Co-Processed API and Regulatory Requirements

In-Person Workshop

July 13-14th

2022

Speaker Biographies

Ramesh K. Sood, Ph.D.
Senior Scientific Advisor
ONDP | OPQ | CDER | FDA

Dr. Ramesh K. Sood is a Senior Scientific Advisor in the Office of New Drug Product, Food and Drug Administration, Silver Spring. He received his Ph.D. in Organic Chemistry from Queen's University, Kingston, Canada. Prior to joining the FDA, Dr. Sood worked for several years in academic settings and biopharmaceutical industry. He joined FDA in 2001 as a Review Chemist. During his period at the FDA, he has held positions of Team Leader, Branch Chief, Division Director and Deputy Office Director for Science and Policy in the Office of New Drug Quality Assessment.

Sau (Larry) Lee, Ph.D.
Deputy Super Office Director of Science
OPQ | FDA

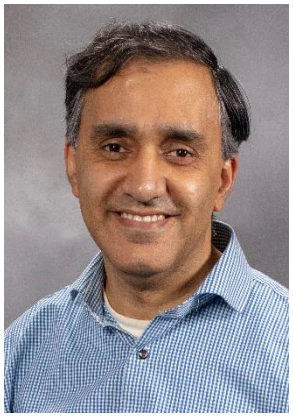
Dr. Sau (Larry) Lee is the Deputy Super Office Director of Science in the Office of Pharmaceutical Quality. He directs the activities of staff members in OPQ sub-offices responsible for the quality assessment of regulatory submissions (OBP, OLDP, ONDP, and OPMA). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval.

Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

Timothy Watson, Ph.D.
Executive Director and Team Leader, CMC Advisory Office (AO)
Pfizer

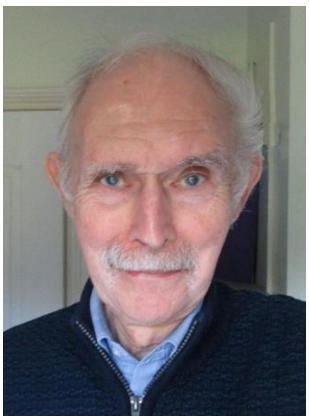
Dr. Timothy Watson is an Executive Director and Team Leader for the CMC Advisory Office (AO) at Pfizer. The AO is a collection of Pfizer experts that provide regulatory & technical guidance to project teams to mitigate risk & integrate CMC policy with product strategies. The AO also leads Pfizer in developing and advocating regulatory and quality policy positions (internally and externally) in partnership with Pfizer's Quality Organization. Dr. Watson currently serves as the PhRMA topic lead on ICHQ9's revision EWG. In the past, he served as a EWG member on the ICHQ11 regulatory guidance document for drug substance, the Rapporteur for the ICHQ11 Q&A Starting Material IWG, member of ICHQ7 IWG Q&A team, and ICHQ3C EWG. He continues to support many other ICH efforts (such as Q12, Q13, and the QDG); and currently serves as Pfizer's representative on the PhRMA Global Quality and Manufacturing team (GQM). Dr. Watson is one of Pfizer's participating Boards of Directors for the International Consortium for Innovation and Quality (currently Vice Chair of IQ) and serves on the ISPE Board of Directors and as the Co-Chair of the ISPE Global RQHC – Regulatory and Quality Harmonization Council. He began his career at Marion Merrell Dow (1994) in chemical research where his responsibilities involved developing new API processes, manufacturing the first GMP API bulk, technology transfers, etc. In 2000, He joined Pfizer, where he continued with process chemistry development responsibilities (Phase II, III, and manufacturing). In 2009, Dr. Watson joined Regulatory Chemistry and Manufacturing Controls (GCMC) in support of QbD and Q11. He holds a Ph.D. from The Ohio State University, under the direction of Dr. Leo Paquette.

