests include the mechanistic understanding and scale translation of roller compaction and film coating.

Stuart holds a Pharmacy degree from the University of Bath and a PhD from the University of Nottingham.

Sonika Chibb, PhD
Visiting Scientist
Massachusetts Institute of Technology



Dr. Sonika Chibh is a Visiting Scientist and Fulbright Nehru Postdoctoral Fellow at the Massachusetts Institute of Technology (MIT) in the laboratory of Prof. Robert Langer/Dr. Ana Jaklenec. She earned her PhD in Chemical Biology with a focus on drug delivery from the Indian Institute of Science Education and Research (IISER), Mohali, India.

At MIT, Dr. Chibh leads research on enhancing the stability and delivery of virus-like particle (VLP)-based vaccines using microneedle and lipid nanoparticle platforms, aiming to develop thermostable, minimally invasive, and pediatric-friendly immunization strategies. She is also developing peptide- and nanoparticle-based approaches for targeted cancer drug delivery and advancing translational projects in women's health. During her postdoctoral fellowship at Tel Aviv University in the laboratory of Prof. Ehud Gazit, she developed monoclonal antibodies in collaboration with industry (TEVA Pharmaceuticals) and engineered peptide-based nanomaterials for drug delivery and cancer therapy.

Dr. Chibh has published extensively in high-impact journals, including *Science Advances* and *Angewandte Chemie*, and has received prestigious awards, including the Fulbright Nehru Fellowship. Her research bridges drug delivery, biomaterials, and vaccine formulation, with a strong emphasis on translating innovative technologies into scalable healthcare solutions.

Jon Collins, PharmD
Senior Director Clinical Pharmacology
ViiV Health Care

Dr. Jon Collins is a Senior Director within the ViiV Clinical Pharmacology division. He received his PharmD from the University of North Carolina–Chapel Hill (UNC) in 2014, after which he completed a joint pharmacology/pharmacometrics fellowship with UNC and GlaxoSmithKline (GSK). He then worked in clinical pharmacology groups at Parexel, Roivant Sciences, and Immunovant, where he served as Director of Clinical Pharmacology. In 2019, he transitioned to the clinical pharmacology modeling and simulation oncology group at GSK, providing pharmacometric and model-based meta-analysis support for the submission of belantamab mafodotin. He later moved to ViiV, where his primary focus is providing strategic direction across all stages of drug development. Specifically, he has been instrumental in guiding the strategic development of long-acting injectables for special populations, including pediatric and neonatal populations. He has extensive experience authoring regulatory documents across all phases of drug development and has contributed to clinical pharmacology and pharmacometric regulatory submissions for four approved drugs across a diverse range of therapeutic areas.

James E. Cummins, Jr., PhD
Chief, Preclinical Microbicide and Prevention Research Branch
DAIDS, NIAID, NIH

Dr. James Cummins, PhD is currently the Chief of the Preclinical Microbicide and Prevention Research Branch in the Prevention Sciences Program within the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID), an institute within the U.S. National Institutes of Health (NIH). As part of the DAIDS mission to develop highly effective HIV prevention strategies, Dr. Cummins leads a team that manages a portfolio of grants and contracts supporting the preclinical development of non-vaccine biomedical prevention products. Active grants in the portfolio support the development and optimization of the next generation of HIV prevention products – including sustained release/long-acting products and multi-purpose prevention strategies. Current contract resources fill key gaps in product development pathways by enabling the acquisition of critical data, development of essential methods, product manufacture and characterization, and completion of studies necessary to advance products into clinical trials. These funding mechanisms have supported the development of a range of formulation types and facilitated the advancement of 12 products into NIAID-sponsored clinical trials. More recently, Dr. Cummins has expanded the capabilities of his Branch to include support for the development of pediatric formulations for HIV treatment and prevention, including comorbidities such as tuberculosis.

