4TH FDA/PQRI CONFERENCE ON ADVANCING PRODUCT QUALITY
Biographies

Day 1 – April 9, 2019 Plenary

Mehran Yazdanian, Ph.D., Senior Director of Scientific Strategy and Operations
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Mehran Yazdanian is the Sr. Director of Scientific Strategy and Operations for development of biologics and biosimilars in Specialty R&D at Teva Pharmaceuticals. He received his BS in biochemistry and MS and PhD in pharmaceutics from the University of Wisconsin-Madison. His career has been focused on directing formulation and analytical development activities from early drug discovery support and preformulation to formulation development and manufacturing for clinical programs and to commercialization. The focus of his research has been on drug delivery from two perspectives: optimization of biopharmaceutical properties and formulation strategies to enhance oral absorption. Previously he was responsible for the Physical Pharmaceutics section of the pharmaceutics department at Boehringer Ingelheim Pharmaceuticals Inc. Before that he held a position at Merck Research Laboratories where he worked on formulation development of transdermal and liquid dosage forms for veterinary applications.

Patrizia Cavazzoni, M.D., Deputy Director of Operations
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Patrizia Cavazzoni is the deputy director for operations at the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA).

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in Psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs and safety surveillance.

Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, a Fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology and recipient of the American College of Psychiatrists' Laughlin Fellowship.

Stephanie L. Krogmeier, Ph.D., Vice President, Global Regulatory CMC Strategy
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Stephanie Krogmeier has been with Vertex Pharmaceuticals in Boston, MA for 14 years. Stephanie earned a Ph.D. in Pharmaceutical Chemistry from the University of Kansas. Previously she earned a B.S. in Pharmacy from Drake University and is a registered pharmacist in Iowa. Stephanie began her career at Vertex in Formulation Development before she moved into Global CMC Regulatory Affairs. Stephanie has led the CMC preparation of multiple marketing applications which have included Quality by Design strategies, drug product continuous manufacturing processes and real time release testing strategies. Recently Stephanie completed a 2 year rotation as the Head of Regulatory Affairs ROW. Stephanie is currently the Vice President of Global CMC Regulatory Affairs at Vertex and continues to pursue innovative CMC regulatory strategies.

Lawrence X. Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality
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Lawrence X. Yu, Ph.D., is the Deputy Director, Office of Pharmaceutical Quality, and acting Director, Office of Process and Facilities, Food and Drug Administration, where he oversees new, generic, and biotechnology product quality review and inspection. Dr. Yu created the Question-based Review, defined the Pharmaceutical Quality by Design (QbD), inaugurated the FDA modern review system - Integrated Quality Assessment (IQA), established the FDA Emerging Technology Team (ETT) program, and developed the FDA historic concept of operations agreement to integrate review and inspection. Dr. Yu is also an adjunct Professor at the University of Michigan. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the AAPS Journal. Dr. Yu has authored/co-authored over 150 papers and given over 300 invited presentations. He is a co-editor of the books entitled “Biopharmaceutics Applications in Drug Development”, “FDA Bioequivalence Standards”, and “Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, 2nd Ed.” Dr. Yu is the winner of numerous awards including AAPS Regulatory Science Achievement award, AIChE PD2M Drug Product QbD Achievement Award, Japan Naigai Foundation Distinguished Lectureship, China Beijing University IPEM graduation commencement address, Department of Health and Human Service Outstanding Leadership Award, FDA Commissioner’s Special Citation, Outstanding Achievement, Group Recognition, and Team Excellence awards.

TRACK 1: NOVEL APPROACHES TO IMPROVE TREATMENT OUTCOME AND PATIENT SAFETY

Session 1: Complex Generics – Challenges and Opportunities

Moderator:

Wenlei Jiang, Ph.D., Senior Science Advisor, Office of Research and Standards
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Dr. Wenlei Jiang currently serves as a Senior Science Advisor in the Office of Research and Standards (ORS)/Office of Generic Drugs (OGD)/Center for Drug Evaluation and Research (CDER). She has been championing regulatory research in the areas of generic nanomaterials, narrow therapeutic index drugs, and modified release products to support review standards development and ensure post-market safety and efficacy of these drug products. Currently she is leading efforts in complex drug product classification and research, and promoting global bioequivalence harmonization. She also serves as Vice Chair at Product Quality Research Institute (PQRI) Biopharmaceutical Technical Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University in 2001.

Presenters:

Daan J.A. Crommelin, Ph.D., Professor Emeritus, Department of Pharmaceutics
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Prof. Daan Crommelin is professor emeritus from the Department of Pharmaceutics at Utrecht University. Until December 2011 he was scientific director of the Dutch Top Institute Pharma – a public private partnership - in Leiden. He is adjunct professor at the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah. Crommelin is co-founder of OctoPlus, a Leiden based company specialized in the development of pharmaceutical (mainly protein based) product formulations and advanced drug delivery systems. He published extensively and edited a number of books. He was Editor-in-Chief of the AAPS book series 'Advances in the Pharmaceutical Sciences'. He advises venture capital groups and acts as a consultant for several big pharma companies and SME's. He chaired the Board of the UCAB Foundation: the Utrecht Center of Excellence for Affordable Biotherapeutics, a WHO supported initiative and the Board of Pharmaceutical Sciences of the International Pharmaceutical Federation (F.I.P.). He was chair of the organizing committee of the Pharmaceutical Sciences World Conference 2007 in Amsterdam. He is past president of the European Federation of Pharmaceutical Sciences (EUFEPS) and past vice-chair of the scientific advisory board of the European Innovative Medicines Initiative (IMI).

Katherine M. Tyner, Ph.D., Associate Director for Science (acting)
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Dr. Katherine Tyner is the Associate Director of Science (acting) in the Immediate Office of the Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research at the United States Food and Drug Administration (FDA). As Associate Director, Dr. Tyner leads the OPQ Science Staff in coordinating the intersection between science, review, and policy in OPQ as well as facilitating interactions between other CDER offices and FDA Centers. She received her PhD in Chemistry from Cornell University and joined the Food and Drug Administration in 2007 as a chemist specializing in nanotechnology. While at the FDA, Dr. Tyner has investigated the quality, safety, and efficacy of complex drug products including drug products containing nanomaterials, and she currently leads the CDER nanotechnology working group and is active in other CDER and FDA nanotechnology initiatives. Dr. Tyner is the author of multiple book chapters and journal articles concerning the appropriate characterization and biological impact of nanoparticle therapeutics and other complex products.

Xiaohui (Jeff) Jiang, Ph.D., Deputy Director, Division of Therapeutic Performance
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Xiaohui (Jeff) Jiang received his Ph.D. in chemistry from the University of California, San Diego. Currently he is working at the U.S. FDA as the Deputy Director of the Division of Therapeutic Performance in the Office of Research and Standards, under the Office of Generic Drugs. His work at the FDA is focused on complex generic drug products, where under the GDUFA regulatory science research program to develop and implement novel scientific methods in establishing active ingredient sameness, pharmaceutical equivalence and bioequivalence for generic drugs. Dr. Jiang's work resulted in the FDA guidance and generic drug approvals. Some notable examples include the approvals of Glatiramer Acetate Injection, Sevelamer and Colesevelam Suspension and Tablets, and the publication FDA guidance on Conjugated Estrogens Tablets and the ANDA peptide guidance which details how to develop synthetic peptides referencing rDNA peptide products. Prior joining the FDA, Dr. Jiang worked in biopharmaceutical industry and government agencies.

Session 2: Developments in Biopharm Characterization of Injectables/Non-Oral Products

Moderator:

Nan Zheng, Ph.D., Senior Staff Fellow
US Food and Drug Administration
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Dr. Nan Zheng is the Scientific Lead for QT at the Office of Clinical Pharmacology, Office of Translational Sciences, US FDA. Previously she worked at the Office of Research and Standards (ORS), Office of Generic Drugs (OGD), US FDA, as a project officer for regulatory science research activities in which quantitative methodologies were applied to support the development of bioequivalence standards for complex parenteral products. She was also responsible for developing product specific bioequivalence guidance and providing consult response to citizen petitions and controlled correspondences that are related to complex parenteral products and narrow therapeutic index drugs. Dr. Zheng received her Ph.D. in Pharmaceutical Sciences from the University of Michigan.

Presenters:

Jeffrey D. Clogston, Ph.D., Principal Scientist, Physicochemical Characterization Section Head
Nanotechnology Characterization Laboratory
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Dr. Jeffrey D. Clogston is a Principal Scientist and the Head of the Physicochemical Characterization Section at the Nanotechnology Characterization Laboratory (NCL). In his position, Dr. Clogston conducts physicochemical characterization and standardization of nanoparticles, develops new analytical methodology for critical quality attributes, and assesses current instrumentation for nanoparticle characterization. Prior to joining the NCL in March 2006, Dr. Clogston received his Ph.D. in Chemical Engineering from The Ohio State University. His research dissertation was on the application of the lipidic cubic phase for drug delivery, wastewater remediation, and membrane protein crystallization. His areas of expertise include physicochemical characterization of and in vitro release from lipid-based drug delivery systems, analytical methodology, and protein and lipid biochemistry.

R. Karl Malcolm, Ph.D., Professor of Drug Delivery, School of Pharmacy
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Karl Malcolm is Professor of Drug Delivery at the School of Pharmacy, Queen's University Belfast. He graduated with a BSc (Hons) Chemistry (1991) and a PhD in Polymer Chemistry (1995), both from Queen's University Belfast. Karl's research interests lie within the general area of sustained and controlled release drug delivery systems, and with a particular emphasis on vaginal drug delivery devices. For the past 15 years, he has specialised in the development of vaginal ring formulations for a range of clinical applications, most notably the long-term administration of antiretroviral compounds for prevention of sexual transmission of HIV. Karl's research is highly collaborative, with partnerships and collaborations extending across the world and involving major global health organisations, charities and industry.

Wenlei Jiang, Ph.D., Senior Science Advisor, Office of Research and Standards
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Dr. Wenlei Jiang currently serves as a Senior Science Advisor in the Office of Research and Standards (ORS)/Office of Generic Drugs (OGD)/Center for Drug Evaluation and Research (CDER). She has been championing regulatory research in the areas of generic nanomaterials, narrow therapeutic index drugs, and modified release products to support review standards development and ensure post-market safety and efficacy of these drug products. Currently she is leading efforts in complex drug product classification and research, and promoting global bioequivalence harmonization. She also serves as Vice Chair at Product Quality Research Institute (PQRI) Biopharmaceutical Technical Committee. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as advanced parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University in 2001.

Session 3: A Novel Approach for Overcoming Barriers to Improve Patient Access for Topical Drugs

Moderator:

Filippos Kesisoglou, Ph.D., Distinguished Scientist
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Filippos Kesisoglou is a Distinguished Scientist in the Biopharmaceutics and Specialty Dosage Forms group, Pharmaceutical Sciences, Merck & Co., Inc., where he has been leading the oral biopharmaceutics and modeling & simulation quantitative biopharmaceutics efforts. His work spans the fields of biopharmaceutics and formulation development, pharmacokinetics, and absorption, PBPK and IVIVC modeling as related to clinical, drug product development and CMC regulatory applications. He has been a key contributor to several new drug applications for currently marketed drug products. He holds a diploma in Pharmacy from Aristotle University of Thessaloniki, Greece and MSc and PhD degrees in Pharmaceutics from University of Michigan. He has authored/co-authored more than 60 manuscripts and more than 70 meeting abstracts/podium presentations in national/international meetings in the fields of biopharmaceutics, PBPK modeling, formulation development and drug delivery. In 2017, he was elected a Fellow of the American Association of Pharmaceutical Scientists (AAPS).