Ahmad Sheikh, Ph.D.
Senior Research Fellow and Head of Solid-State and Computational Chemistry
AbbVie



Dr. Ahmad Sheikh is Senior Research Fellow and Head of Solid-State and Computational Chemistry at AbbVie. He has over 20 years of pharmaceutical development experience across several Fortune 500 Pharma Companies. At AbbVie, Dr. Sheikh has been pivotal in the development and commercialization of a broad range of recently launched medicine including Viekira, Venclexta, Mavyret, Orilissa, and Rinvoq. He earned his B. Eng. and Ph.D. in Chemical Engineering from the University College London in the UK. He has authored over 30 scientific papers, 3 book chapters, and is an inventor on 20 patents.

Patrick McArdle, Ph.D.
Professor
National University of Ireland (NUI), Galway



Dr. Patrick McArdle obtained a B.Sc. and Ph.D. (supervisor A.R. Manning) from University College Dublin, UCD and a D.Sc. from NUI, Galway. He did post-doctoral research with Jack Lewis at UC London and Cambridge UK. He has had sabbatical leave with F.A.Cotton at Texas A&M, Jack Norton at Princeton and Columbia USA, and Guy Dodson at York UK. Dr. McArdle currently researches the areas of crystallography, crystal growth and solid state analysis in collaboration with SSPC.
https://www.nuigalway.ie/our-research/people/chemistry/patrickmcardle/

Alastair Florence, Ph.D.
Distinguished Professor in Pharmaceutical Sciences, Director of CMAC
University of Strathclyde

Professor Alastair Florence is a Distinguished Professor in Pharmaceutical Sciences at the University of Strathclyde and is Director of CMAC providing leadership across the centre's portfolio, engaging with our key stakeholders and driving the Centre's vision to transform the development and manufacture of medicines. He leads a number of major collaborative programmes including the EPSRC Future CMAC Manufacturing Research Hub, Made Smarter Innovation - Digital Medicines Manufacturing Research Centre (DM2) and CMAC National Facility. Leading a national and international academic team he works in close collaboration with our industry partners to understand existing or emerging challenges to inform CMAC priorities. His research interests lie in the science and technology associated with continuous crystallisation, physical form control and advanced characterisation of pharmaceuticals and the development of predictive methods for experimental design, processing and control.

Paresma (Pinky) Patel, Ph.D.
Branch Chief
ONDP | OPQ | CDER | FDA

Dr. Paresma Patel is a Branch Chief in the Office of New Drug Products, Division of New Drug API. She started at the FDA in 2015 as a review chemist supporting the oncology divisions. She has worked across multiple clinical divisions as a drug substance and drug product chemistry, manufacturing and controls (CMC) reviewer, and served as a Quality Lead for two years prior to her current role. Prior to FDA, she worked as a medicinal chemist at the National Institutes of Health with a focus on target validation and lead optimization of small molecule kinase inhibitors. Dr. Patel completed her Ph.D. in Organic Chemistry at The Scripps Research Institute in 2010 working on the development and application of novel chemistry methods. Following her graduate work, she completed a postdoctoral fellowship at the California Institute of Technology working with Dr. Robert H. Grubbs on the development of novel ruthenium-based catalysts and synthesis of bioactive polymers.

Luke Schenck
Principal Scientist
Merck & Co., Inc.

Luke Schenck started in pharmaceutical development at Merck in 2001, gaining scale up expertise with conventional granulation and compression processing routes. He later became involved in Merck's initial hot melt extrusion (HME) development efforts including scale up to achieve Merck's first PhIII HME delivery. In 2008, he moved to chemical process development and commercialization. Here he worked on the filing the enzymatic transamination route for Januvia and filing Belsomra, Merck's first HME compound. The primary motivation for the move to drug substance was to explore opportunities at the drug product interface. This initially involved working to identify HME routes to devolatilize API solvates, and additive mediated crystallization efforts as a means to alter morphology, particle size and form. Since 2015, Luke has been leading the Particle Engineering Lab, identifying routes to manage challenging API properties. The group's focus includes 'bottom up' generation of nano to micron sized neat API for oral, parenteral, and respiratory delivery routes as well as innovative approaches to deliver co-processed API to address needs of increasingly challenging APIs in development. Since 2018, Luke has been co-leading the IQ Co-Processed API working group.

Jeremy Merritt, Ph.D.
Director in SMDD
Eli Lilly & Co.