Trupti Dixit, PhD
Workshop Program Chair, Independent Consultant
Dixit Consulting

Dr. Trupti Dixit is a strategic biopharmaceutical leader experienced in advancing drug development across small molecules and biologics. She builds and leads high performing global teams for managing CMC development of pharmaceutical assets from early research through commercialization. Her expertise spans end-to-end CMC, clinical supply, and regulatory strategies, and includes contributions to the development of several marketed therapeutics. A passionate advocate for pediatric drug development, Dr. Dixit has previously co-led IQ consortium's (International consortium for Innovation and Quality in Pharmaceutical Development) pediatric working group, organized international workshops, contributed to NIH initiatives focused on pediatric HIV therapies, authored a textbook chapter on drug product development, and presented at global scientific conferences. She is committed to advancing collaboration across industry, academia, and regulatory bodies to accelerate the development of safe, effective, and accessible medicines for children.

Currently an independent consultant, Dr. Dixit advises on pharmaceutical drug development focusing on the chemistry manufacturing and controls aspects. Her prior leadership roles include senior positions at Pfizer**,** Seagen**,** and Takeda Pharmaceuticals**,** where she led global CMC portfolios, strengthened governance, contributed to pharmaceutical development of assets, and mentored technical leaders. She holds a PhD from the University of Kentucky, an EMBA from Quantic, and a Bachelor of Pharmacy from the University of Bombay.

Anna Externbrink, PhD
Associate Principle Scientist
Merck

Dr. Anna Externbrink is an Associate Principal Scientist in Analytical Commercialization Technology at Merck. Her experience spans drug development from early stages through regulatory submissions, including contributions to several pediatric programs, risk-based control strategies, and analytical approaches for alternative administration routes that ensure product performance and safe, reliable dosing. She holds a PhD in Biopharmaceutics and Pharmaceutical Technology from the University of Greifswald and previously worked at the FDA, leading regulatory science initiatives.

Elizabeth Galella, MS
Associate Director, Drug Product Development Department
Bristol Myers Squibb

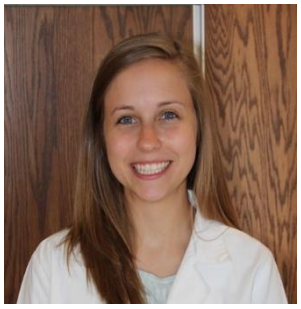
Ms. Elizabeth Galella is an Associate Director in the Drug Product Development Department at Bristol Myers Squibb. She earned her MS in Chemistry from Rutgers University and her BS in Chemistry from Douglass College before joining BMS in 1997.

Elizabeth currently leads a team of analytical scientists focused on analytical method development for small-molecule drug products. Through her role in Drug Product Development, she has expanded her expertise into pediatric product development. She has been an active member of the IQ Consortium's Pediatric Working Group for 13 years and is deeply committed to addressing unmet needs and advancing best practices in the development of pediatric medicines.

Shannon Glueck, PharmD
Branch Chief
DC II, Branch 6, OCQC, OC, CDER, FDA

Dr. Shannon Glueck currently serves as a Branch Chief in the Division of Compounding II within the Office of Compounding Quality and Compliance (OCQC) in the U.S. Food and Drug Administration. Dr. Glueck completed her Doctor of Pharmacy degree at Duquesne University in Pittsburgh, Pennsylvania. Prior to joining the FDA, Dr. Glueck worked in industry handling adverse event and product quality reports and practiced pharmacy in both retail and hospital settings. In her current position within the Division of Compounding II, she oversees the surveillance and investigation of adverse events and product quality issues involving compounded drugs and implements prompt agency action to mitigate potential risks to public health. In addition, she oversees the evaluation of firm compliance with sections 503A and 503B of the Food, Drug and Cosmetic Act.

Alyssa Hager, PharmD, BCPPS
Clinical Pharmacist
Children's National Medical Center



Dr. Alyssa Hager is a Clinical Pharmacist at Children's National Medical Center in Washington, DC. She received her PharmD from Virginia Commonwealth University before completing both her PGY-1 and PGY-2 residency at Children's Hospital of Philadelphia (CHOP). After residency, she worked in the Cardiac Intensive Care Unit at CHOP before moving to Washington, DC in 2023 to practice in the Neonatal Intensive Care Unit. In early 2026, Dr. Hager joined the Epic Implementation Team at Children's National, combining her passions for patient care and information technology. In her current role, she focuses on safe and sustainable medication design, utilizing innovative technology to guide appropriate medication practices.