Flavian Rădulescu, PhD, Associate Professor
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Dr. Flavian Rădulescu is associate professor at the Faculty of Pharmacy, University of Medicine and Pharmacy Carol Davila Bucharest, Department of Biopharmaceutics. He previously worked in the research and development of liquid, oral and ophthalmic dosage forms, but also in bioequivalence studies. His main areas of interest are compendial and non-compendial in-vitro drug release methodologies for solid and semisolid dosage forms, development of formulations for low solubility drugs, in-silico and in-vitro screening of solubility/permeability profiles. For topical semisolids, he coordinates several collaborative projects with the pharmaceutical industry, using correlated in vitro release and rheological assessments for the demonstration of Q3 (microstructural) similarity. Dr. Rădulescu is currently involved in the validation of Topical drug Classification System, a project co-funded by the Product Quality Research Institute and coordinated by Dr. Vinod P. Shah.

Vinod P. Shah, Ph.D., FAAPS, FFIP
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Dr. Shah is a pharmaceutical consultant and was a PQRI Board Member (2013 – 2017). He retired from US FDA (Food and Drug Administration) as a Senior Research Scientist after 30 years of service in July 2005. At FDA, he has developed several Regulatory Guidances for Pharmaceutical Industry in the area of dissolution, SUPAC, bioequivalence and biopharmaceutics. He was President of American Association of Pharmaceutical Sciences (AAPS). He is a Fellow of AAPS and FIP. He is a recipient of Honorary Doctorate from Semmelweis University, Hungary and from University of Medicine and Pharmacy Carol Davila Bucharest, Romania. He is a recipient of FIP Lifetime Achievement Award in Pharmaceutical Sciences and AAPS Distinguished Pharmaceutical Scientist Award.

Tannaz Ramezanli, PhD., Pharm.D., Staff Fellow
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Tannaz Ramezanli currently serves as pharmacologist within the Office of Research and Standard (ORS) at Office of Generic Drugs (OGD) at the U.S. FDA. She currently work as a reviewer in the Topical and Transdermal Team at ORS. She is responsible for the development of product-specific bioequivalence guidances, reviewing and responding to controlled correspondences, and Pre-ANDA meetings. Tannaz Ramezanli is also engaged in the development of regulatory science research initiatives related to topical and transdermal drug products through FDA-funded collaborations with research institutions around the world. She received her Ph.D. in Pharmaceutical Sciences from Rutgers University and her Pharm.D. from Tehran University of Medical Sciences.

Session 4: Predictive Approaches to Gain Insight into the Clinical Performance of Inhaled Medicines

Moderator:

Mehran Yazdanian, Ph.D., Senior Director of Scientific Strategy and Operations
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Mehran Yazdanian is the Sr. Director of Scientific Strategy and Operations for development of biologics and biosimilars in Specialty R&D at Teva Pharmaceuticals. He received his BS in biochemistry and MS and PhD in pharmaceutics from the University of Wisconsin-Madison. His career has been focused on directing formulation and analytical development activities from early drug discovery support and preformulation to formulation development and manufacturing for clinical programs and to commercialization. The focus of his research has been on drug delivery from two perspectives: optimization of biopharmaceutical properties and formulation strategies to enhance oral absorption. Previously he was responsible for the Physical Pharmaceutics section of the pharmaceutics department at Boehringer Ingelheim Pharmaceuticals Inc. Before that he held a position at Merck Research Laboratories where he worked on formulation development of transdermal and liquid dosage forms for veterinary applications.

Presenters:

Jayne E. Hastedt, Ph.D., Managing Director
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Dr. Jayne E. Hastedt has over 30 years of experience in the pharmaceutical field. She has had management and technical leadership responsibilities for the development of more than 35 small molecules, peptides, and proteins with an overall contribution to more than 50 molecule-based R&D programs using various dosage forms, routes of delivery, and technologies leading to successful US and European approvals for 2 products. Her experience ranges from leading physicochemical characterization and early development activities through product development and launch. She has worked on products targeted for various routes of administration at various stages of development; including oral, pulmonary, transdermal, and oral controlled release dosage forms.

Throughout her career, her research interest has been in the area of drug delivery and drug delivery technologies and she is a graduate of the University of Wisconsin – Madison graduate program within the School of Pharmacy where she worked with Professors James Wright and George Zografi. She has had the opportunity to work within the pharmaceutical industry at Boehringer Ingelheim, Glaxo and GlaxoWellcome, Inhale Therapeutic Systems, and ALZA as a division of Johnson & Johnson. Dr. Hastedt has written and/or presented over 40 scientific publications, is an inventor on 5 issued/published patents and applications, has been a scientific reviewer for three pharmaceutical journals, and is a member of the ACS, ISAM, CRS, and the AAPS professional organizations.

Dr. Hastedt is the co-editor of the text Protein Formulation and Delivery, and is an Editor for the AAPS Open journal. She is the past Chair for the AAPS Inhalation and Nasal Technology Focus Group (INTFG). Dr. Hastedt is an Assistant Adjunct Professor in the Division of Pharmacy Professional Development within the UW School of Pharmacy.

Dr. Hastedt formed JDP Pharma Consulting, LLC with her business partner, Dr. Paddy Shivanand, in 2008. The consulting firm provides product development consulting services to the pharmaceutical industry with a focus on pulmonary drug delivery. The consulting firm specializes in providing science-based technical and strategic CMC team leadership to clients with an emphasis on the overall product development strategy and vision. In her previous position at ALZA Corporation, Dr. Hastedt was the Senior Director and Site Leader in the Chemical and Pharmaceutical Development organization responsible for development and launch of controlled release dosage forms.

Per Bäckman, PhD, Senior Inhalation Consultant
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Dr Bäckman is senior inhalation consultant at Emmace Consulting AB in Lund Sweden. He earned a PhD in Thermochemistry from the University of Lund in 1991 and joined Astra Draco in Lund in 1995 following post-doctoral positions at University of Virginia and University of Lund. From 1995 to 2006, Dr Bäckman held several positions within Astra Draco/AstraZeneca in Lund, mainly focusing on the interface between preclinical and clinical development of inhaled medicines. In 2006, he joined Novo Nordisk A/S in Denmark as head of department for inhalation product characterization. Between 2011 and 2016, Dr Bäckman was Principal Scientist at AstraZeneca in Mölndal, Sweden, focusing mainly on research activities related to developing and implementing models that integrate deposition, clearance, dissolution, uptake and systemic disposition of orally inhaled products. In 2016, Dr Bäckman joined Mylan Pharma UK to lead the development of inhalation biopharmaceutics. As from May 1, 2018, Dr Bäckman is responsible for inhalation biopharmaceutics and business development at Emmace Consulting AB, Sweden.

Bing V. Li, Ph.D., Director, Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs, Center of Drug Evaluation and Research
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Dr. Bing V. Li serves as the Director in the Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs, Center of Drug Evaluation and Research, FDA. Her responsibility is to direct and oversee the work of highly skilled staff of professionals in reviewing drug product bioequivalence studies submitted in Abbreviated New Drug Applications (ANDAs), develop guidelines applicable to the completion of reviews, plan and manage the regulatory review operations. Prior to joining FDA in 2004, she was a Research Investigator at Bristol-Myer-Squibb where her responsibilities included Formulation identification, development and optimization for oral solid dosage form formulations.

Dr. Li an expert pharmacologist at FDA in the area of bioequivalence of aerosolized drug products. She has published over 50 papers, meeting abstracts, book chapters, and patents, and has been invited to give many presentations at national and international conferences. Dr. Li is the winner of numerous awards including Thomas Edison Invention Award, AAPS Outstanding Contributed Paper for Regulatory Sciences Awards, National Institute of Health Biotechnology Award, Bristol-Myers Squibb Triumph Award, FDA Center Director's Special Citation Award and FDA Regulatory Science Excellence Award.

She received her Ph.D. in Pharmaceutical Sciences from University of Wisconsin at Madison in 2001, and a bachelor degree in Medical Chemistry in 1990 in Beijing University, China.

Session 5: Enabling Patient-Focused Quality Standards via Modeling and Simulation for Oral Products

Moderator:

Sandra Suarez Sharp, PhD, Master Biopharmaceutics Reviewer
Division of Biopharmaceutics/ONDP/OPQ/FDA
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Dr. Suarez Sharp is currently a Master Biopharmaceutics reviewer at the Division of Biopharmaceutics/ Office of New Drug Products/OPQ supporting all therapeutic areas. Some of her responsibilities in this office include the secondary/tertiary review of submissions containing Biopharmaceutics information such as dissolution, biowaivers, IVIVCs, multivariate models for RTRT, physiologically based PK-biopharmaceutics models in support of drug product quality, and mentoring new reviewers. She joined the FDA in 1999 as a Clinical Pharmacology and Biopharmaceutics reviewer in the Office of Clinical Pharmacology. Prior to this, she spent two years at UNC Chapel Hill as a postdoctoral fellow in the area of drug delivery to the lungs. Dr. Suarez Sharp holds a Ph.D. in Pharmaceutical Sciences from University of Florida and a bachelor's degree in Industrial Pharmaceutical Chemistry from IPN Mexico.

Presenters:

David J. Good, Ph.D., Associate Director
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David is Associate Director in Drug Product Science and Technology (DPST) group at Bristol-Myers Squibb in New Brunswick, NJ. David has been with BMS for nine years and held several roles in oral solid dosage form development including modeling and simulation. His research group is engaged in early formulation development (Ph 1and 2), biopharmaceutics risk assessments, elucidation of degradation mechanisms, as well as modeling of product stability and in vivo performance. David's professional interests include pharmacokinetic absorption modeling and simulation for designing oral formulations. Additionally, David has material science research interests related to crystal form screening and the rational design of supersaturating drug forms. David received his doctoral degree in Pharmaceutics from University of Michigan.

Yang Zhao, Ph.D., Pharmacologist
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Dr. Zhao joined the Division of Biopharmaceutics/OPQ/CDER/FDA as a Reviewer since 2016, where she plays leading roles within the Division in reviewing model-informed drug development for NDA/ANDA/IND submissions. She has reviewed computational modeling supporting over 20 different drug products, mainly Oncology and Hematology Drug Products at various drug development phases. She is currently serving as an active figure in various CDER working groups and scientific interest groups. Prior to joining the FDA, Dr. Zhao was an Assistant Professor in the academia background, leading to her 40 published research articles, reviews, book chapters. She completed her postdoctoral training at Rutgers University and received a Ph.D. in Pharmaceutical sciences from Chinese Academy of Sciences.

Christophe Tistaert, Ph.D., Principal Scientist
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Christophe Tistaert is a Principal Scientist Biopharmaceutics in the Small Molecules Pharmaceutical Development organization of Janssen Research & Development. In this role, he is responsible for the implementation of biopharmaceutical development strategies across the portfolio, predominantly focusing on mechanistic absorption modeling and clinically relevant specifications. Christophe joined Janssen in 2012 as a pharmaceutical scientist. He holds a PhD in Pharmaceutical Sciences from the Universiteit of Brussels (Belgium) and a master's degree in Pharmaceutical Sciences from the Catholic University of Leuven.