Dr. Jeremy M. Merritt is a Director at Eli Lilly and Co. in the synthetic molecule design and development organization (SMDD). He currently leads the Particle Design Lab (PDL) responsible for crystallization process development with a focus on designing the commercial process and enabling physical property attributes for successful integration with drug product processing with emphasis on continuous processing. Prior to leading the PDL, he was a contributor in growing the modeling and simulation capability group for SMDD with emphasis on scale-up and impurity control. Dr. Merritt also advanced the mechanistic understanding behind salt disproportionation in the solid-state through modeling efforts. He received his Ph.D. in Physical Chemistry from the University of North Carolina at Chapel Hill and spent one month as an invited researcher at the Fritz-Haber Institute of the Max-Plank Society in the department of molecular physics (Berlin) before completing a postdoctoral appointment at Emory University. He currently co-leads the IQ Co-processed API Working Group.

Mohan Sapru, Ph.D.
Branch Chief
New Drug Products Division III, Branch V
ONDP | OPQ | CDER | FDA

Dr. Mohan Sapru is the Branch Chief in the Office of New Drug Products/Office of Pharmaceutical Quality (OPQ), FDA. He supervises a team of expert scientists/reviewers, oversees the scientific review and quality pre-marketing evaluation of new drug products, and provides technical and administrative leadership to the team. As a member of Emerging Technology Team (ETT), he serves as ETT Project Lead for evaluating emerging technology-based sponsor proposals aimed towards pharmaceutical innovation and modernization. He serves as a chair and an expert panel member for CMC sessions on oligonucleotides for DIA/FDA Oligonucleotide Conferences and has made several key presentations on regulatory aspects of oligonucleotide and peptide therapeutics for various national and international conferences. Prior to joining the FDA, Dr. Sapru served as a faculty at Northwestern University, Chicago, where his research focus was in the area of innovative technologies such as smart drug designing, drug-induced cellular adaptation, and gene therapy, including RNAi-based allele-specific gene therapy in models of neurodegenerative disorders. Dr. Sapru holds several US patents and has authored a number of research publications in prestigious peer-reviewed journals.

Steven Ferguson, Ph.D.
Assistant Professor, School of Chemical and Bioprocess Engineering; University College Dublin (UCD)
Adjunct Assistant Professor, School of Pharmacy and Pharmaceutical Sciences; Trinity College Dublin
Principal Investigator; National Institute for Bioprocess Research and Training (NIBRT)

Dr. Steven Ferguson is an Assistant Professor in the School of Chemical and Bioprocess Engineering at University College Dublin (UCD). He is also currently an Adjunct Assistant Professor in the School of Pharmacy and Pharmaceutical Sciences at Trinity College Dublin and is a Principal Investigator at the National Institute for Bioprocess Research and Training (NIBRT) focused on the development of downstream processing and advanced manufacturing technologies, for separation and purification of biopharmaceuticals and advanced therapeutic medicinal products. He currently is a theme lead in manufacturing research for the SSPC, the Science Foundation Ireland research center for pharmaceuticals and leads a targeted SPOKE project on 3D-printed technologies in pharmaceutical manufacturing at I-form, the Science Foundation Ireland Research Centre for Advanced Manufacturing. In addition to these roles, he leads a number of targeted research projects, in direct collaboration with multinational pharmaceutical companies aiming at deploying novel technologies in the development and manufacturing of drugs.

Dr. Ferguson received a B.E. from the School of Chemical and Bioprocess Engineering in UCD. He remained at UCD to undertake a Ph.D. in Prof. Brian Glennon's research Group studying continuous crystallization of drugs as part of the SSPC Research Cluster. He then moved to MIT to work as a Postdoctoral Researcher as part of the Novartis-MIT Center for Continuous Manufacturing, under the supervision of Prof. Allan Myerson and Center Director Prof. Bernhardt Trout. Following this, Dr. Ferguson worked as a Scientist within Biogen in Cambridge, MA, working in the research, development, and commercialization of novel therapeutics and associated technologies, before returning to UCD & Ireland to start an academic research lab focused on pharmaceutical engineering research.

http://sspc.ie/manufacturing/
http://www.transpharmtech-dtc.ac.uk
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https://twitter.com/Ferguson_UCD

