3RD FDA/PQRI CONFERENCE ON ADVANCING PRODUCT QUALITY
Rockville, Maryland

Biographies

Day 1 – March 22, 2017 Plenary

Michael Kopcha, Ph.D., R.Ph., Director, Office of Pharmaceutical Quality (OPQ)
Food and Drug Administration
michael.kopcha@fda.hhs.gov

Dr. Kopcha is a leader in the development of innovative solutions to resolve scientific, manufacturing, and commercialization issues worldwide – and in standardizing and harmonizing global processes. With more than 25 years of pharmaceutical industry experience, his areas of expertise include formulation and process development, process validation, technology transfer, off-shoring/outsourcing, and change management. Dr. Kopcha recently served as vice president, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc. in New Jersey. He joined Novartis in 2008 as the global head for pharmaceutical and analytical development, later serving as global head for new technologies and product innovation, and vice president and global head for global product development. At Novartis, Dr. Kopcha led the creation of a global R&D vision and strategies to drive innovation for the cough, cold, and respiratory franchise – through development, sourcing, manufacturing, and supply. He restructured and reorganized global product development to provide for a category-focused, globalized organization, and is credited for the creation of a successful strategic off-shoring/outsourcing program to increase project capacity and efficiency. Before joining Novartis, Dr. Kopcha served as vice president for pharmaceutical development at KV Pharmaceutical, Inc. in St. Louis, where he directed and managed analytical research and development, product development, process development and technology transfer, stability, drug delivery, project management, and external alliance. His experience also includes related roles with Schering-Plough, J&J, and Ivax. Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy, from Rutgers University in New Brunswick, New Jersey. He served as an adjunct assistant professor in the Department of Pharmaceutics, Ernest Mario School of Pharmacy at Rutgers.

Moheb Nasr, Ph.D., Vice President, CMC Regulatory Strategy
GlaxoSmithKline
moheb.m.nasr@gsk.com

Dr. Nasr is responsible for the development and the execution of GSK CMC regulatory strategy and serves as a member of GSK leadership and governance boards accountable for product development, manufacturing and supply, quality and regulatory oversight.

Prior to joining GSK, Dr. Nasr spent over 22 years at FDA. Dr. Nasr established and led FDA's Office of New Drug Quality Assessment (ONDQA). Dr. Nasr represented FDA and PhRMA at ICH and was instrumental in the development of QbD concept and several regulatory ICH guidelines. Dr Nasr continues to play a leading role in global regulatory harmonization and introduction of modern pharmaceutical manufacturing platforms, including Continuous Manufacturing. Dr. Nasr is currently the rapporteur of ICH Q12

Dr. Nasr obtained his Pharmacy degree at the University of Cairo, Egypt, and his Ph.D. degree in Chemistry at the University of Minnesota in Minneapolis, USA. Dr. Nasr is an elected Fellow of the American Association of Pharmaceutical Scientists (AAPS) and the recipient of AAPS Regulatory Science Achievement Award, and University of Wisconsin Pharmaceutical Analysis Excellence Award.

Sarah Pope Miksinski, Ph.D., Director – Office of New Drug Products and Acting Director – Office of Surveillance, Office of Pharmaceutical Quality
Food and Drug Administration
sarah.pope@fda.hhs.gov

Sarah Pope Miksinski, Ph.D., is the Director of the FDA's Office of New Drug Products (ONDP) and the acting Director of the Office of Surveillance, both within the Office of Pharmaceutical Quality (OPQ). She obtained her B.A. from Earlham College (1994), her doctorate in Organic Chemistry from Oklahoma State University (1999), and completed a postdoctoral fellowship from NIH (2000-2002). Sarah joined FDA in May of 2002, serving initially as a Chemistry Reviewer for reproductive/urologic drugs. Since that time, she has held additional positions including Chemistry, Manufacturing and Controls Lead as well as Branch Chief and Division Director. During her years at FDA, she has been active in numerous initiatives including the integration of review/inspection, the development of the team review process, the Pharmaceutical Inspectorate, and the establishment of enhanced collaborative approaches to facilitate the review of urgently needed drugs.

Outside of work, Sarah is an avid skier, CrossFit athlete, runner, and essay writer. She greatly enjoys spending time with her husband (Ted) and 6-year-old son (Adam).

Day 2 – March 23, 2017 Plenary

Stephen Tyler, Director of Quality Assurance
AbbVie
stephen.tyler@abbvie.com

Stephen Tyler is a Director of Quality Assurance at AbbVie, a biopharmaceutical company, in North Chicago, Illinois, USA. Stephen holds B.S. degrees in Applied Biology and Chemical Engineering and a M.S. in Microbiology. Stephen joined AbbVie (Abbott) in 1984 and the Quality Assurance organization in 2008. He is a former international board member for ISPE, former co-chair of the ISPE PQLI technical committee and current chair for the ISPE PQLI Steering Committee. Stephen was the recipient of the 2013 ISPE Richard B. Purdy Distinguished Achievement Award that recognizes an ISPE member who has made significant, long-term contributions to the society. He is the former vice-chair for the PQRI Steering Committee and Stephen is currently the chair of the PQRI Steering Committee.

Robert Femia, Ph.D., Senior Vice President, Chemical Medicines
United States Pharmacopeia (USP)
RZF@USP.org

Robert Femia, Ph.D., is Senior Vice President, Chemical Medicines at USP. Dr. Femia leads all scientific activities for chemical medicines and oversees our Industry Standards Collaboration function.

A widely published researcher and frequent presenter, Dr. Femia most recently served as North American Vice President of Research and Development and Regulatory Affairs at Sun Pharmaceutical. He brings more than twenty five years of leadership experience in various disciplines within the pharmaceutical industry including quality control and assurance, regulatory affairs, research and development and business development to his current role at USP. His earlier employment history includes companies such as GAT/Nortec, Par Pharmaceutical, and Novartis, among others.

Dr. Femia earned his Bachelor of Science degree in Chemistry from Fairfield University and his Master of Science and Doctor of Philosophy degrees in Chemistry from Seton Hall University.

Lawrence X. Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality
Food and Drug Administration
lawrence.yu@fda.hhs.gov

Lawrence X. Yu, Ph.D., is the Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration, where he oversees new, generic, and biotechnology product quality review and inspection functions as well as the FDA CDER quality labs. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan. Prior to joining the FDA, Dr. Yu had worked at Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, Division Director, Deputy Office Director, and Office Director. Dr. Yu's research interests have centered on the prediction of oral drug delivery and the development of pharmaceutical Quality by Design. 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 130 papers, and presented over 100 abstracts, and given over 200 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:
DRUG CLASSIFICATION, RELEASE, AND MODELING FOR SETTING CLINICALLY RELEVANT SPECIFICATIONS

Session 1: Biowaivers and Harmonization Guidelines for Class 1 and Class 3 Drugs

Moderator:

Mehran Yazdanian, Ph.D., Sr. Director of Pharmaceutics
Teva Branded Pharmaceutical Products R&D, Inc.
Mehran.Yazdanian@tevapharm.com

Mehran Yazdanian is the Sr. Director of Pharmaceutics at Teva Branded Pharmaceutical Products R&D Inc. He received his B.S. in biochemistry and M.S. and Ph.D. in pharmaceutics from the University of Wisconsin-Madison. His current responsibilities are concentrated on directing formulation and analytical development activities from early drug discovery support and preformulation to formulation development and manufacturing for clinical programs and 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:

Mehul U. Mehta, Ph.D., Director, Division of Clinical Pharmacology I, OCP
Food and Drug Administration
Mehul.Mehta@fda.hhs.gov

Dr. Mehta is the Director, DCP I (Division of Clinical Pharmacology I), OCP (Office of Clinical Pharmacology), in CDER (Center for Drug Evaluation and Research), FDA. His division is responsible for reviewing the clinical pharmacology and biopharmaceutical aspects of the Cardio-Renal, Neuropharmacological and Psychiatric drug products. He obtained his M.Sc. from University of Bombay in Synthetic Organic Chemistry in 1979, M.S. from University of Houston in Medicinal Chemistry in 1981, and his Ph.D. in Pharmacokinetics from the University of Pittsburgh in 1986 and joined FDA as a reviewer the same year. He has been with the Agency for last 30 years and in his current position for last 18 years. In addition to his review oversight, administrative, and management responsibilities, he continues to play a significant role in broad based regulatory needs. For example, currently he co-chairs the CDER BCS (Biopharmaceutics Classification System) Committee, is a member of the CDER Lifecycle Management Board, is the co-chair of CDER NTI (Narrow Therapeutic Index) WG, member of the FIP BCS SIG, and the FDA Topic Leader for the ICH M9 Biopharmaceutics Classification System-based Biowaivers WG formed in July 2016. Current research interests include therapeutic equivalence of complex modified release products, NTI designation of drug products, efficacy extrapolation in pediatrics for epilepsy drugs, and possible extension of BCS based biowaivers. He has authored numerous publications, guidances and book chapters. He was recognized as AAPS Fellow in 2012.

Barbara M. Davit, Ph.D., JD, FAAPS, Executive Director, Biopharmaceutics Group, Translational Medicine Department
Merck Research Laboratories
barbara.davit@merck.com

Barbara M. Davit, PhD, JD, FAAPS, is an Executive Director in the Biopharmaceutics Group in the Translational Medicine Department at Merck Research Laboratories (MRL), responsible for executing clinical bioavailability/bioequivalence(BA/BE) and IVIVC studies in early- and late-stage drug development. Dr. Davit holds a BS in Chemistry from Georgian Court University, a PhD in Nutrition Science from University of California, Davis, and a JD from George Mason University School of Law. Her graduate work focused on ADME of water-soluble vitamins, and she trained in Pharmacokinetics as a Fellow at the California Primate Research Center. After several years in the CRO industry, Dr. Davit joined the US-FDA as a Pharmacology Reviewer, ascending to positions of increasing responsibility in the Office of Clinical Pharmacology and Office of Generic Drugs. At the US-FDA, Dr. Davit initiated development of regulatory guidances, notably the Dissolution Methods Database, the Product Specific Guidances for Generic Drug Development, and the Global Human Health Guidelines for Developing Fixed-Dose Combination Products to treat HIV AIDS. She contributed to writing the recently-posted FDA guidances on bioanalytical method validation and general BA/BE requirements for both new and generic drugs. Dr. Davit has written nearly 60 original scientific articles and book chapters on various clinical pharmacology and biopharmaceutics-related topics, and has given over 200 national and international invited presentations and poster sessions. She is an active member of the MRL Biopharmaceutics Advisory Team, the MRL Clinically Relevant [Dissolution] Specifications Team, a past member of the International Generic Drugs Regulators Pilot Program, Past-Chair of the MRL Document Review Committee for Phase 1 study proposals, Past-Chair of the AAPS BE Focus Group, and present Secretary of the AAPS Regulatory Sciences Section.