Session 6: Oral Biopharmaceutics: Challenges, Opportunities, and Advancements

Moderator:

Andreas Abend, Ph.D., Director-Analytical Sciences
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Andreas Abend received his doctorate degree in natural sciences from the University of Karlsruhe in Germany. Following a 3 year Post-Doc at the University of Wisconsin's Enzyme Institute, he joined Merck's Manufacturing Division as a Senior Analytical Scientist. Andreas is currently a Director in the Analytical Sciences department at the Merck Research Laboratories' Pharmaceutical Development department. His group provides analytical support to early formulation development and the release and stability testing of clinical supplies. During his 20-year career at Merck, Andreas supported both drug product and API development, contributed to several new drug product submissions, and provided technical support to in-line products. Andreas is a member of the Biopharmaceutical Technical Committee of PQRI, co-chair of the IQ dissolution Working group, and member of dissolution related focus groups of ISPE and FIP.

Presenters:

Gregory E. Amidon, PhD., Research Professor of Pharmaceutical Sciences
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Dr. Amidon received his Bachelor of Science degree in Medicinal Chemistry (1974) and his Ph.D. in Pharmaceutical Chemistry (1979) from the University of Michigan at Ann Arbor, MI. He joined the University of Michigan, College of Pharmacy as Research Professor of Pharmaceutical Sciences in 2007 after 28 years in the pharmaceutical industry. Prior to joining the University of Michigan, Dr. Amidon held research positions in pharmaceutical R&D for Pfizer, Pharmacia, Pharmacia & Upjohn, and The Upjohn Company. He is recognized for his expertise in the physical, chemical, and mechanical property characterization of active pharmaceutical ingredients, excipients, and products as well as the development of scientific strategies for oral solid dosage form development. His current research interests also include oral bioperformance assessment and in vivo predictive dissolution. Dr. Amidon has served in a number of leadership roles in the American Association of Pharmaceutical Scientists (AAPS) as well as the United States Pharmacopeia (USP). Dr. Amidon is a member, Fellow, and past President of AAPS. He is the recipient of the 2014 AAPS Research Achievement Award in Physical Pharmacy and Biopharmaceutics as well as the 1983 Ebert Prize from the American Pharmaceutical Association. He has served as a member and chair of several USP Expert Committees and is currently a member of the USP Board of Trustees representing pharmaceutical sciences.

Adam T. Procopio, Ph.D., Senior Principal Scientist
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Adam Procopio is a member of the Sterile Formulation Sciences organization at Merck & Co., where he leads CMC teams in the development of biologic sterile drug products. Prior to this he was a part of the Device Development group where he was responsible for developing Medical Devices and Combination Products. Before these roles and a major part of his 20-year career at Merck, Adam was a member of the Oral Formulation Sciences group and led the Compaction Research Laboratory where his group was responsible for all aspects of tableting prediction scale-up and mechanical property characterization of drug products from Phase I to Commercial Launch as well as integrating Finite Element Analysis (FEA) in product design. As part of his current full-time job, Adam leads a technology team focused on developing additive manufacturing (3D Printing) to produce oral and non-oral dosage forms. He holds a BS, MS and PhD degrees in Materials Science and Engineering from Drexel University, Philadelphia, PA where he also moonlights as an Adjunct Professor.

Gilbert J. Burckart, Pharm.D., Associate Director for Pediatrics
Office of Clinical Pharmacology/FDA
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Dr. Gilbert Burckart is presently Associate Director for Pediatrics, Office of Clinical Pharmacology, U.S. Food and Drug Administration. Dr. Burckart has served on the faculties of four universities (Buffalo, Tennessee, Pittsburgh, Southern California) as a Professor of Pharmacy, Pediatrics and Surgery for 33 years prior to coming to the FDA. He has previously served as President of the American College of Clinical Pharmacy and as President of the American College of Clinical Pharmacology. He moved to the US FDA in 2008, and his duties include the direction of the Pediatric Clinical Pharmacology program within the Office of Clinical Pharmacology, and participation in the FDA's Pediatric Review Committee. His present educational and research program focuses on pediatric drug development studies.

TRACK #2 EMERGING TECHNOLOGIES AND PATIENT CENTRICITY IN EARLY DRUG DEVELOPMENT

Session 1: Early Drug Development: A Vision for the Future

Moderator:

Geoffrey Wu, PhD, PMP, CPH, Associate Director for Science and Communication
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Commander Geoffrey Wu, Ph.D., PMP, CPH, is a scientist officer in the United States Public Health Service. He is currently the Associate Director for Science and Communication, and a Supervisor for the Immediate Office Review Staff in the Office of Lifecycle Drug Products (OLDP), Office of Pharmaceutical Quality (OPQ). Geoff has been deeply involved, leading or co-leading regulatory review and research for controlled correspondence, ANDAs, and supplemental ANDAs and NDAs in the past eight years. Between 2013 and 2017, he served on the OPQ Emerging Technology Team (ETT). Also he is a core member in multiple policy development efforts, such as emerging technology, continuous manufacturing, and comparability protocols.

Geoff has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, and process analytical technology. His professional specialization is mainly in product design, manufacturing and process analytical technology. He has more than 20 peer reviewed publications, and has been invited to multiple national and international conferences to present or discuss the above related topics. Geoff has a Ph.D. degree in Pharmaceutics and Pharmaceutical Chemistry from University of Utah, and M.S. degree in pharmaceutics and B.S. degree in pharmacy from Peking University, China.

Presenters:

Ramesh K. Sood, PhD., Senior Scientific Advisor
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Dr. Ramesh K. Sood is a Senior Scientific Advisor in the Office of New Drug Products, 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, Ramesh has 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.

Gregory M. Troup, Ph.D., Senior Principal Scientist
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Dr. Gregory Marshall Troup is a Senior Principal Scientist in Formulation Sciences at Merck Research Labs. Developed and deployed PAT/chemometrics methods for ensuring drug product quality. Gregory has served as a lead formulator and product development team leader for numerous Merck compounds, has up Merck's solid oral formulation small scale prototyping laboratories, Installed web-based SCADA system into MRLs non GMP labs and pilot plants for data acquisition. He is currently leading the IT and Automation team for the FLEx center, Merck's new clinical supplies manufacturing facility and laboratory build. Gregory is active in data mining, advanced analytics, advanced process control, and automation technologies. Gregory is a member of the technical review committee for the Chemical Process Control meeting since 2012.

Matthew D. Burke, Ph.D., Senior Director, Head of Drug Delivery
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Matt Burke is Head of Drug Delivery in the Medicinal Science & Technology Department at GlaxoSmithKline. He leads a group guiding the drug delivery strategy at GSK that includes internal development and external partnerships.

He co-chairs the patient centric working group for the IQ Consortium. Dr. Burke is also subject matter expert on long acting injectables, oral modified release and continuous manufacturing. He has worked at multiple sites in the US and UK within GSK. He has 30 articles, patents and presentations. He has served as an adjunct professor at North Carolina State University Biomolecular and Chemical Engineering department and University of North Carolina at Chapel Hill School of Pharmacy.

Session 2: Designing for Delivery: Drug Discovery and the Early Development Interface

Moderator:

Diane Paskiet, Director of Scientific Affairs
West Pharmaceutical Services
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Ms. Paskiet has over twenty years of experience in polymer analysis relating to product failures, deformulation and migration studies. She has served as a project advisor in support of qualification studies associated with container closure systems for regulatory filings. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories.

She is a co-recipient of the United States Pharmacopeia (USP) award for Innovative Response to a Public Health Challenge and currently leading revision of USP Elastomers chapter. She is also Chair of the PQRI Development Technical committee (DTC), Parenteral and Ophthalmic Drug Product (PODP) Leachables and Extractables Working Group and a faculty member of the PDA Training Institute as well as author/co-author of papers on the subject of pharmaceutical packaging.

Presenters:

Christopher D. Breder, MD., Ph.D., Medical Officer
US Food and Drug Administration
Christopher.Breder@fda.hhs.gov

Dr. Breder obtained his MD and PhD at the University of Chicago, elucidating the neural basis of fever, and completed a post-doctoral fellowship at Johns Hopkins University cloning and characterizing novel arachidonic acid metabolizing enzymes from brain. Chris is an anesthesiologist with Fellowship training in Neuroanesthesiology. He practiced at Columbia University's Hospital and spent 11 years in industry. This included Clinical team leader and co-chair of an Early Development platform in Neuroscience at Bristol Myers Squibb, as well the head of clinical development at Supernus Pharmaceuticals. While in industry, Chris designed programs and conducted studies such as Phase 1b pharmacodynamic studies, clinical pharmacology studies for controlled-release formulations, and multicenter trials for marketing applications. Since coming to FDA, Chris has been a reviewer for rare diseases in the Division of Neurology Products and team leader for the Anesthesiology Products in DAAAP. He also serves as the FDA topic leader in the ICH M1 group on MedDRA.

Michael J. Hageman, Ph.D., Valentino Stella Distinguished Professor
University of Kansas
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Michael Hageman has over 30 years of research experience within the pharmaceutical industry, including Upjohn, Pharmacia, Pfizer and Executive Director at Bristol-Myers Squibb. He obtained his BS in Pharmacy and PhD in Pharmaceutical Chemistry from the University of Kansas. He recently joined the faculty of the Department of Pharmaceutical Chemistry at the University of Kansas where his lab focuses on Physical Pharmacy and Drug Delivery (P2D2) for oral delivery of poorly soluble and poorly permeable drugs, including the stabilization, formulation and processing of peptides, proteins and cellular therapeutics.

While in industry, he worked within Discovery organizations for the design and selection of pharmaceutically developable molecules, including small drug-like molecules and other alternative drug modalities such as peptides and protein biologics. Significant emphasis was placed on providing physicochemical property characterization, including the design of formulation enabled preclinical dosage forms for enhanced bioavailability in order to provide successful progression of the drug candidates, yet have a clear line-of-sight to a product dosage form.

He was previously an adjunct professor at Purdue University, University of Kansas, and University of Utah. He is an editor for the Journal of Pharmaceutical Sciences, on the editorial board of AAPS Open and chairs the Pharmaceutics Advisory Committee for PhRMA Foundation. He is an AAPS Fellow and served as Chair of the Physical Pharmacy and Biopharmaceutics Section for AAPS.

Ronald G. Iacocca, Ph.D., Research Fellow
Eli Lilly and Company
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Ronald G. Iacocca, PhD, is a Research Fellow in Delivery and Devices and Connected Solutions. He received his B.S., M.S., and PhD in Materials Engineering, with minors in finance and literature, from Rensselaer Polytechnic Institute. In his current role, he leads the computational engineering group, which oversees the mathematical analysis of devices and packaging systems, and works closely with the materials engineering and testing groups in DDCS to design tests to support the modeling efforts.

Prior to joining DDCS, Ron was the team leader for the Materials Science/Physical Characterization team, where he built the capabilities for the analysis of powders and materials used in solid-oral formulations. He also implemented the surface science and materials engineering functions in ASRD that are now housed within DDCS. For nine years prior to joining Lilly, he was a faculty member in the Department of Engineering Science and Mechanics at The Pennsylvania State University.