Rapti Madurawe, Ph.D.
Division Director
OPMA | OPQ | CDER | FDA

Dr. Rapti Madurawe is a Division Director in the Office of Process and Facilities, Office of Pharmaceutical Quality at FDA. She has broad regulatory experience in the CMC review of investigational, new, and generic drug applications as well as emergency user, breakthrough, and bioterrorism applications. Dr. Madurawe has worked extensively on developing the regulatory framework for continuous manufacturing of pharmaceuticals. She is the FDA topic lead for the ICH Q13 guidance on continuous manufacturing and has presented nationally and internationally on the subject. Dr. Madurawe is a member of CDER's Emerging Technology Team. She holds a Ph.D. and B.E. in Chemical Engineering, and a M.S. in Biochemistry. Prior to joining the FDA, Dr. Madurawe worked in biotech and biopharmaceutical industries as a process development engineer.

Jared Evans, Ph.D.
Senior Director, Drug Substance Regulatory Strategy
Gilead Sciences

Dr. Jared Evans is a Senior Director at Gilead Sciences in the Drug Substance Regulatory Strategy Group, which is a team responsible for the development and communication of phase-appropriate drug substance control strategies that ensure patient safety, enable manufacturing flexibility, and align with global regulatory expectations. He is a CMC program lead whose team is responsible for early development clinical trial material deliverables in several inflammation indications, and Dr. Evans leads a cross-functional team defining the procedures and implementing nitrosamine risk assessments within Gilead's portfolio.

Derek Frank, Ph.D.
Senior Scientist, Particle Engineering Lab, Process Research & Development
Merck

Dr. Derek Frank is a Senior Scientist in the Particle Engineering Lab in Process Research & Development at Merck. He has been at Merck since 2019 after receiving his Ph.D. in Polymer Science from the University of Michigan. Dr. Frank's research interests include amorphous solids, novel excipients, and the functional design of pharmaceutical materials.

Nima Yazdanpanah, Ph.D.
Consultant on Advanced Manufacturing and Modeling and Simulation Applications
Procegence

Dr. Nima Yazdanpanah is a Consultant on Advanced Manufacturing and Modeling and Simulation Applications in Bio/pharmaceutical and fine chemical industries. His area of expertise covers process design, process simulation, particulate matters, and advanced manufacturing.

Prior to starting his consultancy firm (Procegence), he was a research scientist with US Food and Drug Administration. Dr. Yazdanpanah was appointed as a member of an expert team for advancement of emerging technologies to modernize pharmaceutical manufacturing. With more than 15 years of diverse experience in different industries, he has worked at R&D, process design, and MSAT sections. Dr. Yazdanpanah received his Ph.D. from The University of Sydney, Australia. He was a postdoctoral research associate at MIT, and Novartis-MIT Center for Continuous Manufacturing. He has received multiple national and international awards, and published numerous journal papers and book chapters.

Procegence offers comprehensive services on equipment sizing and characterization, scale-up, process development and integration, steady state and dynamic modeling, process control strategies development, risk analysis, developing multi-dimensional virtual DoEs, and CMC packages.
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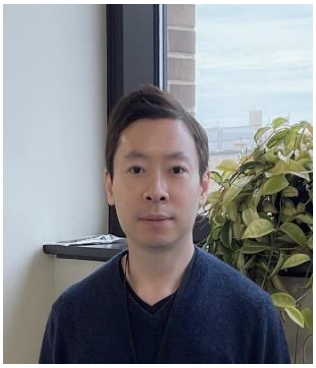
https://procegence.com/