Raimar Löbenberg, Ph.D., Professor and Director
University of Alberta, DDIC
raimar@ualberta.ca

Dr. Löbenberg holds a BS in pharmacy from the Johannes Gutenberg-University in Mainz, Germany. He received his PhD in pharmaceutics from the Johann Wolfgang Goethe-University in Frankfurt in 1996 for his work in drug delivery using nanoparticles. He then joined Dr. Dressman's lab and investigated the dissolution behavior in Biorelevant dissolution media. After that he joined Dr. Amidon's lab in Ann Arbor where he investigated different aspects of oral drug administration including computer simulations. He joined the University of Alberta in 2000.

His research interests are in Biopharmaceutics to predict the oral performance of drugs and botanicals and inhalable nanoparticles to treat lung diseases like lung cancer, tuberculosis or leishmanasis.

He is founder and director of the Drug Development and Innovation Centre at the University of Alberta. He was president of the Canadian Society for Pharmaceutical Sciences 2014-2015. He is vice chair of the United States Pharmacopeia Dietary Supplement Expert Committee. He is vice chair of the Specialty Committee of Traditional Chinese Medicine in Pharmaceutics of the World Foundation of Chinese Medicine Science. He is member of the Health Canada Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology.

Session 2: Dissolution Challenges for CBS Class 2/4 Drugs

Moderator:

Allen C. Templeton, Ph.D., Associate Vice President
Merck & Co., Inc.
allen_templeton@merck.com

As Associate Vice President of the Formulation Sciences organization within Pharmaceutical Sciences & Clinical Supply, Allen is responsible for leading small molecule formulation development at Merck. Before assuming his current position, Dr. Templeton held positions of increasing responsibility, including leadership roles in Preformulation, Discovery Pharmaceutical Sciences, Analytical and Formulation within Pharmaceutical Sciences. He has held past positions with Alcon Laboratories and Texas Instruments.

Dr. Templeton earned a B.S. in Chemistry from Texas A&M at Commerce and a Ph.D. in Chemistry from the University of North Carolina at Chapel Hill in 2000. His research experience and interests have been in the area of materials chemistry and the pharmaceutical sciences. 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 photostability/photochemistry.

Dr. Templeton is an active member in a number of professional organizations, including the American Association of Pharmaceutical Scientists (AAPS) and the American Chemical Society (ACS). He has served in a number of roles for AAPS and is most recently the Chair-Elect of the Physical Pharmacy and Biopharmaceutics Section. He was named as a Fellow of the AAPS in 2015. He was elected to both the 2010-2015 and 2015-2020 United States Pharmacopeia (USP) expert committee terms on physical analysis and has worked to revise a number of USP standards chapters. He participates on a departmental advisory board and holds an adjunct professorship at Purdue University. He also currently serves on the editorial advisory boards for the Journal of Pharmaceutical Sciences and American Pharmaceutical Review.

Presenters:

Richard (Rik) Lostritto, Ph.D., Associate Director for Science (acting), Office of Policy for Pharmaceutical Quality (OPPQ)
Food and Drug Administration
richard.lostritto@fda.hhs.gov

Richard (Rik) Lostritto, Ph.D., joined the FDA in 1995 and currently serves as Acting Associate Director for Science in The Office of Policy for Pharmaceutical Quality (OPPQ).

Previously, Rik served in the Office of New Drug Quality Assessment (ONDQA) as Acting Deputy Office Director for Science & Policy, Biopharmaceutics Lead, CMC Division Director (oncology, hematology, cardio-renal, neurology, and psychiatric drug products), Team Leader (pulmonary, allergy, and oncology drug products), and Review Chemist in several therapeutic areas.

Before joining the Agency, Dr. Lostritto worked at Boehringer Ingelheim Pharmaceuticals leading a group which developed medical aerosol formulations after serving as Assistant / Associate Professor of Pharmacy at The University of Connecticut (1983-1992). He received his M.S. and Ph.D. Degrees in Pharmaceutical Chemistry and Pharmaceutics from the University of Michigan and his B.S. Degree in Pharmacy from The University of Connecticut.

Sandra Suarez-Sharp, Ph.D., Master Biopharmaceutics Reviewer/Biopharmaceutics Lead (acting)
Office of New Drug Products/OPQ/Division of Biopharmaceutics
Food and Drug Administration
sandra.suarez@fda.hhs.gov

Dr. Sandra Suarez-Sharp graduated from UF with a PhD in Pharmaceutical Sciences. She joined the FDA in 1999. She worked as a Clinical Pharmacology reviewer in the Office of Clinical Pharmacology supporting the Division of Pulmonary and Allergy Drug Products, the Division of Antiviral Drugs, the Division of Reproductive and Urology Products, and the Division of Bioequivalence at the Office of Generic Drugs. Currently, she works in the Office of New Drug Products/OPQ/Division of Biopharmaceutics as a Master Biopharmaceutics Reviewer/Biopharmaceutics Lead (acting) supporting all therapeutic areas. Her responsibilities in this office include the primary and secondary review of submissions containing Biopharmaceutics information such as dissolution, biowaivers, IVIVCs, PBPK mechanistic absorption models in support of risk assessment/setting clinically relevant drug product specifications, dissolution models for RTRT, and mentoring new reviewers.

Erika Stippler, Ph.D., Director of the Dosage Form Performance Laboratory
U.S. Pharmacopeia
ess@usp.org

Erika Stippler, Ph.D. is the Director of the Dosage Form Performance Laboratory at the U.S. Pharmacopeia in Rockville, MD. She has more than 20 years of experience in the pharmaceutical industry having been at various contract research organizations in Germany and Switzerland and working at USP for 10 years.

Erika began her career as a scientist at the Central Laboratory of German Pharmacisits in Germany. In 1996 she proceeded to attend the W. J. Goethe University Frankfurt Institute of Pharmaceutical Technology as an external Ph.D. student. With the thesis title “Biorelevant Dissolution Test Methods to Asses Bioequivalence of Drug Products” she received her Ph.D. under the guidance of Prof. Dr. Jennifer B. Dressman. Between 1998 and 2002, she was the head of Biopharmacy/Stability Testing of Laboratory and Quality Services in Eschborn, Germany. Dr. Stippler has also been Technical Director of PHAST laboratories and Project Manager at Solvias, Switzerland before coming to USP.

Her scientific interest is focused on dissolution method development for various dosage forms and on the characterization and standardization of dissolution apparatus and dissolution methods for performance evaluation of pharmaceutical products.
She was the chair of the Biopharmaceutics Technical Committee of PQRI for several years. She is also an active member of In-vitro Release and Dissolution Testing (IVRDT) focus group of American Association of Pharmaceutical Scientists (AAPS).

Session 3: In-Vivo Predictive Dissolution Methods and Modeling

Moderator:

Gregory E. Amidon, Ph.D., Research Professor of Pharmaceutical Sciences
University of Michigan
geamidon@med.umich.edu

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 2015-2016 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. He is currently co-chair of the Food and Drug Administration (FDA) Pharmaceutical Science and Clinical Pharmacology Expert Committee.

Speakers:

Justin Pennington, Ph.D., Director w/in PSCS Analytical Sciences Department
Merck & Co., Inc.
justin.pennington@merck.com

Justin Pennington is a Director at Merck Research Laboratories within the Pharmaceutical Sciences and Clinical Supply with the responsibility of overseeing small molecule and peptide analytical groups in Rahway NJ and West Point PA. Justin obtained his Ph.D. in Pharmaceutical Chemistry from the University of Kansas, Lawrence where he developed chromatographic expertise including high-pressure column packing and fabrication of capillary based monolithic silica columns. His dissertation research focused on the development of fluorescent stable isotope tagging strategies for proteins containing DOPA. Prior to his PhD, Justin completed his Bachelor's degree in Chemistry and Math at Briar Cliff University in Sioux City, Iowa. After graduation from Kansas, he joined Merck (Schering-Plough) in the Respiratory Product Development group where held roles of increasing responsibility prior to his current role. Justin's research interests include the study of in-vitro predictive technologies and the use of mathematical modeling and quantitative mass spectrometry for uniformity analysis and trace level analysis. In addition to actively publishing manuscripts and conference presentations, Justin is active in the external scientific community as a USP expert committee member, and is a member of the executive committee and current president of Eastern Analytical Symposium.

Nikoletta Fotaki, Pharmacist, MSc, PhD, Associate Professor
University of Bath, UK
n.fotaki@bath.ac.uk

Dr. Nikoletta Fotaki is a UK registered Greek Pharmacist, with an MSc in Toxicology and a PhD in Biopharmaceutics-Pharmacokinetics. She participated in several research projects in the School of Pharmacy of the National and Kapodistrian University of Athens and in Hoffman La Roche (Pharmaceutical and Analytical R&D, New Jersey, USA) before her academic appointment at the University of Bath. She has also worked in the National Organisation for Medicines in Greece. Her expertise and research are focused on PBPK modeling, drug absorption, development of in vitro screening tools and associated software for predicting absorption and in vivo performance in normal populations and in special populations (i.e. paediatrics, disease states), biorelevant dissolution methods, dissolution imaging, development of in vitro-in vivo correlations and relations, formulation development, animal models for the prediction of absorption, methods for reduction/ refinement/ replacement of animal experimentation, biowaivers, dissolution testing, design of BA/BE studies, in silico models, pharmacokinetics. She is a reviewer and scientific advisor of several scientific journals, an Associate Editor for AAPS Open and member of the editorial board of Dissolution Technologies and DiePharmazie. She is an Associate Fellow of the Higher Education Academy and has been involved in the evaluation of several research proposals. She is also an Adjunct Assistant Professor in the University of Waterloo (Canada). She is a member of several scientific societies and active member of various steering committees and the chair of the IVRDT Focus Group of AAPS. She has organised and moderated sessions in American Association of Pharmaceutical Scientists annual meetings, in American College of Clinical Pharmacology and has been an invited speaker at several conferences and seminars.

David C. Sperry, Ph.D., Research Advisor
Eli Lilly and Company
sperryda@lilly.com

Dr. Sperry is a Research Advisor in Small Molecule Drug Development at Lilly Research Laboratories. He obtained a B.S. degree in chemistry from Indiana University, Bloomington, IN and a Ph.D. degree in chemistry from the University of Rochester, Rochester, NY. After receiving his degree, he took a postdoctoral research scientist position at Pharmacia & Upjohn where he developed an Artificial Stomach Duodenum model and studied its utility in drug development. Shortly thereafter, he accepted a research scientist position at Pharmacia (later Pfizer), working in the area of in vitro methods and biopharmaceutics. He then moved to Bausch and Lomb where he developed commercial ophthalmic formulations for late stage molecules. In 2007, Dr. Sperry joined Lilly Research Laboratories, where he created a group focusing on in vitro drug product performance techniques and predictions of in vivo performance. In 2013, Dr. Sperry joined a computational modeling group at Lilly. He now supports product development by using existing and creating new models to predict product performance and oral absorption of small molecule drug formulations.