Stephen W. Hoag, PhD
Professor of Pharmaceutical Sciences
Director of UMB GMP Facility
University of Maryland, School of Pharmacy

Professor Stephen W. Hoag received a PhD in Pharmaceutics from the University of Minnesota and a BS in Biochemistry from the University of Wisconsin-Madison. He is the Director of the University of Maryland, School of Pharmacy GMP facility, overseeing quality assurance (QA), quality control (QC) and production. Dr. Hoag has 30 plus years of experience in drug development and pharmaceutical manufacturing research, and he has been the director of the GMP facility since 2008. In addition to his academic experience, he has worked for the World Health Organization, 3M Pharmaceuticals, and Abbott Laboratories. His primary research interests are tablet compaction, excipient functionality and the formulation of amorphous solid dispersions, pediatric dosage form development, controlled release polymers, formulation of nutritional supplements, botanical products and NIR spectroscopy applications in PAT. Dr. Hoag is a member of NIPTE, served on the USP Counsel of Experts for 20 years, Steering Committee for the Handbook of Pharmaceutical Excipients, the editorial board of the journal of *Pharmaceutical Development Technology* and an AAPS Fellow.

Mona Knurana, MD
Pediatric Team Leader
DPMH, ORDPURM, OND, CDER, FDA

Dr. Mona Khurana is board certified in general pediatrics and in pediatric nephrology. She obtained her undergraduate Bachelor of Science and Doctor of Medicine degrees from the George Washington University in Washington DC. Following her internship at Nicklaus Children's Hospital and residency at Yale New-Haven Children's Hospital, she completed a fellowship in Pediatric Nephrology at Children's Hospital Boston. In 2004, she joined the faculty at Children's National Hospital in Washington DC after her fellowship where she was an Assistant Professor of Pediatrics before joining FDA in 2009. Dr. Khurana initially worked as a Medical Reviewer in the FDA's Division of Nonprescription Drug Products in the Center for Drug Evaluation and Research (CDER). She moved to the Division of Pediatrics and Maternal Health (DPMH) as a Medical Reviewer in 2015 and has been a Pediatric Team Leader in DPMH since 2016 where her efforts have primarily focused on working collaboratively with review divisions in the Office of New Drugs to assist with pediatric drug development in all therapeutic areas.

Joanna M. Koziara, PhD
Executive Director, Technical Development Strategy & Operations
Gilead Sciences

Dr. Joanna M. Koziara is a trained pharmacist who received her PhD in Pharmaceutical Sciences from the University of Kentucky. She currently serves as the Executive Director of Technical Development Strategy & Operations at Gilead Sciences, where she leads business strategy, operations, and digital innovation across Technical Development. She has over two decades of experience in formulation and manufacturing process development for small molecules across various modalities, from research through commercialization. She is a recognized leader in pediatric drug product development, serving as the CMC lead on Gilead's global pediatric team since 2012 and providing strategic oversight of the full pediatric asset portfolio. Dr. Koziara is an active contributor to external pediatric and regulatory science initiatives, including the IQ Pediatric Working Group and various advisory efforts.

Yemin Liu, PhD
Senior Prinicipal Research Scientist
AbbVie Inc.

Dr. Yemin Liu is a Sr. Principal Research Scientist in Analytical R&D at AbbVie. Since she joined Abbott/AbbVie in 2008, Yemin has contributed to numerous projects from FIH to commercial approval, including solid oral, liquid oral, and parenteral liquid dosage forms. She is the co-chair of the IQ Consortium Pediatric Working Group, and a member of IQ Analytical Leadership Group.

Erica Long, MEng
Scientist, Drug Product Design and Supply, PharmSci Small Molecule
Pfizer Inc

Ms. Erica Long is a scientist in the Drug Product Design and Supply (DPDS) group within the Pharmaceutical Sciences Small Molecule division at Pfizer. Within DPDS, her role in formulation and process development focuses on designing pediatric medicines, including oral liquids and flexible oral solids, that address the unique needs of young patients. She currently serves as the drug product lead on two pediatric programs and is leading internal efforts focused on enhancing palatability assessment workflows. Her education background includes earning her Master of Engineering in Material Science and Engineering from the University of Connecticut and her Bachelor of Science in Pharmaceutical Sciences from the University of Rhode Island.