San Kiang, Ph.D.
Chief Technology Officer Drug Product
J-Star Research/Porton

Dr. San Kiang deploys particle engineering and co-processing techniques to resolve active pharmaceutical ingredient (API) and formulation issues especially those related to powder flow and dosage form dissolution rates. As a Research Professor at Rutgers University, he worked on research projects in the Engineering Research Center for Structured Organic Particles and the Chemical Engineering Department. His research focus is on continuous manufacturing (CM) and particle engineering. More specifically how the material properties of API can be engineered and how these properties affect CM equipment train and drug product performance. Dr. Kiang's has 35 years of pharmaceutical development and technology transfer experience at Bristol-Myers Squibb covering both API and drug product (DP) areas. He is a Ph.D. chemical engineer with experience in directing multi-disciplinary teams in pharmaceutical, chemical, and biochemical development and manufacture. He has directed and/or participated in 12 NDA projects that were eventually commercialized. He successfully participated in one of the first NDA filing using QBD paradigm. In this filing, Dr. Kiang led the use of risk assessment and process modeling with emphasis on fundamental mechanistic understanding for drug development. He is a well recognized expert in crystallization, particle engineering, reaction engineering, continuous processing (both DP and API), as well as the design of pharmaceutical composite materials through co-processing.

Raimundo Ho, Ph.D.
Principal Research Scientist, Materials Science Center of Excellence Lead
AbbVie Inc.



Dr. Raimundo Ho is currently Principal Research Scientist and Materials Science Center of Excellence Lead at AbbVie Inc. He joined the Solid State Chemistry group at Abbott/AbbVie in 2011 and has more than 11 years of experience in CMC development of pharmaceuticals spanning across pre-clinical development to commercialization. He also has extensive experience in solid form development, materials science at the drug substance/drug product interface including characterization, process development, and physical property control to enhance drug substance and product processing and manufacturing. Dr. Ho received his Masters in Chemical Engineering in 2005 and Ph.D. in 2009 from Imperial College London. He has been an active member of the IQ Co-processed API Working Group since 2019. He has contributed to more than 25 scientific publications, 3 patents, and a number of book chapters in the field of chemical engineering.

Deniz Erdemir, Ph.D.
Associate Scientific Director
Bristol-Myers Squibb

Dr. Deniz Erdemir is an Associate Scientific Director at Bristol-Myers Squibb (BMS). Prior to joining BMS, she received her Ph.D. in Chemical Engineering from the Illinois Institute of Technology. Dr. Erdemir's research focus lies at the drug substance-drug product interface with emphasis on crystal polymorphism and design of materials via particle engineering to enable robust drug products. She is the author of numerous publications on co-processed materials and crystallization process development, the inventor on two US patents and the co-editor of the 3rd edition of Handbook of Industrial Crystallization.

Billie Kline, Ph.D.
Chemical Engineering Senior Fellow
Vertex Pharmaceuticals

Dr. Billie Kline is a Chemical Engineering Senior Fellow at Vertex Pharmaceuticals, focusing on late-stage development of drug substance processes. She has been with Vertex since 2007 and has had increasing responsibility to develop and manage Quality by Design efforts for the last three launched drugs to treat cystic fibrosis. During her tenure, Billie has seen her fair share of drug substance molecules with challenging properties and is happy to represent Vertex in the IQ Working Group for Co-processed APIs. Before joining Vertex, Billie worked for Pfizer specializing first in using enzymes to perform selective transformations and later in implementing automation, parallel reaction technology and *in situ* analytics to understand more about the fundamentals of reactions and crystallizations being performed. Billie has a Ph.D. in Chemical Engineering and a MS in Bioengineering both from University of Pittsburgh and a BS in Chemical Engineering from Lafayette College.

Haitao Zhang, Ph.D.
Associate Research Fellow, Chemical Process R&D
Sunovion Pharmaceuticals Inc.

Dr. Haitao Zhang is an Associate Research Fellow in Chemical Process R&D at Sunovion Pharmaceuticals Inc. In his current role, he is responsible for developing, and demonstrating commercially viable, multi-step, organic syntheses and crystallization for the manufacturing of small-molecule advanced intermediates and active pharmaceutical ingredients. His expertise ranges from the characterization and control of API physical properties at the bulk-pharm interface, process scale-up, crystallization and reaction engineering, process mixing control, use of high-throughput instrumentation and laboratory workflows for process development. Dr. Zhang is also responsible for new technology platform establishment, such as continuous manufacturing, QbD driven process development including the PAT application, simulation and process modeling, etc.