Session 4: Drug Release from Non-Oral Routes

Moderator:

Wenlei Jiang, Ph.D., Senior Science Advisor, Office of Research and Standards/OGD/CDER
Food and Drug Administration
Wenlei.Jiang@fda.hhs.gov

Dr. Wenlei Jiang is currently 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 is mainly responsible for coordinating post-market generic drug safety investigation, representing ORS on OGD's new international harmonization activities, and developing opportunities for scientific outreach. Previously she served as the Acting Deputy Director of ORS, where she provided oversight on Generic Drug User Fee Act (GDUFA) regulatory science research programs. Her research interest has been focused on bioequivalence standard development for generic complex drug products containing nanomaterials, solid oral modified release drug products, and narrow therapeutic index drugs, as well as post-market surveillance of generic drugs. She used to work in the Division of Chemistry, OGD to review the chemistry and manufacturing control (CMC) sections of ANDAs. 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:

Randy Mrsny, Professor, Epithelial Cell Biology
University of Bath
R.J.Mrsny@bath.ac.uk

Randy Mrsny currently holds a Professor's chair of Epithelial Cell Biology at the University of Bath in the Department of Pharmacy and Pharmacology where he studies biological principles associated with normal epithelia cell function and how these are affected in disease states. His work in drug delivery is internationally recognized as evidenced by his election as president of the Controlled Release Society and to co-organize a Gordon Conference on Drug Delivery. He is also the CSO of Applied Molecular transport, a biotech company in the San Francisco bay area. Randy has been selected to the Medicine Maker 100 power lists for 2015 and 2016.

Brad Anderson, Ph.D., Professor-Pharmaceutical Sciences, College of Pharmacy
University of Kentucky
bande2@email.uky.edu

Dr. Brad Anderson is a Professor in Pharmaceutical Sciences at the College of Pharmacy, University of Kentucky. Dr. Anderson received his M.S. and Ph.D. in Pharmaceutical Chemistry from the University of Kansas in 1978. He spent the next five years as a research scientist at The Upjohn Co. for 5 years before joining the University of Utah in 1983 as an Associate Professor in Pharmaceutics and Pharmaceutical Chemistry. Dr. Anderson relocated to the University of Kentucky in 2000 where he served as Chair of the Pharmaceutical Sciences department until 2003 and as Interim Chair in 2012-13. He is a Charter Member of the AAPS and an AAPS Fellow. He has received several awards throughout his career including the Pfizer Young Investigator Award (1985), the Meritorious Manuscript Award from Pharm. Res. (1990), the Outstanding Paper Award in J. Controlled Release (1992), the Ebert Prize for the best paper in J. Pharm. Sci. (1998), the University of Utah Distinguished Research Award (1999), the AAPS Dale E. Wurster Research Award in Pharmaceutics (2012), and the AAPS Outstanding Educator Award (2016). Anderson serves on several editorial advisory boards and is an Editor for J. Pharm. Sci. He holds several patents in prodrug design and drug delivery system design and has approximately 160 publications in drug solubilization and stabilization, prodrug design and drug targeting for the treatment of cancer and AIDS, lipid bilayer transport and liposomal drug delivery, and computational methods for predicting membrane transport and drug formulation properties. His current research interests include lipid bilayer

membrane transport, controlled drug-delivery to solid tumors using nanotechnology, chemical stability in amorphous solid-state formulations, and molecular dynamics simulations to explore the properties of drugs in amorphous formulations.

Douglas Mar, Ph.D., Principal Scientist
Liquidia Technologies, Inc.
Doug.Mar@liquidia.com

Douglas Mar, Liquidia Technologies, Inc. Dr. Mar joined Liquidia in 2007 and is a Principal Scientist in the Analytical group. He earned his Ph.D. in Physics from Harvard and has made original contributions in diverse research areas: semiconductor physics, mathematics, signal processing, neuroscience, and infrared astronomy. He has a keen interest in optical instrumentation. He is a member of ASTM and serves on the Nanotechnology and Particle Characterization Committees.

Session 5: Modeling for Oral and Non-Oral Routes

Moderator:

Filippos Kesisoglou, Ph.D., Senior Principal Scientist
Merck & Co., Inc.
filippos_kesisoglou@merck.com

Filippos Kesisoglou is a Senior Principal Scientist in the Biopharmaceutics and Specialty Dosage Forms group, Pharmaceutical Sciences and Clinical Supply, Merck Research Laboratories (West Point, PA) where he is leading the Oral Biopharmaceutics and Modeling & Simulation Quantitative Biopharmaceutics efforts. His research work and responsibilities include the in vitro, in silico and in vivo biopharmaceutical evaluation of oral and non-oral formulations across development phases from FIH formulation to late stage and life-cycle management stages, including Regulatory Agency interactions and setting of clinically relevant specifications. He holds a diploma in Pharmacy from Aristotle University of Thessaloniki, Greece and MSc and PhD degrees in Pharmaceutics from University of Michigan, Ann Arbor, MI. He has authored/co-authored more than 45 scientific papers or book chapters and more than 60 meeting abstracts/podium presentations in the fields of biopharmaceutics and oral drug delivery. He has been an invited speaker to national/international workshops and meetings in the field of biopharmaceutics and absorption modeling. He is currently serving on the Editorial Advisory Board for Journal of Pharmaceutical Sciences.

Presenters:

Roberto Gomeni, Ph.D., Founder
Pharmacometrica
roberto.gomeni@pharmacometrica.com

Roberto Gomeni, PhD, obtained a degree in Mathematics from the University of Milano (Italy), a PhD in Pharmacokinetics and HDR from the University of Montpellier I (France). He was the former global head of Pharmacometrics at GlaxoSmithKline R&D, King of Prussia, PA (USA). He is the founder of Pharmacometrica, a global provider of consulting services in Pharmacometrics. He is, Adjunct Professor with the Division of Pharmacotherapy and Experimental Therapeutics in the UNC Eshelman School of Pharmacy at The University of North Carolina at Chapel Hill and is author of more than 170 original research papers published in international scientific journals on the identification and on the implementation of strategies based on pharmacometrics approach to enhance drug development process, drive decision making and risk management using drug and disease progression models, clinical trial simulation, Bayesian modelling and knowledge-based computer-assisted drug development processes.

Maureen D. Donovan, Ph.D., Associate Dean and Professor, College of Pharmacy
University of Iowa
maureen-donovan@uiowa.edu

Maureen Donovan is currently Associate Dean for Undergraduate Programs and Professor of Pharmacy at the University of Iowa. Previously, she served as the Head of the Division of Pharmaceutics and Translational Therapeutics, where she led a group of 12 faculty members and over 50 students enrolled in 2 Ph.D programs. Professor Donovan received her B.S. in Pharmacy from the University of Minnesota (1983) and a Ph.D. in Pharmaceutics from the University of Michigan (1989). She has been a faculty member at the University of Iowa since 1989.

Professor Donovan leads a research group involved in the investigation of drug absorption mechanisms. Her research focuses primarily on respiratory drug delivery, with an emphasis on nasal drug absorption and disposition. Dr. Donovan has directed over 40 M.S. and Ph.D. students and visiting scholars. In 2005, she was named the UI College of Pharmacy Teacher of the Year.

Professor Donovan has obtained research funding from federal agencies, foundations, and the pharmaceutical industry. She has been a review panel member for both the NIH and NSF and chaired the NIH Emerging Technologies in Neuropharmacology/Neuroscience SBIR study section from 2009-2011. She was the recipient of an Eli Lilly Young Investigator Award in 1992 and was a visiting scholar at SmithKline Beecham Pharmaceuticals during 1991.

Professor Donovan is a member of the American Association of Colleges of Pharmacy and served as the 1998-99 chair of the Section of Teachers of Pharmaceutics, and she completed an AACP Academic Leadership Fellowship during 2005. She is a member of the American Association of Pharmaceutical Scientists and was elected to the AAPS Executive Council and served as Treasurer from 1998-2000. Dr. Donovan also served on the Board of Directors of the Society for Women's Health (2007-09) and the Board of Trustees of the Eastern Iowa Chapter of the Crohn's and Colitis Foundation of America (1992-95).

David Good, Ph.D., Senior Research Investigator
Bristol-Myers Squibb
DAVID.GOOD2@bms.com

David is a Senior Research Investigator II in Drug Product Science and Technology (DPST) Biopharmaceutics group in New Brunswick, NJ. His 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 joined BMS in 2010 and has held several roles in oral solid dosage form development including modeling and simulation. David received his doctoral degree in Pharmaceutics from University of Michigan.

Session 6: Topical Classification System

Moderator:

Kailas Thakker, Ph.D., Co-Founder and Chief Operating Officer
Tergus Pharma
KThakker@TergusPharma.com

Dr. Kailas Thakker is a Co-Founder and Chief Operating Officer of Tergus Pharma. Dr. Thakker joined Columbia University in New yok after receiving B. Pharm from UDCT (University Department of Technology) now called ICT. After receiving Masters in Pharmaceutical Sciences from Columbia University, she joined University of Kansas where she worked with world renowned, Father of Pharmaceutics Dr. Takeru Higuchi for her doctoral degree. After launching her career at U.S.

Pharmacopeia, she moved to North Carolina and headed the Department of Analytical Development at Sphinx Pharmaceuticals. When Sphinx was acquired by Eli Lilly, Dr. Thakker decided to be an entrepreneur and founded Analytical Solutions with a mission to provide quality analytical services to pharmaceutical industry. Leveraging her experience eat USP and to survive amidst large established CROs, she started working on developing performance test for topical dosage forms. Within 5-6 years. Analytical Solutions emerged as a global leader and premier service provider for performance test for topical dosage forms. In 2012, ASI and Dr. Thakker made a strategic move to partner with Dr. Vijendra Nalamothu to form Tergus Pharma, a one stop shop for topical product development.

Dr. Thakker has presented at USP, PQRI and AAPS workshops on development of performance tests for topical dosage forms and its contribution to product development thru using principles of Quality by Design. Dr. Thakker serves as the chair of the expert panel on topical dosage forms for the Dosage forms expert committee of USP.

Vinod P. Shah, Ph. D., Consultant
PQRI
dr.vpshah@comcast.net

Dr. Shah is a pharmaceutical consultant and is a Board Member of PQRI (2013 – Present). 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.

Dr. Flavian Ștefan Rădulescu, Associate Professor
Center for Drug Sciences, Faculty of Pharmacy University of Medicine and Pharmacy Carol Davila
flavian.radulescu@umf.ro

Dr. Rădulescu is associate professor at the Faculty of Pharmacy, University of Medicine and Pharmacy Carol Davila Bucharest, Department of Biopharmaceutics / Center for Drug Sciences. He previously worked in the research and development of liquid, oral and ophthalmic dosage forms, but also in bioequivalence studies. His main area 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. He is reviewer for national and international pharmaceutical journals.

Sam Raney, Ph.D., Scientific Lead, Topical and Transdermal Drug Products, Office of Generic Drugs
Food and Drug Administration
Sameersingh.Raney@fda.hhs.gov

Dr. Sam Raney is a thought leader in topical and transdermal drug products, with over 25 years of experience in dermatological science, and over 20 years in biotechnology and pharmaceutical drug product development. Dr. Raney has been a researcher and adjunct professor within academia, a principal or sub investigator on over 400 pharmaceutical product research studies, has held senior management roles in industry, serves as an expert panel member in the U.S. Pharmacopeia, and is the chair of the dermatopharmaceutics focus group of the American Association of Pharmaceutical Scientists. He has a broad knowledge of scientific, legal, business and regulatory aspects of drug development.