Ron has authored/co-authored over 70 journal articles, book chapters, and review articles, and has been granted 4 patents. In 2005, he was selected as one of ninety world-wide experts by the Bill and Melinda Gates Foundation to participate in the road-mapping initiative for the development of a world-wide malaria vaccine. Ron also served as an adjunct professor in the Department of Industrial and Physical Pharmacy at Purdue University from 2006-2009, and is a reviewer for a number of scientific journals. From 2010-2015, he was elected to the USP to serve on the Physical Analysis Expert Committee. He is currently a member of the Parenteral Drug Association (PDA), and ASM International.

Session 3: Drug Device Combination Products – Emerging Technologies & the Evolving Regulatory Landscape

Moderator:

Ajit Narang, Ph.D., Senior Scientist
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Ajit Narang works for the Small Molecule Pharmaceutical Sciences Department of Genentech, Inc., in South San Francisco, CA responsible for the pharmaceutical development of new chemical entities through preclinical and early clinical stages. He has served as Adjunct Faculty at the Universities of Tennessee, Memphis, TN; University of Phoenix, Phoenix, AZ; University of Nebraska Medical Center, Omaha, NE; University of the Pacific, Stockton, CA; Campbell University, North Carolina; and Western Michigan University, Kalamazoo, MI. He serves as a panel member of the Biopharmaceutics Technical Committee (BTC) of the Pharmaceutical Quality Research Institute (PQRI) in Arlington, VA; a panel member of the International Pharmaceutics Excipient Council (IPEC) committees; Chair of the Formulation Design and Delivery (FDD) section of the American Association of Pharmaceutical Scientists (AAPS); a member of the Systems-based Pharmaceutics (SBP) alliance of the Process Systems Enterprise, Inc. (PSE) in London, UK; and a Scientific Advisor to the Editors of JPharmSci.

He holds over 15 years of pharmaceutical industry experience in the development and commercialization of oral and parenteral dosage forms and drug delivery platforms across preclinical through commercialization stages for both small and large molecule drugs. In addition to Genentech, he has worked for Bristol-Myers Squibb, Co., in New Brunswick, NJ; Ranbaxy Research Labs (currently a subsidiary of Daiichi Sankyo, Japan) in Gurgaon, India; and Morton Grove Pharmaceuticals (currently, Wockhardt USA) in Gurnee, IL. He holds undergraduate Pharmacy degree from the University of Delhi, India and graduate degrees in Pharmaceutics from the Banaras Hindu University, India and the University of Tennessee Health Science Center (UTHSC) in Memphis, TN.

Ajit has contributed to several preclinical, clinical, and commercialized drug products including NDAs, ANDAs, and 505B2s. He is credited with 54 peer-reviewed articles; 22 editorial contributions; 5 books; 10 patent applications; 47 invited talks; and 85 presentations at various scientific meetings. His current research interests are translation from preclinical to clinical and commercial drug product design; incorporation of QbD elements in drug product development; and mechanistic understanding of the role of material properties on product performance.

Presenters:

Susan Neadle, Senior Director
Johnson & Johnson
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Susan Neadle has a distinguished career at Johnson & Johnson, where she has held roles of increasing responsibility in medical devices, pharmaceuticals, and consumer sectors for almost 25 years. In her current role, she is responsible for Johnson & Johnson's cross-sector Design Quality, ensuring focus on customer, quality, reliability and agility in new product development, as well as for J&J's Combination Products Community of Practice. Over her extensive career, she has played integral leadership roles in R&D product and process development and in Quality Engineering. Among several achievements during her tenure at J&J, Susan led the team that defined and implemented the business model, integrating global cross-functional requirements, to meet Combination Products health authority regulations into Janssen, J&J's Pharmaceutical segment. She is a Design Excellence Blackbelt. Over the course of her career, she has been awarded the Johnson Medal, J&J's highest honor for innovation excellence. She holds numerous patents and publications. Susan earned an M.S. in polymer science & engineering, and a B.S. in biology/chemistry, as well as Fellowship in the American Academy of Optometry.

Kristina J. Lauritsen, Ph.D., Combination Product Policy Advisor
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Kristina Lauritsen, PhD serves as a Combination Product Policy Advisor within the Center for Drug Evaluation and Research (CDER) at the FDA. In this role, she is responsible for engaging in development of CDER's policies related to combination product review and regulation, including activities such as guidance development, facilitating coordination with the FDA's Office of Combination Products, CBER and CDRH, and representing CDER in cross-center combination product working groups. Prior to joining CDER in 2014, she spent four years in the Center for Devices and Radiological Health, followed by seven years in the Office of Combination Products. She holds a B.S. in Biology from Shippensburg University, and a Ph.D. in tumor biology from Georgetown University.

Alan B. Watts, PhD, Senior Scientist
Savara Pharmaceuticals
alan.watts@savarapharma.com

Dr. Alan Watts is currently Senior Scientist at Savara Pharmaceuticals and is responsible for combination product development for inhaled products. He has 10 years' experience in design and characterization of traditional and novel inhaled drug products in programs ranging from early stage pre-clinical to Phase 3. His prior experience has focused predominantly on nebulizers and dry powder inhalers. Dr. Watts is also Adjunct Assistant Professor in the College of Pharmacy at the University of Texas at Austin.

Session 4: Development Considerations for Evolving Non-Traditional Drug Modalities

Moderator:

Allen C. Templeton, Ph.D., Vice President, Pharmaceutical Sciences
Merck & Co., Inc.
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As Vice President of Pharmaceutical Sciences, Allen is responsible for leading drug product formulation development (oral, sterile, biologics, specialty drug delivery routes of administration), analytical testing, device development, and clinical supply manufacture at Merck. Before assuming his current position, Dr. Templeton held positions of increasing responsibility within Pharmaceutical Sciences.

Dr. Templeton earned a Ph.D. in Chemistry from the University of North Carolina at Chapel Hill. He has published over 50 articles, served as co-inventor on 11 patents and authored over 120 presentations in the area of pharmaceutical product research. He has organized a number of symposia and training courses on diverse topics within the field of pharmaceutical research, most notably around his interest in drug product stability.

Dr. Templeton is an active member in a number of professional organizations, including the American Association of Pharmaceutical Scientists (AAPS), International Pharmaceutical Federation (FIP) and the American Chemical Society (ACS). He is currently on the board of directors for AAPS and was named as a Fellow of the Association in 2015 for his scientific achievements. He was elected to both the 2010-2015 and 2015-2020 terms of the United States Pharmacopeia (USP) expert committee on physical analysis. He participates on an advisory board and has taught courses in an adjunct role with Purdue University. He also currently serves on editorial advisory boards for the Journal of Pharmaceutical Sciences and American Pharmaceutical Review.

Presenters:

Rubi Burlage, Ph.D., Executive Director
Merck & Co. Inc.
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Rubi Burlage, Ph.D. is Executive Director, Sterile Formulation Sciences at Merck & Co., Inc. In this capacity, Dr. Burlage leads a group responsible for pharmaceutical product and process development for small molecules and biologics sterile products, and for progressing innovation in dosage form and process design. In previous roles, Dr. Burlage led development of oral solid dosage forms and associated lifecycle management strategies advancing products from first-in-human to commercialization. Dr. Burlage's interests include understanding biopharmaceutical and mechanistic principles influencing dosage form design, studying factors germane to successful product and process scale up, and developing risk-weighted strategies that integrate the aforementioned principles and knowledge. She is a co-author on several publications and co-inventor on 3 patents. Dr. Burlage earned a B.S. in Pharmacy from India and Ph.D. in Pharmaceutical Sciences from The University of Iowa. Dr. Burlage is a member of the American Association of Pharmaceutical Scientists (AAPS) and is currently serving on the Drug Product Leadership Group for the International Consortium for Innovation & Quality in Pharmaceutical Development (IQ).

Serge L. Beaucage, Ph.D., Supervisory Research Chemist
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Serge L. Beaucage obtained a doctoral degree for his research in nucleic acid chemistry under the supervision of Prof. Kelvin K. Ogilvie at McGill University in Montreal. He was then awarded a NRCC postdoctoral fellowship to join the laboratory of Prof. Marvin H. Caruthers at the University of Colorado where he designed, developed, and co-invented deoxyribonucleoside phosphoramidites for the automated synthesis of DNA sequences. Subsequently, Dr. Beaucage held a senior postdoctoral fellowship of the American Cancer Society in the laboratory of Prof. Stanley N. Cohen at Stanford University School of Medicine where he applied nucleic acid chemistry to the mechanistic study of DNA plasmid inheritance in *E. coli*.

Since joining the FDA in 1988, Dr. Beaucage's research interests have encompassed the development of novel synthetic methods aimed at improving the chemical synthesis of DNA/RNA sequences and their analogues for potential therapeutic applications.

Kelvin H. Lee, Ph.D., Director
National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
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Kelvin H. Lee is Gore Professor of Chemical and Biomolecular Engineering at the University of Delaware and is Director of NIIMBL: the National Institute for Innovation in Manufacturing Biopharmaceuticals, one of 14 Manufacturing USA Institutes. He received a BSE in Chemical Engineering from Princeton and PhD in Chemical Engineering from Caltech. He spent several years in the Biotechnology Institute at the ETH in Zurich, Switzerland and also completed a postdoc in Caltech's Biology Division. Prior to his current appointment, he was on the faculty at Cornell University where he held the titles of: Samuel C. and Nancy M. Fleming Chair Professor, Professor in the School of Chemical and Biomolecular Engineering, Director of the Cornell Institute for Biotechnology, and Director of the New York State Center for Life Science Enterprise.

Session 5: New Visualization and Analysis Techniques in Drug Development

Moderator:

Robert Meyer, PhD, Principal Scientist
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Robert Meyer received his BS and PhD degrees in Chemical Engineering from the University of Akron and the University of Pennsylvania, respectively. Since joining Merck in 2002, he has worked in many areas of drug product development, with a focus on emerging technologies such as hot melt extrusion and continuous manufacturing of oral solid doses. As a principal scientist at Merck, he currently leads innovation and new technology development in the area of small molecule pharmaceutical commercialization.

Presenters:

Douglas Kiehl, M.S., Research Advisor
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Douglas Kiehl is a Research Advisor at Eli Lilly and Company and leads the Characterization Mass Spectrometry, Extractables/Leachables and Elemental Impurities team. He is responsible for Lilly's global E&L strategy supporting development and qualification of container/closure and manufacturing systems and drug delivery devices. His team's responsibilities include performing structural characterization of process impurities, related substances, degradation products and contaminants across development and commercialization phases for the small and large molecule portfolios. Mr. Kiehl has over 36 years' experience with application of advanced mass spectrometry in characterization of diverse chemical entities, 24 years of which are in the Pharmaceutical Industry. He is a member of the USP Packaging and Distribution Expert Committee, the USP Expert Panel on Biocompatibility of Materials Used in Packaging Systems, Medical Devices and Implants, the USP Expert Panel on Elastomeric Closure for Injections, the ELSIE (Extractables/Leachables Safety Information Exchange) Board of Directors, the SPIE Defense and Commercial Sensing Committee and AAPS Impurities Steering Committee. His research interests include the development of advanced mass spectrometry based mapping and visualization techniques to enable the rapid and comprehensive characterization of highly complex mixtures of structurally diverse chemical entities.