Laurie Graham-Eure, Ph.D.
Director, Division of Internal Policies and Programs
OPPQ | OPQ | CDER | FDA

Dr. Laurie Graham-Eure is currently the Director of the Division of Internal Policies and Programs (DIPAP) in the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) at the Center for Drugs Evaluation and Research (CDER). DIPAP is responsible for the development and evaluation of CDER's internal policies and programs related to pharmaceutical quality for CDER regulated products, including application assessment and inspection. Prior to joining OPPQ, she had more than 20 years of experience at the FDA, including inspections and application assessments for monoclonal antibodies, novel antibody products, Fc-fusion proteins, and combination products.

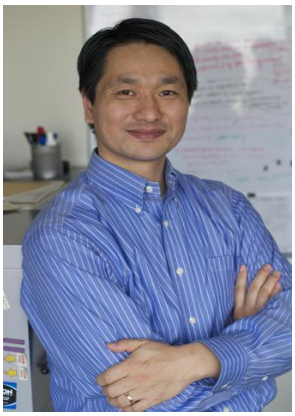
Sharon Page, B.Sc. (Hons)
Director, Global Chemistry, Manufacturing and Controls (GCMC)
Pfizer R&D UK Ltd

Sharon Page is the Director, Global Chemistry, Manufacturing and Controls (GCMC) at Pfizer R&D UK Ltd. She holds a B.Sc. (Hons) in Biochemistry from Kingston University (UK) and has over 20 years' experience in the pharmaceutical industry. Her background is in drug product design working on a wide range of dosage forms from oral presentations through to parenteral products throughout the development cycle. For the past 6 years, she has worked in regulatory affairs with a focus on the CMC aspects of products.

Lindsey Saunders Gorka, Ph.D., RAC-Drugs
Director and Team Leader, Global Regulatory CMC
Pfizer, Inc.

Dr. Lindsey Saunders Gorka is a Director and Team Leader in Global Regulatory Chemistry Manufacturing and Controls (CMC) at Pfizer, Inc. located in Peapack, New Jersey. She manages life-cycle CMC regulatory activities, including developing global regulatory strategies and delivering regulatory submissions for investigational studies, new commercial registrations, and postapproval changes for innovative medicines. Prior to joining Pfizer in 2017, she was a CMC Reviewer in the Office of New Drug Products at the FDA. Dr. Gorka has a B.S. in chemistry from Brandeis University, a Ph.D. in chemistry from Yale University, and she completed a postdoctoral fellowship at the National Cancer Institute. Dr. Gorka earned her Regulatory Affairs Certification (RAC) in 2015 and has previous regulatory experience working at Technical Resources International. Dr. Gorka is currently an active member of the Innovation and Quality in Pharmaceutical Development (IQ Consortium) Co-processed APIs Working Group with an interest in developing regulatory strategies for these promising materials.

Changquan Calvin Sun, Ph.D.
Professor of Pharmaceutics
University of Minnesota



Dr. Calvin Sun is Professor of Pharmaceutics in the Department of Pharmaceutics, University of Minnesota. Dr. Sun's research focuses on formulation development of tablet products through appropriate application of materials science and engineering principles, including 1) crystal and particle engineering, for superior pharmaceutical properties, e.g., powder flowability, tabletability, dissolution, and stability; 2) pharmaceutical unit operations, e.g., blending, granulation, and tableting. He has published more than 230 papers in these areas with an *H*-index of 55 (Google Scholar as of May 17, 2022). Dr. Sun currently serves on the editorial advisory boards for *AAPS Open, CrystEngComm, Int. J. Pharm., J. Pharm. Sci.*, *Mol. Pharmaceutics, and Pharm. Res.* He has served on the Expert Committee in Physical Analysis of the United States Pharmacopeia since 2010. Dr. Sun is an AAPS Fellow and a Fellow of Royal Society of Chemistry. He has received a number of awards, including the 2019 Ralph Shangraw Memorial Award by International Pharmaceutical Excipient Council (IPEC), for his outstanding research contributions in the area of pharmaceutical sciences.

Frank Bernardoni, Ph.D.
Principal Scientist, Analytical R&D
Merck & Co.