Dr. Raney is the Scientific Lead for Topical and Transdermal Drug Products within the Office of Generic Drugs at the U.S. FDA. He is responsible for the development of general and product-specific

bioequivalence guidances, reviewing and responding to controlled correspondences, citizen petitions, and Pre-ANDA meeting requests, and serves as a subject matter expert for internal consultations related to NDA and ANDA reviews. One of Dr. Raney's main responsibilities involves the development of regulatory science research initiatives related to topical and transdermal drug products, and he provides direction and oversight for several FDA-funded collaborations with research institutions around the world.

Dr. Raney holds a B.A. in Molecular Biophysics & Biochemistry from Yale University, an M.Sc. in Biology from Marshall University, and a Ph.D. in Biochemistry & Molecular Biology from the University of British Columbia (Canada). His credentials include numerous research manuscripts, review articles, book chapters and patents, as well as invited roles moderating and presenting at scientific meetings internationally.

TRACK 2 – ACHIEVING PRODUCT QUALITY: NOVEL APPROACHES AND APPLICATIONS

Session Title: Session 1: Clinically Relevant Specifications for Oligonucleotides

Moderator:

Larisa Wu, Ph.D., Senior Chemist and Special Assistant, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research
US Food and Drug Administration
Larisa.Wu@fda.hhs.gov

Larisa Wu, Ph.D., is a Senior Chemist and a Special Assistant in the Immediate Office (IO) of the Office of Pharmaceutical Quality (OPQ), FDA. Larisa joined FDA in 2011 and served as a fellow, product quality reviewer, and team lead. She was a member of the Peptide Team of the Office of Generic Drugs (OGD)/Office of Pharmaceutical Science (OPS) and of the OPS Science and Research Staff, where she performed primary and secondary reviews of applications for products ranging from small molecules to complex drug substances. She contributed significantly to the development of initiatives within OPS 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. 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.

Presenters:

Joe Guiles, Head of Development
Agilent Technologies
joe.guiles@agilent.com

Joe is a Pharma/Biotech senior leader with extensive experience in building and leading technical functions that focus on clinical and commercial stage therapeutic API's. He is currently the Head of Development at Agilent Technologies Nucleic Acid Solution Division in Boulder, CO. His past employers included Medivation, Cedarburg-Hauser, Replidyne, Sanofi-Aventis, and Johnson & Johnson.

Serge Beaucage, Ph.D., Research Chemist
Food and Drug Administration
Serge.Beaucage@fda.hhs.gov

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. Specifically, Dr. Beaucage's research has focused on

the development of innovative 2'-hydroxyl protecting groups for solid-phase RNA synthesis, in the context of RNA interference applications, and on the implementation of thermolabile groups for phosphate/thiophosphate protection in the preparation of thermolytic oligonucleotide prodrugs. More recently, the use of amphipathic trans-acting polythymidylic or poly-2'-O-Methyluridylic thiophosphate triester elements to improve the cellular/tissue delivery of nucleic acid-based drugs has become an important theme of Dr. Beaucage's research program.

Mohan Sapru, M.S., Ph.D., CMC Lead for Cardiovascular and Renal Products, Office of New Drug Products, Office of Pharmaceutical Products, CDER
Food and Drug Administration
mohan.sapru@fda.hhs.gov

Mohan Sapru, M.S., Ph.D., is the CMC Lead for Cardiovascular and Renal Products, Office of New Drug Products, which is within the Office of Pharmaceutical Quality, FDA. He serves as chair and as expert panel member for CMC sessions on oligonucleotides for DIA/FDA Oligonucleotide-Based Therapeutics Conferences. As an application technical lead (ATL), Dr. Sapru is involved with leading, managing, coordinating, and integrating OPQ team reviews and review teams, and performing overall patient-centric product risk assessment and communicating the risk assessment to all the stakeholders, including the clinical divisions. As a member of Emerging Technology Team (ETT), Dr. Sapru is involved with guiding pharmaceutical innovation. Prior to joining the FDA, he served as a faculty at Northwestern University, Chicago where his research focus was on drug design, small interfering RNA designs, oligonucleotide therapeutics, and RNAi-based allele-specific gene therapy in models of neurodegenerative disorders. Dr. Sapru holds several US patents, and has authored a number of research publications in prestigious peer-reviewed journals.

Session 2: PQRI PODP Working Group Recommendations on Extractables and Leachables

Moderator:
Diane Paskiet, Senior Director – Scientific Affairs
West
diane.paskiet@westpharma.com

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 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

Dennis Jenke, Ph.D., Chief Executive Scientist
Triad Scientific Solutions, LLC
dennisjenke@triadscientificsolutions.com

Dennis Jenke is currently the Chief Executive Scientist for Triad Scientific Solutions, LLC, where he uses good science, practically applied, to address and overcome the challenges associated with managing interactions that occur between drug products and their manufacturing, packaging and delivery systems, insuring that such interactions (for example, extractables, leachables and drug binding) do not adversely affect the product's key quality attributes including safety, purity, efficacy, stability, and suitability for use. Previously, Dr. Jenke was a Distinguished Scientist at Baxter Healthcare Corporation

where for more than three decades he led activities for establishing material/product compatibility, specifically with respect to establishing the suitability for use of packaging systems, manufacturing systems and administration devices for pharmaceutical products (for example, extractables/leachables and product ingredient binding). In this role, Dr. Jenke prepared, reviewed and defended product registration submissions. Dr. Jenke created and shaped domestic and global policies in the areas of product characterization, thereby developing, optimizing, and implementing Corporate-wide strategies for material/solution compatibility assessment. As a highly published, globally recognized expert in the field of chemical evaluation of material/solution interactions, Dr. Jenke has driven international efforts to generate standards for material/solution compatibility assessments.

Christopher Houston, Ph.D., Director, Analytical Chemistry
iuvo BioScience
Chris.Houston@iuvobioscience.com

Chris Houston is the Director of Analytical Chemistry at iuvo BioScience. He has been active in the field of extractables and leachables (E&L) since 2001 with a particular emphasis on ophthalmic drug products that began while he was at Pharmacia and continued into Pfizer. In the decade prior to joining iuvo BioScience, he created and directed a successful E&L program at Bausch + Lomb that supported both new product development and marketed pharmaceutical products. His other areas of specialty include analytical method development, mass spectrometry, and structure elucidation. He has a BS in Chemistry from the University of Michigan - Flint and a PhD in Analytical Chemistry from Indiana University - Bloomington that focused on the use of mass spectrometry to solve biochemical problems. Chris is a member of the PQRI-PODP E&L working group.

Session 3: Extractables and Leachables – The Future

Moderator:
Reggie Saraceno, Ph.D., Director, Chemical Analysis
Boehringer Ingelheim Pharmaceuticals
reggie.saraceno@boehringer-ingelheim.com

Dr. Saraceno is Director of Chemical Analysis in the Material and Analytical Sciences Department of Boehringer Ingelheim Pharmaceuticals, Inc. located in Ridgefield, CT. His work in the pharmaceutical industry spans the areas of drug development, pharmaceutical analysis, and preparation of regulatory dossiers to support international product registration activities.

Dr. Saraceno has been active for the last 12 years with the Product Quality Research Institute (PQRI) where he is currently the chair of the PQRI Development Technical Committee.

Dr. Saraceno earned academic degrees in chemistry from The Pennsylvania State University (Ph. D.) and the University of Notre Dame (B.S.).

Michael Hodgson, Ph.D., Global Extractables & Leachables Senior Manager
Baxter International Inc.
michael_hodgson@baxter.com

An analytical scientist by training, Mike graduated from the University of Nottingham with a PhD in flavour and aroma science in 2004. The sample preparation and trace analysis experience gained during his time analysing and modelling the real time release and delivery of common flavour substances facilitated the transition into Pharma, and specifically the area of Extractables & Leachables. Over the past 13 years, Mike has held roles of increasing responsibility within GSK and Pfizer, where he has been accountable for defining and executing the regulatory strategy that mitigates the risk of patient exposure to leachables for a variety of product types including inhalation (DPIs and MDIs), parenteral (LVP, PFS and lyophilised formulations), biopharmaceutical (manufacturing processes, primary container closure and administration) and most recently cell & gene therapy products. In October 2016 Mike

joined the Advanced Chemical and Investigations group within Baxter as the Global Extractables and Leachables Senior Manager. Areas of technical interest include coupling micro-extraction and enrichment techniques to high end chromatographic and mass spectrometry instrumentation in a highly automated fashion to enable the creation of large databases that support a scientifically led risk based approach through effective retrieval of knowledge and collaboration with the material supply chain.

John Iannone, Director, Extractables/Leachables & Impurities
Albany Molecular Research Inc. (AMRI)
John.Iannone@amriglobal.com

John Iannone has a background in Biomedical Engineering from Boston University, where he later became a research engineer. Since going from Academia to Industry 14 years ago, John has assisted multiple pharmaceutical & medical device companies with the development of their product safety evaluation strategies. Previously a Technical Specialist at Toxikon, he now is the Director of Extractables/Leachables and Impurities at Albany Molecular Research, Inc (AMRI). His areas of expertise include Material Qualification & Biocompatibility, Extractables & Leachables, Chemical Characterization, and attainment of Biological or Toxicological risk assessments for medical devices, pharmaceutical container systems, bioprocessing systems, and combination products. John has given numerous technical presentations and has led several workshops on Extractable & Leachable Considerations, Biocompatibility, Microbiology, and Regulatory Testing Requirements. He also participates in the development of both industry groups' recommendations and regulatory guidelines through Expert Panel membership, global Technical Committees, and industry collaborations. In addition to leading the AMRI E&L lab operations, his responsibilities also include providing technical consultation to clients regarding unique testing requirements in an effort for them to meet global regulatory expectations.

Timothy W. Robison, Ph.D., D.A.B.T., Pharmacology and Toxicology Team Leader, Division of Pulmonary, Allergy Products and Rheumatology Products
Food and Drug Administration
timothy.robison@fda.hhs.gov

Timothy W. Robison, Ph.D., D.A.B.T. is a Pharmacology and Toxicology Team Leader in the Division of Pulmonary, Allergy Products, and Rheumatology Products in the Center for Drug Evaluation and Research at the Food and Drug Administration in Silver Spring, MD. Prior to becoming a Team Leader, he was a Pharmacology and Toxicology Reviewer in the Division of Pulmonary, Allergy Products, and Rheumatology Products and Division of Gastrointestinal and Coagulation Drug Products. Tim earned a B.S. degree in Biochemistry and a Ph.D. degree in Pharmacology and Toxicology from the University of California at Davis. He became a Diplomat of the American Board of Toxicology in 2004. Tim is a member of numerous professional and honorary societies both at the local and national level. He serves on the FDA/CDER Genetic Toxicology, Computational Toxicology, Pharmacokinetic/Toxicokinetic, and Biologics Subcommittees. He serves on a working group for extractables and leachables in parenteral drug products. Dr. Robison has been the recipient of several research awards including the National Institutes of Health. He has authored numerous publications and been an invited speaker at various societies and institutes specific to his field throughout the United States.