Eric J. Munson, Ph.D., Professor
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Eric Munson is currently the Dane O. Kildsig Chair and Head of the Department of Industrial and Physical Pharmacy at Purdue University. He received his B.A. degree from Augustana College in Sioux Falls, South Dakota, in 1987. After studying one year in Munich, Germany, on a Fulbright Fellowship, he received his Ph.D. in 1993 from Texas A&M University, and was a postdoctoral fellow at the University of California, Berkeley in 1994. He was in the Chemistry Department at the University of Minnesota before moving in 2001 to the Pharmaceutical Chemistry Department at the University of Kansas, to the Pharmaceutical Sciences Department at the University of Kentucky in 2010, where he was the Patrick DeLuca Endowed Professor in Pharmaceutical Technology. In 2018 he moved to Purdue University to become the Dane O. Kildsig Chair and Head of the Industrial and Physical Pharmacy Department. His research program is focused on the characterization of pharmaceutical solids using a variety of analytical techniques, with an emphasis on solid-state NMR spectroscopy. Dr. Munson is a co-inventor on three patents and has published more than 100 research, review, and book chapters.

Marcus Adams, Senior Specialist
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Marcus Adams earned his BEng and MS in Chemical Engineering from the University of Delaware and Villanova University, respectively. His more than decade of experience at Merck spans the bio-pharmaceutical spectrum and includes experience in pre-clinical PK/PD modeling, product commercialization, in-line technology support, procurement, and vaccine distribution technology development. Currently he works as a part of the Digital Proactive Process Analytics team, leveraging Merck's Big Data Platform in the development of manufacturing information data models, report automation tools, and integrated-systems analysis applications. His professional interests include effective digital visualization, reproducible research/analysis, and convincing his coworkers of the diverse, flourishing world beyond Microsoft Excel.

Session 6: Emerging Technologies for Improving Patient Adherence

Moderator:

David R. Schoneker, Director of Global Regulatory Affairs
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David R. Schoneker is the Global Regulatory Director – Strategic Relationships at Colorcon. His responsibilities include global coordination of Colorcon's worldwide regulatory activities and market expansion projects to gain regulatory acceptance of Colorcon's products and components for various target markets. Mr. Schoneker also works closely with Colorcon's customers to provide regulatory training and advice.

He received his B.S. degree from Ursinus College and M.S. in Chemistry from Villanova University. His previous position at Colorcon was Director of Quality Assurance and Quality Control. He has been at Colorcon since 1977. Mr. Schoneker has been active in many professional organizations such as AAPS, PQRI, RAPS, ASQ, ACS, AOAC and the Delaware Valley Chromatography Forum. He also is involved with a number of trade organizations such as the International Pharmaceutical Excipients Council (IPEC), the International Association of Color Manufacturers (IACM), the Consumer Health Products Association (CHPA), the International Food Additives Council (IFAC), the Council for Responsible Nutrition (CRN) and the Institute of Food Technologists (IFT).

Mr. Schoneker is currently the President of IACM. In this role he will coordinate IACM's international regulatory activities related to Synthetic and Natural colorants for use in foods and drugs and will participate as one of IACM's NGO representatives at the Codex Committee on Food Additives (CCFA).

Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee. He is now serving as the Vice Chair for Science and Regulatory Policy where he is actively involved with the development of Regulatory, Safety, Excipient GMP and Supplier Qualification related guidelines to improve Excipient Acceptability, Safety and Global Supply Chain Security. Mr. Schoneker also Co-Chairs IPEC's QbD/Product Development Committee, Composition Committee and IID Working Group. He also is a member of the Board of Directors of the IPEC Foundation. He is the Global Expansion Coordinator for the IPEC Federation and has been critically involved in the development of many of the IPEC groups and Partnerships around the world.

He has acted as an interface with many international regulatory agencies and pharmacopeias for the organization. He previously was the USP Liaison for IPEC-Americas and represented them as a member of the United States Pharmacopeial Convention for many years. Mr. Schoneker previously coordinated International Harmonization efforts for IPEC-Americas and participated in the development of IPEC's Good Manufacturing Practices Guide and Auditing Guide for Bulk Pharmaceutical Excipients. He has also led IPEC's efforts in developing guidelines for excipient qualification, significant change notification and the appropriate use of certificates of analysis. Additionally, Mr. Schoneker chairs a number of harmonization working groups on various excipients and has been chairing the Coalition for Rational Implementation of the Elemental Impurity Requirements since 2010.

Mr. Schoneker has participated in the area of Color Science for many years and is author of the chapter "Coloring Agents for Use in Pharmaceuticals" in the 4th edition of the Encyclopedia of Pharmaceutical Technology which was published in 2013. He has also authored many other excipient quality and safety related papers in various journals and trade magazines.

Presenters:

Douglas Throckmorton, MD, Deputy Director for Regulatory Programs
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As Deputy Director for Regulatory Programs, Dr. Throckmorton shares the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks.

Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.

Stephanie E. Barrett, Ph.D., Senior Principal Scientist
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Stephanie E. Barrett, PhD., is a Senior Principal Scientist at Merck & Co., Inc. She received her B. Sc. from McMaster University (Hamilton, Ontario, Canada) and her Ph.D. in Chemistry from the University of North Carolina at Chapel Hill. Stephanie is one of Merck's leading experts in polymer and bioconjugate chemistry for enabled delivery of small molecule and macromolecular drugs, having made influential contributions to the discovery of novel polymer conjugates for siRNA therapeutics, polymer excipients for oral dosage forms, and polymer-based long acting injectables. Throughout her time at Merck, she took on roles of increasing responsibility and is currently leading the team responsible for the design of Merck's next generation of long acting implant products—with potential applications in HIV and other infectious diseases. Dr. Barrett was recently recognized by Business Insider as one of the top 30 under 40 biopharma leaders shaping the future of medicine.

Ali Rajabi-Siahboomi, Ph.D., Vice President and Chief Scientific Officer
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Ali Rajabi-Siahboomi is Vice President and Chief Scientific Officer at Colorcon, based at the Global Headquarter, USA. He obtained his B.Pharm. & Ph.D. in Pharmacy, from University of Nottingham (UK). Ali has held various academic positions in Nottingham and Liverpool JM Universities in the UK, before joining Colorcon as Technical Director, responsible for Europe, Middle East and Africa in 2000. Ali's main research interests are in the area of solid dosage form pharmaceutics, pharmaceutical technology with emphasis on oral drug delivery systems, solubility enhancement to improve bioavailability and consistency of drugs and bioequivalence formulations. He has published over 300 articles, book chapters, abstracts and patents.

TRACK 3: Novel Manufacturing Technologies and Challenges for the Production of Patient-Centric Drug Products

Session 1: Novel Manufacturing Technologies and Challenges for Cell and Gene Therapies

Moderator:

Michael Skidmore, Independent Consultant
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Mr. Michael Skidmore is an independent consultant with Pharmaceutical Quality Consulting, Inc. and has over 25 years' experience in biopharmaceuticals in technical transfer, validation, process engineering, process development, R&D, and QA. He is currently leading Process Validation for a combination gene and cellular therapy product in clinical trials in the US and Europe for a cervical cancer treatment and prevention as well as assisting a vaccine manufacturer in China with a starting new commercial site. Previously he consulted for CSL Behring to assist in their integration of Calimmune developing a gene therapy for the treatment of sickle cell disease and β-thalassemia. During 2017 he lead the Tech Transfer, PMO and startup of Adaptimmune's new US Clinical Manufacturing Site from completion of architecture to dosing the first patient with their second CAR-T product. Previously he led the Tech Transfer of Sanofi's Dengvaxia from France to the US over 2 years. Prior to becoming a consultant, Mr. Skidmore was at Merck as Assoc Director of Bio/Sterile Validation responsible for validation of containers and single use systems for aseptic processing, intermediate, and finished goods containers at the West Point site as well as serving as a Center of Excellence to support the vaccine network with physical and microbiological testing of single use systems, filters, syringes and vials. Mr. Skidmore has also held positions at Watson Pharmaceuticals, Amgen and the FDA as a Microbiologist. Michael has been an active member of the PDA for more than 14 years. He co-authored the PDA Technical Report No 60-2: Process Validation: A Lifecycle Approach - OSD/SSD Annex. Mr. Skidmore attended the University of California, San Diego studying Biochemistry and Cell Biology and also UC, San Diego School of Medicine with a masters in Molecular Pathology.

Presenters:

Palani Palaniappan, Ph.D., Sr. Vice President, Head of Global Technical Operations
Sarepta Therapeutics, Inc.
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Palani Palaniappan, Ph.D., has more than twenty-five years of pharmaceutical experience. He currently serves as Senior Vice President and Head of Global Technical Operations at Sarepta Therapeutics, Inc., where he leads the Company's Technical Operations team responsible for all stages of development from research through commercial. His team focuses on the development of Sarepta's RNA and gene therapy portfolios.

Prior to joining Sarepta, Dr. Palaniappan held leadership positions of increasing responsibility at Takeda Pharmaceuticals, most recently leading biologics and new modality development. Before Takeda, he spent a number of years each at Millennium Pharmaceuticals, Biogen, Gilead Sciences and Par Pharmaceuticals. Over the course of his career he has contributed to the development and commercialization of over ten products in small molecule, biologics, antibody drug conjugate and stem cell modalities.

Dr. Palaniappan has completed executive leadership education at the University of Oxford and Insead. He received his Ph.D. in chemistry from the Indian Institute of Technology, Kanpur and completed his post-doctoral studies in biochemistry and biophysics at the University of California, Riverside and Virginia Commonwealth University. He holds a MS in chemistry and a BS in chemistry, physics and mathematics from Annamalai University. Additionally, since 2017, Dr. Palaniappan has served on the Board of the International Consortium for Innovation & Quality (IQ), and from 2016 to 2018 he was IQ's Chair of the Biologics CMC Leadership Group.

Michael Havert, PhD
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Mike was trained as a virologist and has regulatory experience in the development of genetic medicines for the treatment of rare diseases and cancer. Mike recently joined bluebird bio as a part of the regulatory CMC team. Prior to his current position, Mike served as a CMC reviewer in the Gene Therapy Branch at the FDA from 2004-2019. Mike's accomplishments at FDA include serving as BLA Chair for a genetically modified autologous T-cell immunotherapy and championing the release of new Gene Therapy guidance documents. Prior to joining FDA, Mike received a Ph.D. from the University of Wisconsin and conducted postdoctoral fellowships at Johns Hopkins University and National Institutes of Health.

Ramjay Vatsan Ph.D., CQA, Team Leader, Gene Therapy Branch, Division of Cellular and Gene Therapies
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Dr. Ramjay Vatsan PhD is a Team Leader in the Gene Therapy Branch in the Office of Tissues and Advanced Therapies (OTAT) in CBER/FDA. He joined CBER in 2006 and prior to that he had worked in basic and translational research at National Cancer Institute/NIH and Washington University in St. Louis. Dr. Vatsan has extensive research experience in viral and bacterial vector development, gene delivery and immunotherapy. Dr. Vatsan is an expert in the CMC aspects of Cell and Gene Therapy and has co-authored several regulatory articles and CMC guidance documents. Dr. Vatsan is an ASQ Certified Quality Auditor and a full-time CMC Master Reviewer at FDA.