Dr. Frank Bernardoni is a Principal Scientist within the Small Molecule Analytical Research and Development department at Merck Research Labs. Over a 19-year career at Merck, he has co-authored >20 publications and was a key contributor to many commercialized programs, most notably, Januvia, Letermovir, Marizev, Recarbrio, and Vericiguat. Dr. Bernardoni is a key member of the Merck Mutagenic Impurities Council and served as the drug substance analytical team lead for the rapid development and commercialization of Molnupiravir (Lagevrio) for the treatment of COVID-19. His research interests include hydrophobic silicas with well-defined chemistry and geometry and the development of green analytical chemistry techniques.

Don Parsons, Ph.D.
Vice President, Early Technical Development and Lipid Nanoparticle Process Development
Moderna

Dr. Don Parsons is Vice President, Early Technical Development and Lipid Nanoparticle Process Development at Moderna. He has over 25 years of experience in the pharmaceutical industry leading nanoparticle and small molecule process and analytical development. In his role at Moderna, he leads the development of manufacturing processes for lipid nanoparticle products as well as small molecule process chemistry; he also plays a matrix leadership role coordinating CMC activities for Moderna's early-phase clinical pipeline. Prior to his tenure at Moderna, Dr. Parsons spent six years with BIND Therapeutics in Cambridge, Massachusetts, where he led analytical development and process chemistry functions as Vice President, Pharmaceutical Development. He has extensive experience in the clinical translation of complex drug delivery systems, including process development, analytical characterization, and application of Quality by Design principles to these systems. He has a B.A. in Chemistry from Dartmouth College (1987) and a Ph.D. in Physical Chemistry from University of Wisconsin-Madison (1994).

Peter Capella, Ph.D.
Director
Division of Immediate and Modified Release Drug Products | OLDP | OPQ | CDER | FDA

Dr. Peter Capella received a Ph.D. in Analytical Chemistry from the University of Kansas in 1991. He has over 15 years in pharmaceutical development experience from both the NDA and ANDA side, as well as nearly 15 years at the FDA supporting generic drug quality review across a wide range of therapeutic areas.

Ben Stevens, Ph.D., M.P.H.
Director CMC Policy and Advocacy
GSK

Ben Stevens is a Director of CMC Policy and Advocacy at GSK and has nearly 15 years of drug discovery and regulatory experience. Prior to GSK, Ben was a Director of Regulatory Affairs CMC at Alnylam where he led the clinical regulatory CMC development and initial US NDA and EU MAA submissions of an siRNA product. Before Ben joined Alnylam, he was a Principal Consultant at PAREXEL and an acting Branch Chief in the Office of New Drug Products (ONDP) at the FDA. At FDA, Ben worked closely with several key policy groups (OPPQ, ORP), partnered with CDRH on matters related to combination product review, and was a government liaison to USP. Before FDA, Ben spent seven years in medicinal chemistry R&D at Pfizer and Merck. Ben has broad regulatory CMC experience in small molecules, peptides, oligonucleotides, botanicals, and combination products, with recent focus CMC policy and advocacy for biologics and CGT at GSK. He received a Ph. D. in Chemistry from the University of Pittsburgh, a M.P.H. from the Johns Hopkins and is a co-author of over 30 publications and patents.

Mahesh Ramanadham, Pharm.D., M.B.A.
Deputy Director
OPPQ | OPQ | CDER | FDA

Commander (CDR) Ramanadham is the Deputy Director for the Office of Policy for Pharmaceutical Quality, within the Office of Pharmaceutical Quality (OPQ). He joined the Agency in November 2009 after graduating with his Doctor of Pharmacy degree from the University of Maryland and his M.B.A. from the University of Baltimore. Within FDA, he has served in leadership roles in the Office of Compliance and the Office of Pharmaceutical Manufacturing Assessment within OPQ. Prior to joining FDA, CDR Ramanadham had experience in solid oral dosage manufacturing ranging from OTC products to schedule II narcotics. Outside of FDA, CDR Ramanadham continues to practice pharmacy in the community setting to maintain perspective on the clinical relevancy and impact of our efforts in pharmaceutical quality.