Dominic Markwordt, JD, MBA
Regulatory Counsel
OCQC, OC, CDER, FDA

Mr. Dominic Markwordt is a Regulatory Counsel in the Office of Compounding Quality and Compliance (OCQC) at the Center for Drug Evaluation and Research (CDER) in the U.S. Food and Drug Administration (FDA). As a member of the compounding staff in OCQC's Division of Compounding III, he works to develop and implement human drug compounding initiatives, including through guidance documents and notice-and-comment rulemaking, on a variety of topics to protect the American public from unsafe, ineffective, and low-quality compounded drug products. Mr. Markwordt began his career in the FDA's Center for Tobacco Products (CTP) and has worked at FDA for over 15 years. He received his law degree from the University of Baltimore School of Law and his MBA from the University of Baltimore.

Katie Metzler, MS
Director, Formulation Development
Vertex Pharmaceuticals, Inc

Ms. Katie Metzler is a Director of Formulation Development at Vertex Pharmaceuticals, Inc., where she leads formulation development for multiple programs, including several pediatric programs. With over 15 years in formulation and materials assessment roles at Vertex, Katie has extensive knowledge in areas such as compression optimization, Quality by Design (QbD) application, and late-stage product lifecycle management including regulatory filings. She has collaborated externally with CDMOs to advance the development of both pediatric and adult programs. Katie has supported multiple regulatory filings and collaborates closely with the commercial team on control strategies. With a strong background in chemical and biological engineering, she has extensive experience in formulation optimization, cross-functional collaboration, and managing manufacturing processes. Prior to joining Vertex, Katie completed a Master's degree in Chemical and Biological Engineering from Colorado State University and a Bachelor's degree in Chemical Engineering from Bucknell University.

Rachel Meyers, PharmD, BCPS, BCPPS, FPPA
Clinical Professor
Ernest Mario School of Pharmacy, Rutgers University
Pediatric Clinical Pharmacist
Cooperman Barnabas Medical Center, Livingston NJ

Dr. Rachel Meyers is a Clinical Professor at the Ernest Mario School of Pharmacy at Rutgers University, and the Pediatric Clinical Pharmacist at Cooperman Barnabas Medical Center in Livingston, New Jersey. Dr. Meyers completed her undergraduate degree at the University of Mary Washington and her Doctor of Pharmacy degree at the University of Connecticut. After graduation she completed a PGY-1 residency at the University of Wisconsin Hospital and Clinics in Madison, Wisconsin, and a PGY-2 residency in Pediatric Pharmacotherapy at the University of North Carolina Children's Hospital in Chapel Hill, North Carolina. In her current position, Dr. Meyers provides both didactic and experiential education in pediatric pharmacotherapy for pharmacy students and residents. She practices in both the Pediatric Intensive Care Unit and General Pediatric Unit at Cooperman Barnabas Medical Center. Dr. Meyers has been a participant in two clinical trials. Her research interests are focused on dosage forms for pediatric patients and medication safety for children.

Ndidi Nwokorie, MBBS
Senior Scientist
DPMH, OND, CDER, FDA

Dr. Ndidi Nwokorie is a pediatric emergency medicine physician by training and joined FDA in 2019 as a medical reviewer in the Division of Pediatrics and Maternal Health. The Division of Pediatrics and Maternal Health oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population and improve safety data collection and product labeling for pregnant and lactating individuals. In her role, Dr. Nwokorie serves as a consultant to staff in the Center for Drug Evaluation and Research to address pediatric-specific questions for investigational products in development across all therapeutic areas that are intended for both prescription and nonprescription use in the US pediatric population. Dr. Nwokorie graduated from University of Nigeria College of Medicine in 1985. She completed her residency in general pediatrics in 1993 followed by a fellowship in pediatric emergency medicine in 1995 from Montefiore Medical Center, Albert Einstein School of Medicine, Bronx, New York.

Dr. Nwokorie practiced pediatric emergency medicine for over 25 years in the community, primarily in the Baltimore area, before joining FDA.

Kirsten O'Brien, BS
Director of Packaging Development
Gilead Sciences

Ms. Kirsten O'Brien is the Director of Packaging Development at Gilead Sciences, with over 20 years of experience in pharmaceutical packaging engineering. She provides technical oversight for packaging design and development of biologics, combination products, and oral solid dose products across clinical development through commercial readiness and launch, including a strong focus on pediatric programs involving tablet and granule formulations. Her technical expertise includes primary and secondary packaging development, material selection, and packaging process control and oversight at packaging sites.