Session 2: Implementation and Regulatory Impact of Continuous Manufacturing (Part I)

Moderator:

Robert Meyer, PhD, Principal Scientist
Merck & Co., Inc.
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Robert Meyer received his BS and PhD degrees in Chemical Engineering from the University of Akron and the University of Pennsylvania, respectively. Since joining Merck in 2002, he has worked in many areas of drug product development, with a focus on emerging technologies such as hot melt extrusion and continuous manufacturing of oral solid doses. As a principal scientist at Merck, he currently leads innovation and new technology development in the area of small molecule pharmaceutical commercialization.

Presenters:

Cenk Undey, PhD., Executive Director,
Amgen
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Dr. Undey joined Amgen in 2003 and has held positions of increasing responsibility in Process Development which included providing manufacturing support, continuous process improvement of commercial products, and technology transfers. He has formed the Digital Integration and Predictive Technologies in 2013, a corporate group with a mission to transform Amgen business from data rich to decision smart. His group's aim is to improve process and product understanding, process optimization, reduce process development cycle time hence increasing speed to market with reduced development costs using Machine Learning, Smart Sensors and Computational Predictive Technologies. Dr. Undey led the introduction of real-time multivariate statistical process monitoring technology, Watson intelligent search via Natural Language Processing and various Process Analytical Technology initiatives resulting in significant business benefits. Dr. Undey and his team's work were externally recognized receiving CIO100 Award in Life Sciences in 2013 for Amgen implementing advanced data analytical solutions.

Prior to joining Amgen, Dr. Undey has worked at the Illinois Institute of Technology (IIT), Dept. of Chemical and Biological Engineering in Chicago, IL as a Sr. Postdoctoral Researcher. He has co-authored and co-edited two books, published in scientific journals and books in the areas of process systems engineering, PAT, artificial intelligence, process monitoring, control, supervision, biotechnology and bioengineering.

He has received his B.Sc., M.Sc. and Ph.D. degrees all in Chemical Engineering from Istanbul University, Turkey. He also holds an Executive MBA degree from the University of California, Los Angeles, Anderson School of Management.

Dr. Undey is based in the headquarters in Thousand Oaks, CA, USA.

Thomas O'Connor, Ph.D., Senior Chemical Engineer
Office of Testing Research, Office of Pharmaceutical Quality, CDER
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Dr. O'Connor is a senior chemical engineer in Division of Product Quality Research in the OPQ's Office of Testing and Research and is a member of CDER's Emerging Technology Team. His responsibilities included coordinating and directing regulatory science projects to support the implementation of emerging technologies in pharmaceutical manufacturing. His team's independent research has centered on advancing the utilization models to aid the risk assessment of advanced manufacturing processes. He originally joined the FDA as chemistry reviewer in the Office Generic Drugs and has served as a primary and secondary reviewer for ANDAs and controlled correspondence. Tom is a co-author of several papers and book chapters on continuous manufacturing and emerging technology. He has consulted on several regulatory applications utilizing continuous manufacturing and is one of the government liaisons to the US Pharmacopeia expert committee on continuous manufacturing.

Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Before leaving he was the technology owner for a set of operator guidance tools including fault detection. He is an experienced practitioner of advanced process control techniques including statistical process control and holds patents related to the development of statistical monitoring systems for industrial plants. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

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Thomas De Beer graduated in pharmaceutical sciences in 2002 at the Ghent University in Belgium. He obtained his PhD at the same university in 2007. For his PhD research, he examined the suitability of Raman spectroscopy as a Process Analytical Technology tool for pharmaceutical production processes. Within his PhD research period, he worked four months at University of Copenhagen in Denmark, Department of Pharmaceutics and Analytical Chemistry (Prof. Jukka Rantanen). After his PhD, he was an FWO funded post-doctoral fellow at the Ghent University (2007-2010). Within his post-doc mandate, he worked 9 months at the Department of Pharmacy, Pharmaceutical Technology and Biopharmaceutics from the Ludwig-Maximilians-University in Munich, Germany (Prof. Winter and Prof. Frieβ). In February 2010, he became professor in Process Analytics & Technology at the Faculty of Pharmaceutical Sciences from the university of Ghent. His research goals include bringing innovation pharmaceutical production processes (freeze-drying, hot-melt extrusion, continuous from-powder-to-tablet processing etc.). More specifically, Prof. De Beer contributes to the development of continuous manufacturing processes for drug products such as solids, semi-solids, liquids and biologicals (continuous freeze-drying of unit doses). Thomas De Beer is also director of Ghent University's Center of Excellence in Sustainable Pharmaceutical Engineering (CESPE) which is founded in 2016. In 2018, Thomas De Beer became co-founder and CTO of the Ghent University spin-off company RheaVita which provides a continuous freeze-drying technology for the pharmaceutical market.

Session 3: Implementation and Regulatory Impact of Continuous Manufacturing (Part II)

Moderator:

Pramod Kotwal, PhD, Director, CMC Policy
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Pramod is a Director in the CMC Policy group at Merck & Co., Inc. and supports activities related to review of global draft and final policies impacting CMC and Quality, manages internal and external communications as well as stakeholder training. Pramod also serves as an advisor to internal CMC teams for developing CMC regulatory strategies, risk assessments, and dossiers content for global product registrations. He is a member of several governance and advisory committees. Prior to this position, Pramod directed activities of a CMC regulatory team which managed global pre- and post-approval submissions for a portfolio of products in several therapeutic areas including breakthrough therapy products. He also managed due diligence activities for the Licensing and Business Development projects. Prior to Merck, Pramod held positions of increasing responsibilities in the Pharmaceutical Development department at PRI (JnJ). Pramod holds a Ph.D. in Pharmaceutical Chemistry from the Univ. of Kansas.

Speakers:

Arthur Hewig, Ph.D., Executive Director
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Art Hewig is an Executive Director of Process Development at Amgen where he leads an integrated group that is designed to deliver early phase end-to-end drug substance processes. His team bridges the R&D and Manufacturing organizations and serves them by enabling fast to clinic approaches as well as developing state-of-the-art processes to manufacture molecules in Amgen's synthetics and biologics pipeline. This team incorporates and develops the best technical advances and combines them with extensive commercial process development experience to develop robust processes. This includes developing manufacturing platforms for new modalities entering Amgen's early phase pipeline. Art has been with Amgen since 2002 and has held numerous scientific and leadership roles for both early and late phase Process Development. Art holds a PhD in Chemical Engineering from Carnegie Mellon University.

Paul C. Collins, PhD, Senior Director, Small Molecule Design and Development
Eli Lilly and Company
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Paul Collins is currently the Senior Director of Small Molecule Design and Development at Eli Lilly and Company in Indianapolis. In this role, Paul has responsibility for product and process development activities for Lilly's post-FHD small molecule development portfolio. He is also in charge of ongoing efforts for technology platform development, including continuous manufacturing of both API and drug product. Prior to accepting this position, Paul was in Director roles in Bioprocess Development, Chemical Technology Development, and Chemical Process Development. During his time at Lilly, Paul has been instrumental in recruiting and developing both new and experienced engineers, as well as starting new technical capabilities necessary for Lilly's current efforts in continuous manufacturing and modeling. Paul started his career with Merck and Company, working in both manufacturing and R&D. Across both companies, Paul has been involved in the process development, registration, and commercialization of six marketed pharmaceuticals. Outside of Lilly, Paul has been heavily involved with AIChE's Pharmaceutical Division over the past decade, shaping future programming directions as well as chairing the pharmaceutical forum in 2015 and 2016. He also is part of ISPE's PQLI programming team looking at future technical-regulatory interaction topics for advanced manufacturing platforms.

Paul received his BE in Chemical Engineering from Vanderbilt University in 1988 and his PhD in Biochemical Engineering from Northwestern in 1997.

Sharmista Chatterjee, Ph.D., Division Director, Process Assessment II, Office of Process & Facilities
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Sharmista Chatterjee is currently the Division Director in Division of Process Assessment II, within FDA's Office of Process & Facilities (OPF). Sharmista has been with the FDA since 2006. During her tenure she has been actively involved in new drug's Quality by Design efforts and FDA-EMA pilot program. She served as the CMC Lead for QbD (Quality by Design) in the Office of New Drug Quality Assessment (ONDQA) and as the technical lead for the FDA-EMA QbD pilot. She is an Agency Expert in CMC Modeling and Simulation. In addition to her current responsibilities, she is serving as one of OPF representatives in CDER's Emerging Technology Team. Prior to joining the agency in 2006, she spent around 10 years in industry. Her industry experience was primarily in process development and modeling in diverse areas that ranged from consumer goods to pharmaceuticals with companies such as United Technologies Corporation (UTC), Procter and Gamble (P&G), and Forest Laboratories (now Allergan). She received a bachelor's degree in Chemical Engineering from Indian Institute of Technology and a PhD in Chemical Engineering with a co-major in Biomedical engineering from Iowa State University.

Session 4: Regulatory Submission Lifecycle Management

Moderator:

Susan Rosencrance, Ph.D., Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research
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Dr. Susan Rosencrance currently serves as the Director for the Office of Lifecycle Drug Products in the Office of Pharmaceutical Quality (OPQ). In this capacity, she directs procedures and processes for evaluating and assessing drug product quality during the lifecycle of both brand name and generic drug products. Prior to joining the FDA, Susan worked at Merck & Co.'s R&D Laboratories in Rahway, New Jersey. She joined the Office of Generic Drugs (OGD) in 1991 and spent the majority of her tenure in CDER working on generic drug products. She held various roles within OGD including senior chemistry reviewer, team leader, deputy division director, and OGD Deputy Director for Chemistry. Susan also served as the Deputy Director for Generic Drug Chemistry in the Office of Pharmaceutical Science prior to the formation of OPQ. Susan holds a Ph.D. in Chemistry from American University and completed her dissertation research at the NIH Laboratory of Biophysical Chemistry conducting a molecular dynamics study on hydrophobic interactions in alpha-helical coiled coils found in proteins. She received her bachelor's degree in Biochemistry from Hood College and also completed studies at the University of Strasbourg in Strasbourg, France in the Institute Internationale D'Etudes Française – Université Louis-Pasteur.

Presenters:

Andrew C. Chang, Ph.D., Vice President
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Dr. Andrew Chang has more than twenty years of experience in the development, regulation and quality of biologics and pharmaceuticals. At his current capacity as a Vice President, Quality and Regulatory Compliance, Quality Intelligence and Inspection, Novo Nordisk, Inc., he is responsible for external affairs, providing strategic advice and solutions for quality and regulatory related issues, and expert support to inspection preparation. Since 2013, Andrew has represented Novo Nordisk at several work groups in industry trade organizations, e.g., PhRMA, BIO to advocate patient and industry's interests by developing position papers and participating liaison meetings with the regulatory authorities. He is also a member of PhRMA and BIO's ICH Work Groups, and representing

PhRMA as an expert to ICH Q12 Expert Working Group for developing guideline on Pharmaceutical Products Lifecycle Management.