Session 4: Elemental Impurities

Moderator:

Anthony J. DeStefano, Ph.D., Consultant
PQRI
anthodestefa@aol.com

Tony DeStefano obtained his BS in Chemistry from Villanova University and his MS and PhD degrees in Physical Chemistry from Cornell University. He began his career as a mass spectroscopist at Procter & Gamble. After P&G acquired Norwich Eaton Pharmaceuticals, he managed Physical Measurement and Method Development Sections for several years, after which he established Norwich's first Bioanalytical Section. In 2002, he returned to Cincinnati to manage the bioanalysis programs for multiple clinical studies. He has spoken and written extensively in the areas of regulated bioanalysis and analytical and bioanalytical validation and outsourcing. He retired from P&G in 2008 and joined the US Pharmacopeia as its Vice President of General Chapters. At USP, he led initiatives to maintain, update and redesign its General Chapters. He was promoted to Senior Vice President and had responsibility for the Health Care Quality Standards, Excipients, Dietary Supplements and Food Ingredients groups. He was a member of the ICH Q3D Expert Working Group on metal impurities and the Pharmacopoeial Discussion Group. He is currently a consultant through YourEncore and Nuventra Pharma Sciences, consulting on analytical, compendial, bioanalytical and quality-related issues. He is a member of the American Chemical Society (ACS), Chair of the Board of the Product Quality Research Institute (PQRI), and a past president of the American Association of Pharmaceutical Scientists (AAPS).

Presenters:

Nancy Lewen, Research Fellow and Supervisor – Atomic Spectroscopy Laboratory
Bristol-Myers Squibb
nancy.lewen@bms.com

Nancy Lewen has nearly thirty years of experience in the pharmaceutical industry and is a Research Fellow and supervisor of the Atomic Spectroscopy Laboratory in Analytical R&D at Bristol-Myers Squibb. Nancy has served as a USP volunteer for over 10 years, having chaired the Elemental Impurities Advisory Panel and the <191>--Identity Tests sub-committee. She is currently the chair of the Chemical Analysis Expert Committee.

Her work focuses heavily on the use of the techniques of atomic spectroscopy to solve analytical problems in the pharmaceutical industry, and also includes the use of XRF for use as a rapid screening technique for process development work.

Nancy has written papers and lectured on the subject of pharmaceutical applications of atomic spectroscopy, and has taught several short courses on that subject, as well. Nancy is the recipient of the 2008 New Jersey Association of Biomedical Research "Outstanding Women of Science" award, the Bristol-Myers Squibb 2005 Chemistry Leadership Award, the 2014, USP Award for "An Innovative Response to a Public Health Challenge" as a member of the USP Elemental Impurities Advisory Panel and the 2015 BMSIARC Award.

Donna Seibert, Ph.D., Senior Manager, Analytical Research and Development, Consumer Healthcare
Perrigo Company
Donna.Seibert@perrigo.com

Donna S. Seibert, PhD is Sr. Manager in Analytical Research and Development in Consumer Healthcare at Perrigo Company, a leading global healthcare supplier that develops, manufactures and distributes OTC and generic prescription pharmaceuticals, infant formulas, nutritional products, and active pharmaceutical ingredients. Seibert has over 15 years of pharmaceutical R&D experience spanning branded, generic prescription, and generic OTC product lines. In her current role, Seibert's responsibilities include new product development, raw material change management, as well as both organic and elemental impurity aspects of the USP monograph modernization initiative. Seibert holds a BA in Chemistry from Transylvania University and a Ph.D. in Analytical Chemistry from Wayne State University.

Danae Christodoulou, Ph.D., Acting Brach Chief, Office of New Drug Products/OPQ/CDER
Food and Drug Administration
Danae.Christodoulou@fda.hhs.gov

Danae Christodoulou is an Acting Branch Chief in the Office of New Drug Products/OPQ/CDER. Danae joined FDA in 1998 and served as primary reviewer in the Office of New Drugs, as a Chemistry, Manufacturing and Controls Lead and Acting Branch Chief since 2013.

Danae has a background in Inorganic Chemistry and received her Ph.D. from the University of Michigan, Ann Arbor, MI.

Prior to FDA, Danae worked at Johnson Matthey Inc. R&D Drug Discovery as a Senior Research Chemist and at the National Cancer Institute, in Frederick, MD. Danae served as the Chair for the EI Implementation Working Group at FDA.

Session 5. Drug/Device combination products: Quality

Moderators:

Laura O'Brien, Ph.D., Senior Research Fellow
Boehringer Ingelheim
laura.obrien@boehringer-ingelheim.com

Dr. Laura O'Brien is Senior Research Fellow in Boehringer Ingelheim's Global CMC Experts group. She has broad expertise in her responsibility for scientific planning and review of documents authored by CMC Development scientists for the Quality section of regulatory submissions, from early NCE drug development through global product registration and approval. She is past co-chair of the AAPS CMC Focus Group, with experience organizing its annual workshop discussions on diverse CMC current topics.

Nina S. Cauchon, Ph.D., Global Regulatory Affairs CMC Lead
Amgen Inc
ncauchon@amgen.com

Dr. Nina S. Cauchon is a Global Regulatory Affairs CMC Lead in the Department of Global Regulatory Affairs and Safety at Amgen Inc in Thousand Oaks, CA. She is currently responsible for regulatory strategy and oversight of a variety of clinical stage compounds, including biologics, small molecules, and novel modalities. She has also worked in the commercial space through global product registration and postapproval changes. Prior to this role, she worked in Pharmaceutics/Process Development at Amgen for 15 years. She is actively involved with the AAPS CMC Focus Group steering committee, and has extensive experience organizing its annual workshop discussions on hot topics of interest to CMC professionals including combination products, API starting materials, and risk-based approaches to biologics.

Presenters:

Douglass Mead, MSBME, RAC, Senior Director, Global Regulatory Affairs - CMC, Medical Devices and Combination Products
Janssen Research & Development, LLC
DMead1@its.jnj.com

Doug is 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, implants, and nasal and inhalation 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 30 years of experience in the medical device, pharmaceutical, and combination products industries.

Clint Judd, Principal Quality Engineer
Amgen Inc.
clinton@amgen.com

Clint has 7 years experience in medical device design and manufacturing process development, with focus on electro-mechanical delivery devices for combination products. Clint has contributed to successful development programs and marketing applications in the US, Europe, Japan, Canada, and others. Prior to working in medical devices, he designed and fabricated automated assembly equipment for automotive components. Clint holds Bachelor and Master of Science degrees in mechanical engineering from Cal Poly, San Luis Obispo.

Ramesh Raghavachari, Ph.D., Chief, Branch I, Division of Post Marketing Assessment I, Office of Life Cycle Drug Products/OPQ/CDER
Food and Drug Administration
Ramesh.Raghavachari@fda.hhs.gov

Dr. Ramesh Raghavachari is currently Chief of Branch I in the Division of Post Marketing Assessment I, Office of Life Cycle Drug Products in the Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, FDA. He joined FDA as a New Drug chemistry reviewer in 2003. His experience includes variety of dosage forms and products in many different therapeutic areas both in New Drug Pre-marketing and Post-marketing applications. Before joining the Agency he worked in the Biotechnology industry for about eight years working in R&D, Manufacturing & Quality at different times. Ramesh obtained his Ph.D. from Temple University, Philadelphia, Post-Doctoral work at the College of Pharmacy, University of Georgia and as a Research Associate jointly at Baylor College of Medicine/Rice University & Texas A& M University.

Session 6: Drug/Device Combination Products: Bioequivalence

Moderators:

Bing Li, Ph.D., Director, Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs, Center of Drug Evaluation and Research
Food and Drug Administration
bing.li@fda.hhs.gov

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.

Andrew LeBoeuf, Regulatory Counsel, Office of Generic Drug Policy, Office of Generic Drugs, Center of Drug Evaluation and Research
Food and Drug Administration
Andrew.Leboeuf@fda.hhs.gov

Andrew LeBoeuf is a Regulatory Counsel in the Office of Generic Drug Policy (OGDP) in the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research (CDER). In his role, Andrew represents OGD in multiple Center- and Agency-level working groups that are responsible for developing new and analyzing current policies impacting the review and approval of generic drug products, including generic drug-device combination products.

Prior to joining CDER, Andrew held positions in FDA's Center for Devices and Radiological Health and its Office of Regulatory Affairs; focusing on investigations and enforcement of the Quality System Regulations as well as the associated regulatory provisions on advertising and promotion issues. Andrew received his B.S. in Biology from Loyola University Chicago, his M.S. in Applied Physiology from Rosalind Franklin University of Medicine and Science, and his J.D. from The John Marshall Law School.

Presenters:

Andrea C. Redd, Director, Regulatory Affairs Combination Products
Fresenius Kabi USA, LLC
Andrea.Redd@fresenius-kabi.com

Andrea C. Redd, Director, Regulatory Affairs Combination Products, at Fresenius Kabi USA, LLC has over 16 years of experience in the pharmaceutical industry in R&D, regulatory, project management, and quality control organizations. Currently serving as the CMC Regulatory Affairs director for Fresenius Kabi's generic injectable product portfolio. Manages a team of regulatory specialists responsible for the entire life-cycle of the product, including feasibility through post-approval changes and annual reports. Areas of focus include development of generic molecules in differentiated packaging systems, most notably in pre-filled syringes and autoinjectors. Responsible for the establishment and roll-out of design control procedures into a historically drug-focused R&D organization with the establishment of the

cGMPs for combination products in 2015. In addition, served as the regulatory lead for the integration of the former BDRx pre-filled syringe products into the larger Fresenius Kabi injectable portfolio after the successful purchase of BDRx in 2016. Has successfully filed and obtained approval on 10+ combination product applications.

Irene Z. Chan, Pharm.D., BCPS, CDR, U.S. Public Health Service, Deputy Director, Division of Medication Error Prevention and Analysis, CDER/OSE/OMEPRM/DMEPA
Food and Drug Administration
Irene.Chan2@fda.hhs.gov

CDR Irene Z. Chan received a B.S. in Pharmacy and Doctor of Pharmacy degree from Rutgers University Ernest Mario School of Pharmacy. Upon graduation from pharmacy school, she was called to active duty by the U.S. Public Health Service and assigned to Gallup Indian Medical Center (GIMC) in Gallup, New Mexico, an Indian Health Service facility, where she completed a PGY1 Pharmacy Practice Residency. After completing her residency, she worked with the Indian Health Service (IHS) for over five years in both Gallup, NM and Santa Fe, NM, in both inpatient and outpatient pharmacy settings. During her time with IHS, her responsibilities included chairing a multidisciplinary medication safety task force, serving as Supervisor of Inpatient Pharmacy Services, and serving as the pharmacy Residency Program Director. While stationed in New Mexico, CDR Chan also worked closely with the New Mexico Pharmacists Association (NMPhA), serving in various leadership positions within the state association.

In 2009, CDR Chan transferred to the Food and Drug Administration (FDA) where she currently serves as Deputy Director in the Division of Medication Error Prevention and Analysis (DMEPA), responsible for leveraging her knowledge of regulatory science, human factors, and risk management to provide oversight of safety recommendations regarding drug nomenclature, labels, labeling, packaging, and product design.