Smita Salunke, PhD
Chief Scientific Officer
European Paediatric Formulation Initiative
Senior Research Fellow
University College London School of Pharmacy
Founder
Paediatric Medicines Healthcare Initiative (PMHI) India

Pharmacist and a paediatric formulation scientist, Dr. Smita Salunke is Chief Scientific Officer of European Paediatric Formulation Initiative (EuPFI), Senior Research Fellow at University College London School of Pharmacy, and Founder of Paediatric Medicines Healthcare Initiative (PMHI), India. She has over 20 years of experience across industry and academia in paediatric health.

She holds a degree in pharmacy and a PhD in Pharmaceutical Sciences from University College London, UK focused on excipient safety in children. This work underpins her research in paediatric formulations, including design, administration, and acceptability. She has a particular interest in low- and middle-income countries, where she addresses challenges in medicine use and access. Her work informs health policy and product development.

She has published over 45 peer-reviewed papers and delivered more than 60 invited talks. Her work has been featured in The Telegraph. She has served as a consultant to organisations including the World Health Organization and the Bill & Melinda Gates Foundation and works closely with pharmaceutical companies. She has also contributed as a visiting expert to the European Medicines Agency.

She pioneered the STEP (Safety and Toxicity of Excipients for Paediatrics) database, an open-access resource recognised as an impact case study in the Research Excellence Framework 2021. Her work has received international recognition, including the Outstanding Women Researcher in Pharmaceutics Award (VIWA) and shortlist recognition for the Royal Pharmaceutical Society OPERA Awards 2025.

Daniel Schaufelberger, PhD
Adjunct Assistant Professor
John Hopkins, School of Medicine

Dr. Daniel Schaufelberger is a pharmaceutical executive with over 30 years of experience in pharmaceutical development, including pediatric products. He spent 25 years at Johnson & Johnson, where he co-chaired the J&J internal Pediatric Formulation Network. He led the pharmaceutical development of several pediatric products, e.g., the new chewable/dispersible tablet of mebendazole for donation through WHO. He is a consultant for pharmaceutical companies, government and non-government organizations, including the US National Institute of Health, and WHO's Global Accelerator for Paediatric Formulation Development (GAP-f). Daniel holds a degree in pharmacy (ETH Zurich) and a doctorate from the University of Lausanne. He is a member of the Pediatric Working Group of the International Consortium (IQ) for Quality in Pharmaceutical Development and a formulation expert for the pan-European "Conect4Children" initiative. Daniel is a founding member of the society of "Paediatric Medicines and Health Initiative", based in Mumbai, India. In 2020, he joined Johns Hopkins University, School of Medicine, All Children's Hospital in St. Petersburg, FL as Adjunct Assistant Professor, where he is the founding co-chair of the annual symposium on "AI/ML in Pediatric Research". Daniel is a frequent speaker and moderator at domestic and international conferences with a focus and passion for "developing better medicines for children".

David Tan, PhD
Senior Director
Vertex Pharmaceuticals Inc

Dr. David Tan is the Senior Director of Formulation Development at Vertex Pharmaceuticals Inc. Prior to joining Vertex, he held roles at AbbVie Inc., where he led the development of both early and late-stage assets across a diverse range of oral dosage forms and parenteral products.

David earned both his Bachelor of Science and PhD in Pharmacy from the National University of Singapore. With over 16 years of experience in pharmaceutical development, he has developed profound passion for the field, with particular focus on advancing pediatric drug development.

In addition to his professional roles, David has also contributed to the broader research and development community. He has served as the Chair of the IQ Consortium's Drug Product Leadership Group (DPLG) and as the Co-Chair of the DPLG Pediatric Working Group, where he has played key role in driving collaboration across the R&D landscape.

Karen Cassidy Thompson, BA, PhD
Distinguished Research Scientist
Merck & Co., Inc., Rahway, NJ

Dr. Karen Thompson is a Distinguished Research Scientist in Preclinical Development. She received a BA in Chemistry from Dartmouth College and a PhD in Physical Chemistry from Duke University. Following a post-doctoral appointment at Columbia University, she joined Merck Research Labs where she has pursued formulation development for 38 years. She is a member of the IQ Pediatric Working Group and participated in the nasogastric tube feeding and neonate development sub teams.