Prior to Novo Nordisk, Andrew served more than eleven years at US FDA, most recently as an Associate Director for Policy and Regulation, Acting Deputy Director and Senior Regulatory Scientist in the Division of Hematology, Center for Biologics Evaluation and Research (CBER). During his tenure, Andrew received numerus high level FDA awards for his exceptional and outstanding performance on regulatory review and management, GMP inspection, and policy development. These include, but are not limited to FDA Commissioner's Special Citation for successfully completing FDA's initiative on product quality regulation and CBER's Public Health Achievement Award for outstanding regulatory review performance that resulted in averting a crisis in product availability. In 2002, the FDA recognized Andrew as the FDA regulatory expert in the regulation of new and novel recombinant products as well as naturally-derived biological products.

Andrew's formal scientific training includes post-doctor in immunology from the National Institutes of Health, Ph.D. in Biochemistry from the State University of New York, and B.S. in Pharmaceutical Chemistry from the China Pharmaceutical University. He has published numerus peer reviewed scientific papers in JAMA, J.Exp.Med., Blood, J.Immunol., Dev. Immunol. Thromb Haemost., Haemophilia, Pharmaceutical Engineering etc., and has been a frequent speaker at national and international conferences.

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LCDR Ramanadham is currently the Acting Senior Scientific and Policy Advisor for the Office of Process and Facilities, within the Office of Pharmaceutical Quality. He is primarily responsible for the strategic oversight and implementation of emerging policies and initiatives. 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. Prior to joining FDA, LCDR Ramanadham had experience in solid oral dosage manufacturing ranging from OTC products to schedule II narcotics. Outside of FDA, LCDR Ramanadham continues to practice pharmacy in the community setting to maintain perspective on the clinical relevancy and impact of our efforts in pharmaceutical quality.

Bhagwant Rege, Ph.D., Division Director, Division of Modified Release Products/OLDP/OPQ/CDER
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Dr. Bhagwant Rege is the Division Director for the Division of Modified Release Products in CDER/OPQ/OLDP at the FDA. Prior to joining FDA in 2010, he worked at Merck & Co. for about 9 years in oral biopharmaceutics and formulation development groups. His division at FDA is responsible for collaborative evaluation and assessment of Abbreviated New Drug Applications (ANDAs) for modified release drug products, nasal and inhalation drug products and making risk-informed recommendations on their approvability. 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), ICH Q12 Expert Working Group (EWG), and FDA liaison on the USP expert committee on dosage forms general chapter (2015-2020).
Bhagwant received his Bachelors and Masters in pharmacy from the University of Mumbai, India and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore.

Session 5: Challenges with Drug Device Combination Products Post Approval

Moderator:

Susan Neadle, Senior Director
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Susan Neadle has a distinguished career at Johnson & Johnson, where she has held roles of increasing responsibility in medical devices, pharmaceuticals, and consumer sectors for almost 25 years. In her current role, she is responsible for Johnson & Johnson's cross-sector Design Quality, ensuring focus on customer, quality, reliability and agility in new product development, as well as for J&J's Combination Products Community of Practice. Over her extensive career, she has played integral leadership roles in R&D product and process development and in Quality Engineering. Among several achievements during her tenure at J&J, Susan led the team that defined and implemented the business model, integrating global cross-functional requirements, to meet Combination Products health authority regulations into Janssen, J&J's Pharmaceutical segment. She is a Design Excellence Blackbelt. Over the course of her career, she has been awarded the Johnson Medal, J&J's highest honor for innovation excellence. She holds numerous patents and publications. Susan earned an M.S. in polymer science & engineering, and a B.S. in biology/chemistry, as well as Fellowship in the American Academy of Optometry.

Presenters:

John K. Towns, Ph.D., Senior Research Fellow
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John Towns Ph.D. is Senior Research Fellow in Global Regulatory Affairs at Eli Lilly and Company with responsibilities for Lilly's portfolio of stand-alone devices and combination products. John's prior experiences include Senior Director of CMC Regulatory Affairs and Head, Bioanalytical Development. John has presented and published on injectable combination products with a focus on Human Factors, and his research interests center on the reduction of medication errors through clear product differentiation, clarity of instructions for use and appropriate user training. John is also involved with several external organizations to set standards to clarify and harmonize the filing requirements for combination products.

John received his BS in Chemistry from Cal Poly San Luis Obispo, CA and his PhD in Analytical Chemistry from Purdue University.

QuynhNhu Nguyen, MS, Commander, U.S Public Health Service, Associate Director for Human Factors, Division of Medication Error Prevention and Analysis/CDER
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CDR QuynhNhu Nguyen is an engineer officer currently stationed at the Food and Drug Administration (FDA). She has been with FDA for more than 14 years. She has been working with evaluating human factors (HF) and use safety of medical products, originally, with the MedSun project in the Office of Surveillance and Biometrics, then with the Human Factors Premarket Evaluation Team in the Office of Device Evaluation within the Center for Devices and Radiological Health, and now with the Division of Medication Errors and Prevention Analysis (DMEPA) within the Center for Drug Evaluation and Research.

Her regulatory review experience includes performing specialized biomedical engineering reviews and human factors reviews of a variety of premarket submissions including combination products (drug/device, biologic/device). In addition, she has participated in Agency guidance development efforts with specific focus on

HF considerations for medical devices and combination products. She has led a number of HF-focus training and outreach efforts with internal FDA staff and external stakeholders.

She currently serves as the Associate Director for Human Factors with DMEPA. In this capacity, she works with DMEPA management to develop policy and best practices for HF reviews to ensure clarity and consistency.

She received her Bachelor in Biomedical Engineering from George Washington University in 2005, and Masters in Systems Engineering from Johns Hopkins University in 2013. She also received the Admiral Jerrold Michael Global Health Graduate Certificate from University of Maryland in 2010.

Douglass Mead, MSBME, RAC, Senior Director, Global CMC Regulatory Affairs - Medical Devices and Combination Products
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Doug Mead is Senior Director, Global Regulatory Affairs, Medical Devices and Combination Products, for Janssen Research & Development LLC, and is responsible for establishing and implementing the worldwide regulatory strategy for the development of drug delivery systems and drug-device combination products. These include a variety of injector and infusion systems, microcatheters, and nasal spray devices. Before joining J&J's Centocor in 2006, he held positions at a regulatory law firm, a pharmaceutical company specializing in drug delivery, various surgical instrument companies, and a medical device testing laboratory. He has an M.S. Degree in Biomedical Engineering from Drexel University and over 35 years of experience in the medical device, pharmaceutical, and combination products industries.

Session 6: CMC Innovation in the 21st Century – Global Regulatory Perspectives

Moderator:

Nina S. Cauchon, Ph.D., Regulatory Affairs – CMC
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Nina S. Cauchon, PhD, works at Amgen Inc. in Thousand Oaks, CA, and is currently leading external engagement activities within Regulatory Affairs - CMC. She has been a Global Regulatory CMC Lead for many early phase to commercial programs, including both small molecules and biologics, and prior to that she was a director leading Analytical Development within Pharmaceutics/Process Development. She holds a PhD in Medicinal Chemistry from the School of Pharmacy at Purdue University, and a RAC certification from RAPS.

She is the current chair of the AAPS CMC Community, and has been a member of its steering committee (which organizes the annual CMC Regulatory Exchange Forum) for the past 7 years. She is active on the ISPE Expedited Regulatory Pathways workstream including an upcoming white paper. She is also active in other external organizations and organizing committees including CASSS, PQRI, and PhRMA, and is the PhRMA Deputy Topic Lead on the ICH Expert Working Group for ICH Q14/ICH Q2(R1).

Her areas of interest are: regulatory challenges for innovative modalities and emerging technologies, CMC aspects of expedited review pathways, regulatory harmonization, and science and risk-based approaches to regulations. In addition to numerous technical publications, her regulatory publications include a comprehensive review article on regulating innovation in CMC, and cover articles for the AAPS Newsmagazine on the past, present, and future of pharmaceutical regulations and on combination products.

Presenters:

Sven Stegemann, Ph.D., Director, Pharmaceutical Business Development, Capsugel and Professor, Graz University of Technology
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Prof. Dr. Sven Stegemann is director, pharmaceutical business development at Capsugel, and professor of patient centric drug design and manufacturing at the Graz University of Technology, Austria. Over the course of his 21-year career at Capsugel, Dr. Stegemann has worked as an advisor to major pharmaceutical companies on ways to improve the design, development and manufacture of pharmaceutical products so they better address the individual needs of patients. In his academic role, Dr. Stegemann's focuses his research on the rational development of patient centric drug products and their associated manufacturing technologies, as well as education and training of students and young scientists. Dr. Stegemann is the founder and chair of the AAPS Focus Group on Patient-Centric Drug Development, Product Design, and Manufacturing as well as the founder and President of the Geriatric Medicine Society e.V.. He recently started the industrial-academic collaboration partnership Patient Centric Medicine (PaCeMe) to suitable and meaningful guidance for patient centric drug product design. He is the editor of the book "Developing Drug Products in an Aging Society - From Concept to Prescribing", a multidisciplinary approach towards patient centric drug development for the older and multimorbid patient populations.

Yoshihiro Matsuda, Ph.D., Senior Scientist (for Quality)
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Dr. Matsuda is a pharmacist and a senior scientist for Quality, Pharmaceuticals and Medical Devices Agency (PMDA).

He received his Ph.D. degree in Medicine from Tokyo Medical and Dental University in 2003.

He joined the Pharmaceuticals and Medical devices Evaluation Center, the predecessor of PMDA, in 2003 and he is currently responsible for quality assessment of medicines. He was a member of ICH Q9 Expert Working Group, ICH Quality Implementation Working Group (Q-IWG) and ICH Informal Quality Discussion Group (IQDG). He leads Innovative Manufacturing Technology Working Group (IMT-WT) at PMDA and he is a regulatory chair of ICH Q13.

Celia Cruz, Ph.D., Director, Division of Product Quality Research
Office of Testing and Research/FDA
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Celia Cruz is the Director of the Division of Product Quality Research in the Office of Testing and Research at FDA. Before joining the FDA in 2010, Celia worked in industry for eleven years, where she led teams responsible for the development and commercialization of solid oral drug products. As a black belt in Design for Six Sigma, she was an early adopter of Quality by Design and the use of quality risk assessments for guiding drug product development.

At FDA, Celia's division is responsible for developing and implementing CDER regulatory research goals on product and process understanding, in support of review, policy and inspections. Celia has served as a product and process reviewer for new and generic drugs, as liaison for Quality by Design, and as a former Lead of the CDER Nanotechnology Working Group. She currently a member of the FDA Emerging Technology Team, focusing on continuous manufacturing applications and has spoken nationally and internationally on the subject.

Celia Cruz has a B.S. and Ph.D. in Chemical Engineering from Brown University and Carnegie Mellon University, respectively.

FDA Roundtable on KASA Initiative

Moderator:

Lawrence X. Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality
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Lawrence X. Yu, Ph.D., is the Deputy Director, Office of Pharmaceutical Quality, and acting Director, Office of Process and Facilities, Food and Drug Administration, where he oversees new, generic, and biotechnology product quality review and inspection. Dr. Yu created the Question-based Review, defined the Pharmaceutical Quality by Design (QbD), inaugurated the FDA modern review system - Integrated Quality Assessment (IQA), established the FDA Emerging Technology Team (ETT) program, and developed the FDA historic concept of operations agreement to integrate review and inspection. Dr. Yu is also an adjunct Professor at the University of Michigan. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the AAPS Journal. Dr. Yu has authored/co-authored over 150 papers and given over 300 invited presentations. He is a co-editor of the books entitled "Biopharmaceutics Applications in Drug Development", "FDA Bioequivalence Standards", and "Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, 2nd Ed." Dr. Yu is the winner of numerous awards including AAPS Regulatory Science Achievement award, AIChE PD2M Drug Product QbD Achievement Award, Japan Naigai Foundation Distinguished Lectureship, China Beijing University IPEM graduation commencement address, Department of Health and Human Service Outstanding Leadership Award, FDA Commissioner's Special Citation, Outstanding Achievement, Group Recognition, and Team Excellence awards.