TRACK 3: ENHANCING PRODUCT QUALITY THROUGH CONTINUOUS MANUFACTURING

Session 1: Where are We Now

Moderator:

Stephen Tyler, Director of Quality Assurance
AbbVie
stephen.tyler@abbvie.com

Stephen Tyler is a Director of Quality Assurance at AbbVie, a biopharmaceutical company, in North Chicago, Illinois, USA. Stephen holds B.S. degrees in Applied Biology and Chemical Engineering and a M.S. in Microbiology. Stephen joined AbbVie (Abbott) in 1984 and the Quality Assurance organization in 2008. He is a former international board member for ISPE, former co-chair of the ISPE PQLI technical committee and current chair for the ISPE PQLI Steering Committee. Stephen was the recipient of the 2013 ISPE Richard B. Purdy Distinguished Achievement Award that recognizes an ISPE member who has made significant, long-term contributions to the society. He is the former vice-chair for the PQRI Steering Committee and Stephen is currently the chair of the PQRI Steering Committee.

Celia Cruz, Ph.D., Director, Division of Product Quality Research, Office of Testing and Research
Food and Drug Administration
Celia.Cruz@fda.hhs.gov

Celia Cruz is the Director of the Division of Product Quality Research in the Office of Testing and Research at FDA. She responsible for developing and implementing CDER regulatory research goals on product and process understanding, in support of review, policy and inspections. 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 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.

Michael P. Thien, Sc.D., SVP, Global Science, Technology & Commercialization
Merck & Co., Inc.
michael_thien@merck.com

Dr. Thien has worked in new product and process development at Merck for over 25 years. After receiving his B.S. in Chemical Engineering from Caltech (1982), an Sc.D. from MIT in biochemical engineering (1988) and a post doc at the Whitehead Institute of Biomedical Research, Mike joined the Merck Research Labs, working in vaccines and recombinant proteins. In 1991, Dr. Thien led a process development group for compounds made by organic synthesis, continuing in that capacity until 1997. During this time Dr. Thien was named a Merck Research Labs "Divisional Scientist" as a result of his development and plant start-up work on CRIXIVAN, one of the first HIV protease inhibitors in the marketplace. Between 1997 and 2003 Mike held roles of increasing responsibility including Senior Director of chemical pilot plant operations and Executive Director of chemical process development. Dr.

Thien was named Vice President, Process R&D in 2003 covering analytical and engineering development of Merck's small molecules.

In 2005, Mike co-led a team to re-define the paradigm by which Merck brings new drugs to market. This effort resulted in the creation of a new function at Merck: the Global Pharmaceutical Commercialization organization. This group includes engineers and analysts from both R&D and manufacturing and reports up through manufacturing. In 2005 Mike was appointed to head this group and was made responsible for both late stage process development and the making of clinical and commercial launch supplies for all of Merck's new small molecule drugs, with responsibility for chemical and formulation development and manufacturing efforts at facilities in New Jersey, Pennsylvania and Ireland. In October of 2008 Mike took on the additional responsibilities of leading technical support for Merck's in-line small molecule products. In April of 2009, Dr. Thien was appointed to Senior Vice President, Global Science, Technology and Commercialization where he became additionally responsible for the analytical sciences, statistics and packaging technology for manufacturing. In 2012, he also took in responsibility for technical support of commercial sterile operations. In 2013, Mike's role added new product development and in-line support for therapeutic proteins, vaccines and Animal health products.

Mike has made numerous invited conference presentations and guest lectures on the pharmaceutical industry and has served on advisory boards for MIT and the U. Texas at Austin, serves on the board at Johns Hopkins and chairs a similar board for the Department of Chemical and Biomolecular Engineering at Tufts University. He is on the Board of Governors for the Robert Wood Johnson Rahway Hospital.

Diane J. Zezza, Ph.D., Vice President and Global Head Regulatory Affairs – CMC
Novartis Pharmaceuticals
diane.zezza@novartis.com

Diane Zezza, Ph.D., is currently the Vice President and Global Head Regulatory Affairs - Chemistry, Manufacturing, and Controls (CMC), at Novartis Pharmaceuticals Corporation. In this role, Diane has global responsibilities for CMC regulatory strategies and activities for all development products and lifecycle management for commercial products.

Diane has been involved in numerous industry initiatives that have supported global Quality topics. She has been a speaker at conferences on current regulatory topics including Global Harmonization, Risk-Based Regulatory Assessments, Breakthrough Therapy Products, and Continuous Manufacturing.

Diane holds a B.S. in Biology and a Ph.D. in Molecular Biology.

Session 2: API Focus

Moderator:
Robert Meyer, Ph.D., Principal Scientist
Merck & Co., Inc.
robert_meyer2@merck.com

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 innovative manufacturing platforms. These include hot melt extrusion and continuous manufacturing, where he has coauthored papers, book chapters and presentations. As a principal scientist at Merck, he currently leads a team focused on innovation and new technology development for small molecule drug product commercialization.

Paul Collins, Ph.D., Senior Director in Small Molecule Design
Eli Lilly and Company
collins_paul_compton@lilly.com

Paul Collins is Senior Director in Small Molecule Design at Eli Lilly and Company in Indianapolis. Paul has responsibility for both drug product and API process development activities for Lilly's small molecule portfolio. He is also responsible for continuous manufacturing development and ensuring these technologies are applied to portfolio development work. Paul started his career with Merck & Co., Inc., 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 over the past decade and was the Chair of the Pharmaceutical Forum for 2015 and 2016.

Paul received his BE in Chemical Engineering from Vanderbilt University and his Ph.D. from Northwestern University.

Aaron Côté, Ph.D., Distinguished Scientist
Merck & Co., Inc.
aaron_cote@merck.com

Dr. Aaron Côté has worked in Merck's Chemical Engineering Research & Development (CERD) Department for the last 16 years, since graduating with his PhD in Chemical Engineering from Purdue University. He holds the title of Distinguished Scientist as he leads the CERD Technology Labs, a group of Subject Matter Experts which focuses on crystallization process development, particle engineering, reaction engineering, biocatalysis, process modeling, continuous processing, and data-rich experimentation methodologies. Prior to this position, Aaron was the Director of Merck's Crystallization Lab for 8 years. Currently, Aaron serves on numerous technical and strategic review committees responsible for both new technology innovation and direct pipeline support, including several that have cross-functional responsibilities across the drug substance/drug product interface.

Aaron continues to be very active in the crystallization community, leading the Enabling Technology Consortium's Crystallization Working Group, serving on the International Society of Industrial Crystallization Scientific Committee, and serving as a member of the Association for Crystallization Technology steering committee.

Thomas O'Connor, Ph.D., Chemical Engineer, Office of Pharmaceutical Quality, CDER
Food and Drug Administration
thomas.oconnor@fda.hhs.gov

Thomas O'Connor is currently the Manufacturing Science team leader for the Office of Pharmaceutical Quality's (OPQ) Science Staff at the U.S. FDA and a member of OPQ's Emerging Technology Team. His work at the FDA is focused on regulatory research in the area of emerging technologies such as utilizing process models to aid the risk assessment of continuous manufacturing processes. He originally joined the FDA as chemistry reviewer in the Office Generic Drugs. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he was the technology program leader responsible for abnormal event detection, alarm management, sequential process control, and HMI development. 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.

Session 3: Drug Product Focus

Moderator:

Sharmista Chatterjee, Division Director, Process Assessment II, Office of Process & Facilities
Food and Drug Administration
SHARMISTA.CHATTERJEE@FDA.HHS.GOV

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 CDERs 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.

Eleni Dokou, Senior Director, Head of Formulation Development
Vertex Pharmaceuticals Incorporated
eleni_dokou@vrtx.com

Eleni has a diploma in Chemical Engineering from the Aristotle University of Thessaloniki in Greece and a Ph.D. in Chemical Engineering from the University of Delaware. She has 16 years of experience in the pharmaceutical industry covering both early and late stage drug product development. Initially she worked for Merck & Co. Inc. in the formulation design group and for the last 9.5 years she has been with Vertex Pharmaceuticals Inc. supporting multiple projects in formulation and process development of solid oral dosage forms from early phases to commercialization and line extensions. She has also been responsible for the creation and operation of the Vertex clinical and commercial drug product manufacturing facility in Boston and the launch of the first fully integrated continuous tablet manufacturing production line with RTRT. He group is currently responsible for the formulation and process development of all drug products at Vertex, including the transfer and process optimization of products on Vertex's continuous manufacturing Development and Launch Rig.

Eric J. Sanchez, MS, Director
Janssen Supply Chain Global Technical Services, a division of Johnson and Johnson
esanche8@its.jnj.com

Eric J Sanchez, MS, is currently a Director for Janssen Supply Chain Global Technical Services, a division of Johnson and Johnson. He is currently designated the Process Development Lead for the technology transfer of continuous process and real time release for a major product line for Janssen Supply Chain, LLC.

Eric has a master degree in science with major in molecular biology from the University of Puerto Rico. His career spans for 27 years at various Johnson and Johnson manufacturing facilities in Puerto Rico.

Gilfredo Navarro, Associate Director, CMC Regulatory Affairs
Janssen Research and Development
GNavar87@its.jnj.com

Gilfredo Navarro is currently an Associate Director, CMC Regulatory Affairs for Janssen Research and Development, located in Puerto Rico. In this role, he is the global CMC regulatory lead for a product portfolio covering all the product formulations and technologies, including Continuous Manufacturing (CM), PAT, Real Time Release testing (RTRt) and dissolution modeling.

Gilfredo has also been QA Manager in Janssen Supply Chain, Gurabo, Puerto Rico. He was QA Lead for the introduction of Continuous Manufacturing (Continuous Manufacturing), Process Analytical Technology (PAT), and Real Time Release testing (RTRt).

Gilfredo has worked in the Pharmaceutical Industry for Eli Lilly, Pfizer, Watson Pharmaceuticals, IVAX, Schering, McNeil, and Wyeth. As part of his professional career, Gilfredo has held positions, such as, Senior Scientist, Technical Services Manager, Technical Operations Director, and Independent Consultant. He also has experience on Technology Transfer, Process Validation, Cleaning Validation, Equipment and Facilities Qualification, and Computer Systems Validation.

Gilfredo obtained a Bachelor's Degree in Pharmacy from the University of Puerto Rico, a Master's Degree in Industrial Pharmacy from Purdue University in Indiana, and doctoral studies in Industrial Pharmacy from Rutgers University in New Jersey.

David R. Schoneker, Director of Global Regulatory Affairs
Colorcon
dschoneker@colorcon.com

David R. Schoneker is the Director of Global Regulatory Affairs 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.

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. He 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 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 of Scientific and Regulatory Affairs 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.

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. Mr. Schoneker previously coordinated International Harmonization efforts for the 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.