Cinzia Gazziola, Ph.D.
Pharma Technical Drug Regulatory Affairs Manager
F. Hoffmann-La Roche, Switzerland

Dr. Cinzia Gazziola is Technical Drug Regulatory Affairs Manager at F. Hoffmann-La Roche AG (Roche) since 2013. She is currently accountable for the global CMC regulatory strategies for early and late-stage development small molecule products with particular focus on oligonucleotides. She covered a leading role on a core commercial biologic during the first 6 years with Roche. Before joining Roche, she led various regulatory activities covering quality, non-clinical and clinical on generics and biosimilars at Synthon BV, The Netherlands. Dr. Gazziola received her Master's degree in Biology and her Ph.D. in Evolutionary Biology from the University of Padova, Italy. She spent about 10 years working as scientist at various Universities. Since 2018, Dr. Gazziola is also a member of the European Pharmaceutical Oligonucleotide Consortium (EPOC) where she co-authored 2 articles on API in solution. She joined the IQ Consortium Co-processed API Working Group in 2021.

Llorente Bonaga, Ph.D.
Director, Regulatory Affairs, CMC, Global Regulatory Affairs and Clinical Safety
Merck & Co. USA

Dr. Llorente V. Bonaga is an experienced Regulatory Affairs professional and is currently a Director in RA CMC at Merck leading a team supporting global clinical studies and marketing applications for the company's small molecule portfolio. He has held Regulatory CMC positions in several small to large global companies in the US and Switzerland. He has worked directly on several approved drug products in the market for cystic fibrosis, HCV, cancer and some ultrarare diseases.

Dirk Wandschneider, Ph.D.
Laboratory Manager Particle Characterization
EMD Serono/Central Analytical Services at Merck KGaA, Darmstadt, Germany

Dr. Dirk Wandschneider is a Laboratory Manager in the Central Analytical Service Lab focusing on particle characterization. He joined Merck KGaA, Darmstadt, Germany in 2006 after receiving his Ph.D. in Physical Chemistry from the University of Rostock, Germany. His work experience includes a broad range of analytical technologies as well as particle engineering, with a focus on optimization of API with regards to particle size, particle shape, and related powder properties to ensure bioavailability and manufacturability.

Sandra Masanes Marza
CMC Leader Diabetes; Manufacturing Science & Technology
EMD Serono/Merck KGaA, Darmstadt, Germany

Sandra Masanes Marza is CMC Leader of Marketed Product, driving the Technical Life Cycle Management for Diabetes franchise leading cross-functional, international teams that oversees all related CMC activities. She joined Merck KGaA, Germany in 1992 and has extensive technical and scientific background with over +25 years' experience (first locally in Spain and now globally) from different positions which includes Galenical Development analyst, Pharmaceutical Technology technician, Solids Bulk Manufacturing Manager, and Global Process Expert within MS&T.

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

Dr. James E. Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption and formulation, involving laboratory and clinical research. He has served as advisor to 24 Ph.D. 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).

Stephen Hoag, Ph.D.
Professor of Pharmaceutical Sciences
University of Maryland, Baltimore

Dr. Stephen Hoag is a Professor of Pharmaceutical Sciences at the University of Maryland, Baltimore; he received his Ph.D. in Pharmaceutics from the University of Minnesota-Twin Cities and a B.S. in Biochemistry from the University of Wisconsin-Madison. He has been a visiting professor at 3M Pharmaceuticals and Abbott Laboratories. His primary research interests are in the area of solid oral formulations, excipient functionality testing, pediatric formulation taste and texture analysis, tablet coating, coating polymers, tablet press instrumentation, tablet compaction modeling. His research has included studies in formulation and process development of tablets, capsules and gels, formulation of folic acid in multivitamin and mineral supplements, taste and texture analysis of pediatric formulation, polymer science, pigment stability in coating polymers and thermal and rheological analysis of polymers, powder flow, and formulation stability. Dr. Hoag has studied the application of near infrared spectroscopy to the analysis of excipient identification, tablet quality and production monitoring for process analytical technology (PAT) applications. Working with Dr. Larry Augsburger, he has edited a four volume set of books on tablet compaction and capsules. Dr. Hoag is a member of NIPTE (National Institute of Pharmaceutical Technology and Education) Executive Committee, and he is an AAPS fellow. In addition, he serves on the International Steering Committee for the Handbook of Pharmaceutical Excipients, and he serves on the editorial board of the journal of Pharmaceutical Development Technology.