Presenters:

Susan Rosencrance, Ph.D., Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research
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Dr. Susan Rosencrance currently serves as the Director for the Office of Lifecycle Drug Products in the Office of Pharmaceutical Quality (OPQ). In this capacity, she directs procedures and processes for evaluating and assessing drug product quality during the lifecycle of both brand name and generic drug products. Prior to joining the FDA, Susan worked at Merck & Co.'s R&D Laboratories in Rahway, New Jersey. She joined the Office of Generic Drugs (OGD) in 1991 and spent the majority of her tenure in CDER working on generic drug products. She held various roles within OGD including senior chemistry reviewer, team leader, deputy division director, and OGD Deputy Director for Chemistry. Susan also served as the Deputy Director for Generic Drug Chemistry in the Office of Pharmaceutical Science prior to the formation of OPQ. Susan holds a Ph.D. in Chemistry from American University and completed her dissertation research at the NIH Laboratory of Biophysical Chemistry conducting a molecular dynamics study on hydrophobic interactions in alpha-helical coiled coils found in proteins. She received her bachelor's degree in Biochemistry from Hood College and also completed studies at the University of Strasbourg in Strasbourg, France in the Institute Internationale D'Etudes Française – Université Louis-Pasteur.

Andre Raw, Ph.D., Acting Senior Scientific and Policy Advisor, Office of Lifecycle Drug Products
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Andre Raw received his B.S. degree from the Massachusetts Institute of Technology and his Ph.D. degree in chemistry from the University of California at Berkeley. He joined the FDA as a reviewer within the Office of Generic Drugs (OGD). During his tenure within FDA, he has been promoted to FDA Agency Expert and to Chemistry Division Director. Currently he is Acting Senior Scientific and Policy Advisor in the Office of Life Cycle Drug Products (OLDP) in the Office of Pharmaceutical Quality (OPQ).

Dr. Raw was involved in the development of several important FDA initiatives, including the Guidance on Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications (ANDAs), Regulations on Listing of Polymorph Patents in the "Orange Book", and Question Based Review - Quality by Design (QbD) Initiative, QbD Example for Generic Modified Release Products, and Guidance for Industry: Pharmaceutical Solid Co-Crystals. He has also been active in addressing the scientific and regulatory issues raised in citizen petitions, in defining regulatory policy that impact ANDAs. He was instrumental in FDA's recent approval of generic versions of complex active ingredients including Lovenox (enoxaparin sodium) and Copaxone (glatiramer acetate).

More recently, Dr. Raw has been active in Risk Based Review and Quality Informatics Initiatives including Knowledge-Aided Assessment and Structured Application (KASA).

Derek Smith, Ph.D., Director, Division of Inspectional Assessment/OPF/OPQ/CDER
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Derek Smith received his B.S. in Physics from Washington College (2003) and his Ph.D. in Chemical and Biochemical Engineering from University of Maryland, Baltimore County (2008). He completed a NRC postdoctoral fellowship at NIST (2008-2010) prior to joining the CDER's Office of Compliance. There, he spent 2 years in the Division of Good Manufacturing Practice Assessment as a compliance officer for pre-approval facility evaluations. Later, he joined Office of Generic Drugs as a CMC reviewer of ophthalmic, topical, and injectable drug products. In these positions, he was involved in several important regulatory initiatives including Quality by Design, Process Analytical Technologies, and the Risk-Based Review Initiatives. In the Office of Pharmaceutical Quality, Derek has served as a Quality Assessment Lead (Acting), Branch Chief and is currently the Director of the Division of Inspectional Assessment in the Office of Process and Facilities where he oversees the assessment of the manufacturing process and facilities for biologics and small molecule drug applications and INDs with a focus on the integration of application assessment and inspection findings and data reliability assessments. He also serves as the co-chair for the New Inspection Protocol Project (NIPP) initiative for pre-approval inspections and is a member of the Knowledge-aided Assessment and Structured Application (KASA) initiative steering committee.

Mary Ann Slack, Director, Office of Strategic Programs
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Ms. Slack has 30+ years extensive leadership and management experience in both the public and private sectors, developing informatics strategy and implementing business solutions. She currently serves as Director of FDA's CDER Office of Strategic Programs. OSP plays a lead role in many of the Center's strategic initiatives and modernization efforts, including decision support, data standards, program analysis, informatics and governance. Since joining CDER in 2003, Ms. Slack has led numerous large, complex initiatives with broad stakeholder impact, including establishing CDER's data standards program and leading a team of experts in defining FDA's operational implementation of the FDA-EU mutual recognition agreement. Ms. Slack serves on several Boards and Committees where she supports FDA's needs and perspectives.

Panelists:

Susan Rosencrance, Ph.D., Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research

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Dr. Susan Rosencrance currently serves as the Director for the Office of Lifecycle Drug Products in the Office of Pharmaceutical Quality (OPQ). In this capacity, she directs procedures and processes for evaluating and assessing drug product quality during the lifecycle of both brand name and generic drug products. Prior to joining the FDA, Susan worked at Merck & Co.'s R&D Laboratories in Rahway, New Jersey. She joined the Office of Generic Drugs (OGD) in 1991 and spent the majority of her tenure in CDER working on generic drug products. She held various roles within OGD including senior chemistry reviewer, team leader, deputy division director, and OGD Deputy Director for Chemistry. Susan also served as the Deputy Director for Generic Drug Chemistry in the Office of Pharmaceutical Science prior to the formation of OPQ. Susan holds a Ph.D. in Chemistry from American University and completed her dissertation research at the NIH Laboratory of Biophysical Chemistry conducting a molecular dynamics study on hydrophobic interactions in alpha-helical coiled coils found in proteins. She received her bachelor's degree in Biochemistry from Hood College and also completed studies at the University of Strasbourg in Strasbourg, France in the Institute Internationale D'Etudes Française – Université Louis-Pasteur.

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Sharmista Chatterjee is currently the Division Director in Division of Process Assessment II, within FDA's Office of Process & Facilities (OPF). Sharmista has been with the FDA since 2006. During her tenure, she has been actively involved in new drug's Quality by Design efforts and FDA-EMA pilot program. She served as the CMC Lead for QbD (Quality by Design) in the Office of New Drug Quality Assessment (ONDQA) and as the technical lead for the FDA-EMA QbD pilot. She is an Agency Expert in CMC Modeling and Simulation. In addition to her current responsibilities, she is serving as one of OPF representatives in CDER's Emerging Technology Team. Prior to joining the agency in 2006, she spent around 10 years in industry. Her industry experience was primarily in process development and modeling in diverse areas that ranged from consumer goods to pharmaceuticals with companies such as United Technologies Corporation (UTC), Procter and Gamble (P&G), and Forest Laboratories (now Allergan). She received a bachelor's degree in Chemical Engineering from Indian Institute of Technology and a PhD in Chemical Engineering with a co-major in Biomedical engineering from Iowa State University.

Mahesh R. Ramanadham, LCDR, PharmD, Acting Senior Scientific and Policy Advisor for the Office of Process and Facilities/OPQ/CDER

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LCDR Ramanadham is currently the Acting Senior Scientific and Policy Advisor for the Office of Process and Facilities, within the Office of Pharmaceutical Quality. He is primarily responsible for the strategic oversight and implementation of emerging policies and initiatives. 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. Prior to joining FDA, LCDR Ramanadham had experience in solid oral dosage manufacturing ranging from OTC products to schedule II narcotics. Outside of FDA, LCDR Ramanadham continues to practice pharmacy in the community setting to maintain perspective on the clinical relevancy and impact of our efforts in pharmaceutical quality.

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Paul received his BS in Biochemistry from the University of Maryland at College Park in 1999. Shortly thereafter, he received his Ph.D. in Pharmaceutical Sciences in 2004, from the University of Maryland, Baltimore, focusing in the area of biopharmaceutics and pre-formulation. Paul has worked for the FDA for over 14 years, and has gained experience in the Office of Generic Drugs, Office of Pharmaceutical Science, and Office of New Drug Quality Assessment. He currently oversees the direction and review processes of the Division of Biopharmaceutics in the Office of New Drug Products, as they pertain to NDA and ANDA related Biopharmaceutics issues. Additionally, his professional experience included time at the National Institute of Standards and Technology, Shire Labs, Inc., and the Walter Reed Army Institute of Research.

Ramesh K. Sood, PhD., Senior Scientific Advisor
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Dr. Ramesh K. Sood is a Senior Scientific Advisor in the Office of New Drug Products, 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, Ramesh has 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.

Geoffrey Wu, PhD, PMP, CPH, Associate Director for Science and Communication
CDER/OPQ/OLDP/US Food and Drug Administration
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Commander Geoffrey Wu, Ph.D., PMP, CPH, is a scientist officer in the United States Public Health Service. He is currently the Associate Director for Science and Communication, and a Supervisor for the Immediate Office Review Staff in the Office of Lifecycle Drug Products (OLDP), Office of Pharmaceutical Quality (OPQ). Geoff has been deeply involved, leading or co-leading regulatory review and research for controlled correspondence, ANDAs, and supplemental ANDAs and NDAs in the past eight years. Between 2013 and 2017, he served on the OPQ Emerging Technology Team (ETT). Also he is a core member in multiple policy development efforts, such as emerging technology, continuous manufacturing, and comparability protocols.

Geoff has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, and process analytical technology. His professional specialization is mainly in product design, manufacturing and process analytical technology. He has more than 20 peer reviewed publications, and has been invited to multiple national and international conferences to present or discuss the above related topics. Geoff has a Ph.D. degree in Pharmaceutics and Pharmaceutical Chemistry from University of Utah, and M.S. degree in pharmaceutics and B.S. degree in pharmacy from Peking University, China.

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Larisa Wu, Ph.D., is a Senior Chemist and a Special Assistant in the Immediate Office of the Office of Pharmaceutical Quality (OPQ), FDA. Since she joined FDA in 2011, Larisa contributed significantly to various projects that became pivotal to the launch of OPQ, including integrated team-based quality assessment, risk-based review, CMC GDUFA hiring, and ANDA backlog review and management. In her current role as Special Assistant, Larisa worked extensively on several FDA, CDER, and OPQ level working groups and initiatives including: Knowledge-aided Assessment and Structured Assessment (KASA), Concept of Operations (ConOps) for

Inspection of Human Drugs, OPF Process and Facility Integration, OPQ Secondary Assessment, DMF Implementation into Panorama, and BARDA-FDA Drug Shortage Program. Her contributions have been recognized in various award ceremonies at the agency, center, and office level. Larisa received her Ph.D. degree in Bioengineering from University of Utah, followed by a postdoctoral fellowship in Pharmaceutical Sciences at University of Maryland, School of Pharmacy. She also holds an M.S. degree in Chemistry and a B.S. degree in Biomedical Engineering.