Sandip B. Tiwari, PhD
Head of Technical Services–Pharma Solutions, North America
BASF Corporation, Tarrytown, NY

Dr. Sandip B. Tiwari is Head of Technical Services – Pharma Solutions, North America at BASF Corporation (Tarrytown, NY), where he leads cross-functional programs supporting pharmaceutical and biopharmaceutical teams on formulation development, excipient selection, dissolution science, process development, and scale-up/commercialization across multiple dosage forms. He brings 25+ years of leadership experience spanning BASF, Teva/Actavis/Allergan, Colorcon, and Zydus, with technical depth in oral immediate- and modified-release products, enabling technologies, and performance-based formulation strategies. He completed postdoctoral research in nanotechnology at Northeastern University (Boston, MA), strengthening his translational foundation at the interface of formulation science and advanced delivery technologies.

Dr. Tiwari has authored 100+ research papers, abstracts, book chapters, and patents, and serves as Chief Editor of the *Desk Book of Pharmaceutical Dissolution Science and Applications* (Society for Pharmaceutical Dissolution Science, SPDS). His work and speaking engagements emphasize clinically relevant performance testing, dissolution/IVIVC, and risk-based CMC decision-making. He has served as an invited speaker/panelist at the FDA/CDER Office of Generic Drugs FY2025 *Generic Drug Science and Research Initiatives* Public Workshop, contributing to scientific discussions relevant to dissolution, IVIVC, and regulatory assessment of complex products. He is also an Adjunct Professor in the Department of Translational Science & Medicine at the University of Alabama (CCHS), supporting translational science through academic–industry collaboration and mentoring.

Lario Viljoen, PhD, MA (Sociology)
Senior Researcher and Sociobehavioural Lead
Desmond Tutu TB Centre, Department of Paediatrics and Child Health
Stellenbosch University, Cape Town, South Africa

Dr. Lario Viljoen is the sociobehavioural lead at the Desmond Tutu TB Centre at Stellenbosch University in Cape Town, South Africa. For more than a decade, I have been working in the field of public health, particularly HIV prevention, sexual reproductive health, stigma, and paediatric care in low-and middle-income countries. Partnering with various organisations, including NGOs, academic institutions, research organisations, and government bodies, I have implemented a broad scope of projects in diverse settings – primarily in sub-Saharan Africa. Specifically, I have worked on the landmark HPTN 071 PopART trial (community based-HIV prevention) which included formative research and a stigma ancillary study. Recently, I led the sociobehavioural components of the Unitaid-funded Benefit Kids project, which included the PETITE DTG study (acceptability of novel DTG formulations in neonates born to mothers living with HIV) and the CATALAYST study (acceptability of novel paedaitric formulations for drug-resistant TB). I am also the lead social scientist for the multi-country EDCTP-funded ENABLE study (bNAbs in infants with HIV). I am an elected member serving on the behavioural and social sciences (BSS) committee at the ACTG and a Weill Cornell Women's Infectious Diseases Global Scholar (2026 – 2028). I leading a group of multidisciplinary social scientists at the DTTC, regularly contributing to the evidence that shape both national and international paediatric treatment guidelines.

Tianyi Zhang, PhD
Human Factors Reviewer
DMEPA I, OMEPRM, OSE, CDER, FDA

Dr. Tianyi Zhang is a Human Factors Reviewer in the Division of Medication Error Prevention and Analysis I (DMEPA I) in the Office of Surveillance and Epidemiology at the FDA, where he applies his extensive human factors knowledge in medication error prevention across multiple therapeutic areas to increase the safe and effective use of drugs, biologics, and combination products by minimizing use errors related to the naming, labeling, packaging, or product design. Beyond his review responsibilities, he serves in multiple working groups as the DMEPA I representative, contributing to the development and updating of FDA policy documents and human factors research collaborations with the Office of Generic Drugs. He holds a Bachelor of Science and Master of Science in Industrial and Systems Engineering from the University of Wisconsin-Madison, and a doctorate in Systems and Industrial Engineering from the University of Arizona.