Arwa El Hagrasy, Ph.D., Acting Quality Assessment Lead, Office of Process and Facilities
Food and Drug Administration
arwa.elhagrasy@fda.hhs.gov

Dr. Arwa El Hagrasy is currently Acting Quality Assessment Lead, Office of Process and Facilities at FDA. Arwa has been with FDA for almost 4 years and has reviewed a wide variety of drug product applications submitted to the Agency, including those implementing emerging technologies and advanced pharmaceutical manufacturing. Arwa has over 8 years of experience in industry and academia, with focus on the implementation of process analytical technology tools and continuous manufacturing in the pharmaceutical industry. Arwa received her Ph.D. in Pharmaceutical Sciences from Duquesne University in Pittsburgh and did a post-doctoral appointment in the Chemical Engineering Department at Purdue University.

Session 4: Strategies to Support Continuous Manufacturing

Moderator:

Linda Evans O'Connor, M.B.A, Head of Business Processes and Regulatory
Lachman Consultant Services, Inc.
L.EvansOConnor@Lachmanconsultants.com

Linda Evans O'Connor is Head of Business Processes and Regulatory at Lachman Consultants. Ms. Evans O'Connor delivers project oversight / management, work planning and work flow analysis, and quality assurance. She has a thorough understanding of the pharmaceutical industry and delivers thought leadership on projects. She maintains current industry / leading practices knowledge and understanding to build on her comprehensive knowledge of the pharmaceutical industry, including the ability to understand and interpret current / envisioned regulatory and compliance processes and procedures. As an accomplished Quality professional with extensive, progressive experience and successful contribution in quality management, project management, and leadership of diverse, global and cross-functional teams, Ms. O'Connor assists Lachman Consultants' clients in quality management systems, regulatory inspection preparation, and GXP audits. She is experienced in solid oral, semi-solid (creams and ointments), parenterals, and liquid dosage forms.

Presenters:

Lieutenant Commander Patric Klotzbuecher, Investigator (Drug Specialist)
U.S. Department of Health and Human Services/U.S. Food and Drug Administration/Office of Regulatory Affairs
Patric.Klotzbuecher@fda.hhs.gov

Lieutenant Commander Patric Klotzbuecher began his service as an airman while pursuing undergraduate studies. Enlisting shortly after September 11, 2001, he served with the U.S. Air Force primarily as a weapons armament systems specialist and a tactical aircraft maintainer since 2002. Through several deployments, recalls to active duty, and special assignments in support of Operations Iraqi Freedom, Enduring Freedom, and Noble Eagle, he rose to the rank of Staff Sergeant. In balancing his responsibilities as an active duty servicemember and a non-traditional student, he earned Bachelors' Degrees in Biomedical Engineering & Biomathematics from Rutgers University. Soon after conferring he continued with graduate studies, was offered a commission with the USAF, and was selected as a Special Tactics Air Liaison Officer.

In late 2007, he was recruited by the U.S. Public Health Service (USPHS) liaison to the U.S. Food and Drug Administration's Office of Regulatory Affairs. That November he transferred as an officer of the Commissioned Corps of the USPHS, accepting an assignment as an Investigator with the U.S. FDA's Baltimore District Office, based in the Northern Virginia Resident Post. He was later transferred to an overseas duty station supporting the drug program of FDA's San Juan District, then selected as a Senior Regulatory Operations Officer/Drug Specialist with the Division of Foreign Field Investigations' Dedicated Drug Cadre, and in that time, conferred his MBA in Engineering Management from Drexel University.

He was presented with the opportunity to continue his work abroad, while sharing much of his experience with the domestic drug program and in training new investigators, and in February 2014 accepted the position of Senior Regulatory Officer/Drug Specialist with the Generic Drug Program in the New York District. To date, LCDR Klotzbuecher has conducted operations in over 30 different countries, to include the inspection of both small and large molecule manufacturers, all varieties of profile classes, and the facilities associated with the first U.S. FDA-approved continuous manufacturing drug application. He is currently a candidate for an M.S. in Biochemical Engineering at the New Jersey Institute of Technology, has served as a U.S. FDA delegate to the PIC/S Expert Circle on Quality Risk Management, and is a Certified Public Health Professional.

Fernando Muzzio, Ph.D., Distinguished Professor of Chemical Engineering
Rutgers University
fjmuzzio@yahoo.com

Fernando Muzzio is a Distinguished Professor of Chemical Engineering at Rutgers University. For the last 22 years, pharmaceutical product and process design has been Professor Muzzio's main research and educational focus. His research interests comprise continuous manufacturing, powder mixing, powder flow, segregation, compression, mixing and flow of liquids and suspensions, capsule filling, tablet dissolution, and tablet coating. He is a frequent advisor and lecturer at FDA events, and in 2010 he was appointed a voting member of the FDA committee on Pharmaceutical Sciences and Clinical Pharmacology.

Professor Fernando Muzzio is also the director of the National Science Foundation Engineering Research Center on Structured Organic Particulate Systems. The center, which has a total budget in excess of $8 million per year, focuses on pharmaceutical product and process design, with special emphasis on continuous manufacturing, particle engineering, and personalized medicine. FDA and 45 companies are currently members of the center.

Ahmad Almaya, Ph.D., Research Advisor
Eli Lilly and Company
almaya_ahmad@lilly.com

Dr. Ahmad Almaya is a Research Advisor at Eli Lilly and Company, Indianapolis, IN. Ahmad holds a bachelor degree in Pharmacy, a Ph.D. degree in Pharmaceutics (The University of Iowa), and an Executive Certificate in the Business of Life Sciences (Kelley School of Business, Indiana University). He joined Lilly in 2002 and has been leading formulation and process development teams for various NCE molecules. Ahmad served as the scientific team leader for the investigation and optimization of a continuous direct compression line within Lilly's R&D organization during the period 2012-2014. Since then, he has led development teams on implementing continuous manufacturing for several Lilly portfolio molecules.

Session 5: Challenges to Implementing Continuous Manufacturing

Moderators:

Ganapathy Mohan, Ph.D, Head of Small Molecule Development Quality
Merck, Sharp and Dohme corp.
ganapathy_mohan@merck.com

Ganapathy Mohan is the head of Small Molecule Development Quality, which is responsible for ensuring GMP compliance and release of all materials and investigational Medicinal Products for use in clinical trials.

Prior to this he was the head of Global CMC regulatory Affairs (Small Molecules) at Merck. Prior to joining Merck he was Associate VP of Global Analytical Sciences at Sanofi and was there for 23 years.

Mohan has a Ph.D in Analytical Chemistry from Kansas State University and his area of interests are in separation sciences, application of PAT and science driven risk based approaches towards global registrations of pharmaceuticals and biologics.

Mohan was past Chair of the AAPS Regulatory Sciences Section in 2014.

Sau (Larry) Lee, Ph.D., Deputy Director, Office of Testing and Research/OPQ
Food and Drug Administration
sau.lee@fda.hhs.gov

Sau (Larry) Lee is a Senior Biomedical Research Scientist (SBRS). He is a Deputy Director of the Office of Testing and Research in the Office of Pharmaceutical Quality (OPQ), and the chair of the OPQ Emerging Technology Team. He is leading the effort in advancing OPQ research and in manufacturing science, complex drug substances and products, as well as in developing the regulatory policy, scientific standards as well as computational and modeling tools supporting quality review and inspection in OPQ. In early 2013, Larry was promoted to Expert Regulatory Scientist in recognition of his expertise in evaluation of complex drug substances and products. Larry received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

Roger Nosal, Vice President and Head of Global Chemistry, Manufacturing & Controls
Pfizer
roger.nosal@pfizer.com

Roger Nosal is Vice President & Head of Global Chemistry, Manufacturing & Controls at Pfizer. Roger has contributed to the evolution of Quality by Design & has advocated for global regulatory harmonization through several PhRMA, ICH, ISPE, PQRI, AAPS, IFPAC, ACS & DIA technical committees. He is currently the PhRMA Topic Leader for ICH M9, Chair of ISPE Pharmaceutical Engineering and co-chair of ISPE Regulatory Track and DIA Quality Program Committees.

Roger's 35 years of experience at G. D. Searle, Monsanto, Pharmacia & Pfizer, includes 22 years in regulatory CMC. Prior to his regulatory role, Roger was a Medicinal Chemist, author of 24 patents for several medicinal candidates (PAF, leukotriene, 5-HT3 & 5-HT4 antagonists & agonists, COX-2 & serotonin inhibitors) & a Process Chemist, focused on synthetic development & analytical control of derivatives of aspartame & manufacturing optimization of prostaglandin syntheses.

Rapti Madurawe, Ph.D., Division Director, Office of Process and Facilities
Food and Drug Administration
Rapti.Madurawe@fda.hhs.gov

Rapti Madurawe is a Division Director in the Office of Process and Facilities at FDA. She has broad regulatory experience in the CMC review of new, investigational and generic drug applications as well as emergency user and bioterrorism applications. Rapti has worked extensively on developing the regulatory framework for implementing continuous manufacturing of pharmaceuticals and has presented nationally and internationally on the subject. She is a member of CDER's Emerging Technology Team. Rapti has a Ph.D. in Chemical Engineering. Prior to joining the FDA, she worked in biotech and biopharmaceutical industries as a process development engineer.

Dolores Hernán Pérez de la Ossa, Ph.D., Quality Specialist
European Medicines Agency (EMA)
Dolores.Hernan@ema.europa.eu

Dr. Dolores Hernán Pérez de la Ossa graduated in Pharmacy from the Complutense University, Madrid and earned a European PhD in Pharmacy and Pharmaceutical Technology from the same institution. She has conducted several research stays abroad in diverse institutions including the University of Washington, Virginia Commonwealth University and the Italian National Research Council. Her main research work has been focused on the pharmaceutical development and characterization of controlled release delivery systems based on micro and nanotechnologies. She has published several scientific papers in international peer-reviewed journals. In 2012 she received an award from a Spanish Royal Academy of Pharmacy for her research work in drug development. Since 2010 she has been working as Quality Specialist in the Quality Office of the European Medicines Agency (EMA), where she is also a member of the Innovation Task Force on Nanotechnology and the scientific secretariat of the PAT team and the Quality Working Party Core Team.

Yoshihiro Matsuda, Ph.D., Pharmacist and Senior Scientist
Pharmaceuticals and Medical Devices Agency (PMDA)
matsuda-yoshihiro@pmda.go.jp

Dr. Matsuda is a pharmacist and a senior scientist for Quality, Pharmaceuticals and Medical Devices Agency (PMDA).

Dr. Matsuda received Ph.D. degree in Medicine from Tokyo Medical and Dental University in 2003. He holds a Bachelor of Pharmacy Degree from Toho University and a Master's degree in Pharmacy from Toyama medical and Pharmaceutical University.

Dr. Matsuda 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.

Session 6: Where are We Heading in Continuous Manufacturing?

Moderator:
Richard Levy, Ph.D., Senior Vice President of Scientific and Regulatory Affairs
Parenteral Drug Association (PDA)
levy@pda.org

Richard Levy is currently Senior Vice President of Scientific and Regulatory Affairs at the Parenteral Drug Association (PDA) in Bethesda Maryland. In this capacity, he is responsible for directing and managing the scientific, technical, regulatory affairs and quality activities of a 10,000 member association focused on pharmaceutical and biotechnological manufacturing. He is also responsible for the Association publications: the PDA Journal of Pharmaceutical Science and Technology, PDA Technical Reports and Surveys, and the PDA Letter (association magazine). Dr. Levy's other key activities include working with PDA members to prepare and write consensus positions on proposed international regulations and guidance documents, and developing the scientific content of PDA's global meetings and forums. In this capacity, Dr. Levy works directly with global industry associations such as A3P, AAMI, ASTM, BIO, IABS, ISPE, PhRMA and R3-Nordic to coordinate and harmonize scientific and regulatory activities involving FDA and other international regulatory authorities (EMA, FDA, GDFDA, MHRA, MHLW, SHFDA,SFDA,TGA) and standard setting organizations (e.g., AAMI, ANSI, ASTM, EDQM, ICH, ISO, and USP). He is also a member of the Steering Committee of the Product Quality Research Institute (www.pqri.org).

Prior to joining PDA in the fall of 2005, Dr. Levy was Corporate Vice President and General Manager of PAREXEL Consulting, a newly formed PAREXEL INTERNATIONAL business unit created by the merger of KMI, Barnett, and Worldwide Regulatory Affairs of PAREXEL. Dr. Levy joined KMI/PAREXEL International in January of 2001 as Vice President of Consulting Services. Prior to joining KMI, Dr. Levy was with MILLIPORE Corporation for 16 years in a variety of Business, R&D, Regulatory and Quality Systems senior management positions. He was Chair-elect of the Parenteral Drug Association (PDA) Board of Directors (2004-2005), and served on that Board from 1999-2005. Dr. Levy is active in industry programs and task forces on aseptic processing, process validation, microbial and viral clearance, regulatory affairs and quality systems and has made more than 100 presentations at various national/international industry symposia. He has published articles on biotechnology, aseptic processing, filter validation, sterile filtration, microbial retention testing, and viral clearance in American Pharmaceutical Review, BioPharm, BioProcess International, Pharmaceutical Technology, PDA J. Parenteral Science and Technology, J. American Water Works Association, Blow-Fill-Seal Society Journal, and BioProcess International. He has also authored chapters in textbooks on these subjects.

Dr. Levy was Chairman of the 2007 Committee of Revision for Technical Report No. 1, Validation of Moist Heat Sterilization and was a member of the PDA committee and co-author of "Sterilizing Filtration," Technical Report No. 26 (1998 and 2008 Revisions) and TR 33 (2013 Revision) Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. Dr. Levy is a member of the American Association of Pharmaceutical Scientists (AAPS), the International Society of Pharmaceutical Engineering (ISPE), the Parenteral Drug Association (PDA), the Regulatory Affairs Professional Society (RAPS), the International Alliance for Biological Standardization (IABS) and the American Society for Microbiology (ASM). In 2006, Rich received the Frederick Charleton Award for his work on the PDA Board of Directors, and in 2009 he received the first PDA Special Recognition Award for his work as a PDA staff member.

Dr. Levy received his B.A. in Biology from the Colby College (Waterville, ME), and an M.A. in Biology from Clark University located in Worcester, Massachusetts. He received his Ph.D. in Environmental Health Sciences from Worcester Polytechnic Institute in Worcester, Massachusetts.

Sau (Larry) Lee (see Session 5)

Robert Meyer (see Session 2)

Charles L. Cooney, Ph.D., Robert T. Haslam (1911) Professor of Chemical Engineering, Emeritus
Department of Chemical Engineering
Massachusetts Institute of Technology
Faculty Director, Emeritus
Deshpande Center for Technological Innovation
ccooney@mit.edu

Charles Cooney is the Robert T. Haslam (1911) Professor of Chemical and Biochemical Engineering, Emeritus in the Department of Chemical Engineering and was the founding Faculty Director of the Deshpande Center for Technological Innovation. His degrees include a Bachelor's degree in Chemical Engineering from Penn and Master's and Ph.D. in Biochemical Engineering from MIT. He was elected (2009) to the first class of American Chemical Society Fellows and awarded *Honoris Causa* by Ramon Llull University in Barcelona. He serves as a consultant to a number of biotech and pharmaceutical companies, is on multiple editorial boards of professional journals, sits on the Boards of Directors of Mitra Biotech (India), GreenLight Bioscience, Pronutria, Inc., Boyd Technologies, Levitronix Technologies, and Innovent Biologics (China). He was previously on the Boards of Genzyme, Cuno, Inc., Pall Corp., Biocon (India), Polypore International and Astra AB. He chaired the FDA Advisory Committee for Pharmaceutical Science from 2004-2006. HIs research interests include manufacturing in the pharmaceutical, biotech and bioprocess industries, as well as bioprocess design, operation and control, and processing of pharmaceutical powders and technological innovation strategy. As founding faculty director of the Deshpande Center he is interested in the process of stimulating technological innovation and translating innovation into new company creation. In addition, Prof. Cooney is a Trustee Emeritus of Boston Ballet, and an Overseer of the Boston Symphony Orchestra. Other interests include: high altitude mountaineering (with assents of Denali, Ama Dablam, Mont Blanc, Kilimanjaro, Huascaran), scuba diving, skiing and antique map collecting.

Global Harmonziation Roundtable:

Moderator:

Louis W. Yu, Ph.D., Chief Quality Officer, Global Quality and Compliance
Valeant Pharmaceuticals
Louis.Yu@valeant.com

Louis W. Yu, Ph.D. currently serves as the Chief Quality Officer, Global Quality and Compliance for Valeant Pharmaceuticals International company, reporting directly to the CEO. He previously served as the Executive Vice President, Global Quality and Compliance of the Perrigo Company for more than 9 years. As EVP of Global Quality at Perrigo, a company with operations in more than 30 countries, he provided strategic direction and overall quality as well as in Pharmacovigilance and Global Patient Safety for one of the largest manufacturers of generic and branded OTC, prescription drug and device products. As the long time former Global head of Quality & Compliance for Forest Laboratories, Inc., he was responsible for global GMP compliance, QA, QC Operations spanning 11 international facilities. Prior to that, he was Vice President of Quality & Compliance at Solvay Pharmaceuticals, a Belgium based conglomerate.

Earlier in his career, Dr. Yu served for over 15 years at Johnson & Johnson, where his career spanned roles in pharmaceutical R&D, Director QC and Quality Systems at J&J's Ortho Pharmaceutical arm; and head of Compliance at J&J's McNeil CPC. In 1994, he was first named VP Analytical R&D/QC, then Vice President, Scientific Affairs at Par Pharmaceuticals.

Dr. Yu studied chemical engineering and chemistry and graduated from the University of Wisconsin. He also holds M.S. and Ph.D. degrees in Analytical Chemistry from Rutgers University. He served as adjunct faculty and planning committee member for the Annual U. of Wisconsin Land of Lakes Pharmaceutical Analysis Conference for over 25 years and is currently an adjunct professor at Purdue University Polytechnic Institute. He also volunteers in the in the Biotechnology Innovation and Regulatory Science program in East Africa at the Kilimanjaro School of Pharmacy in Tanzania. He is a member of AAPS, PDA and ISPE professional societies. He currently serves as an expert working group member of the ICH Q12 team. Currently and since 2011, he is a Board member and Treasurer on the Board of Directors of the Product Quality Research Institute (PQRI).

Roundtable Panelists:

Ashley Boam, Director, Office of Policy for Pharmaceutical Quality (OPPQ), OPQ, CDER
Food and Drug Administration
Ashley.Boam@fda.hhs.gov

Ashley Boam currently serves as Director of the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). OPPQ is responsible for developing and clearly communicating science- and risk-based policies and standards related to drug product quality, including application review and inspection. This Office also coordinates OPQ's work with international regulatory authorities on quality issues, leads CDER's compendial operations, coordinates CDER's involvement in quality standard-setting organizations, and addresses policy issues related to drug-device combination products.

Prior to joining CDER in 2013, Ashley spent nearly 20 years in the Office of Device Evaluation (ODE) in FDA's Center for Devices and Radiological Health (CDRH), serving as a scientific reviewer, a Branch Chief in the Division of Cardiology Devices, and finally as Associate Director for Regulations and Guidance for ODE. Ashley received her MSBE from the University of Alabama at Birmingham and her BSE from Tulane University, both in Biomedical Engineering.

Robert Iser, M.S., Director , Office of Process & Facilities / OPQ / CDER
Food and Drug Administration
robert.iser@fda.hhs.gov

Bob joined the FDA in 2003. He is currently the Director of the Office of Process & Facilities (OPF), in the Office of Pharmaceutical Quality (OPQ). Prior to the formation of OPQ, Bob was acting Associate Director for Policy Development in the Office of Pharmaceutical Science. He was also a Division Director and CMC Team Leader in the Office of Generic Drugs. He is currently the ICH Q12 topic lead for CDER.

Prior to joining the FDA, Bob spent seven years in the pharmaceutical industry with industrial experience related to management of quality systems, analytical method development, and support of manufacturing process development, scale-up and validation.

Christine Moore, Ph.D., Global Head and Executive Director of CMC Policy
Merck, Sharp and Dohme
christine.moore@merck.com

Dr. Christine Moore is the Global Head and Executive Director of CMC Policy at Merck, Sharp and Dohme. She joined Merck in 2016 after 11 years at FDA in various positions, including Acting Office Director of the Office of New Drug Quality Assessment and of the Office of Process and Facilities. Christine has been at the forefront of development of scientific and regulatory approaches for advancing pharmaceutical manufacturing technologies, modernizing regulatory approaches and progressing international harmonization. She was involved in ICH working groups for ICH Q8(R2) and the concept paper for ICH Q12. Prior to joining FDA, Christine worked for 10 years for Pfizer and Searle/Pharmacia in the areas of API process development, PAT, scale-up and technology transfer.

Keith Webber, Ph.D., Senior Director of Regulatory Affairs
Perrigo Company
Keith.Webber@perrigo.com

Keith Webber, PhD is Senior Director of Regulatory Affairs for the Rx Division at Perrigo Company where he oversees the regulatory activities for a wide variety of new and generic drug products. Prior to joining industry, he served at the US Food and Drug Administration in both the Center for Drug Evaluation and Research and the Center for Biologics. During his 18 years with the Agency, his roles included Director of the Office of Pharmaceutical Science, Director of the Office of Generic Drugs, Director of the Office of Biotechnology Products, and Director of the Division of Monoclonal Antibodies. While in government service, Dr. Webber led the development of policies on environmental assessments regarding drugs and the production of drugs in recombinant plants. He also served as the Quality Lead for CDER's representatives to the International Conference on Harmonization during the development of the Q8, Q9, and Q10 guidelines. While Directing the Office of Generic Drugs, Dr. Webber was a member of the FDA's negotiating team that established the first Generic Drug User Fee Amendments (GDUFA-I) that led the way to modernization of FDA's generic drug review program. He also served on the industry team during negotiation of GDUFA-II. Dr. Webber's educational background includes a Bachelor of Science degree in Chemistry from the University of Denver, Colorado, a Doctorate in Biological Chemistry from the University of Michigan, and post-doctoral research at the National Institutes of Health where he studied the genetic control of embryonic developmental and antibody engineering for cancer detection and treatment.

Yoshihiro Matsuda (See Session 5)
Dolores Hernán (See Session 5)