PQRI Workshop: ***Managing Excipient and API Impact on Continuous Manufacturing***

May 17 - 18, 2022

Bios

MODERATOR/WORKSHOP ORGANIZING COMMITTEE CHAIR

David R. Schoneker, President/Owner
Black Diamond Regulatory Consulting, LLC
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David R. Schoneker is currently the President/Owner of Black Diamond Regulatory Consulting, LLC, a consulting firm specializing in providing regulatory and quality consulting for the pharmaceutical, dietary supplement, food and related industries. The firm provides expert advice for difficult problems and training on excipient and food additive regulatory, quality and supply chain concerns.

With over 44 years of experience working in these areas, he has developed strong networks with trade associations, regulatory agencies and pharmacopeias around the world. He is also an Adjunct Professor at Temple University's School of Pharmacy in their RA/QA Master's Program where he teaches courses in Global Excipient Regulations and the Regulation of Dietary Supplements and Functional Foods.

Prior to August 2019, David R. Schoneker was the Global Regulatory Director – Strategic Relationships at Colorcon, Inc. His responsibilities included global coordination of Colorcon's worldwide regulatory activities. He was at Colorcon from 1977 until 2019.

Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee, where he is actively involved with the development of Regulatory, Safety, Excipient GMP and Supplier Qualification related guidelines to improve Excipient Acceptability, Safety and Global Supply Chain Security. Mr. Schoneker represents IPEC-Americas on the PQRI Steering Committee and belongs to several PQRI Technical Committees.

Mr. Schoneker also Chairs IPEC's QbD/Composition Committee and is the Global Expansion Coordinator for the IPEC Federation where he has been critically involved in the development of many of the IPEC regional groups and partnerships around the world.

Mr. Schoneker was the President of the International Association of Color Manufacturers (IACM) in 2019 and was on the IACM Board for many years. In these roles he coordinated IACM's international regulatory activities related to Synthetic and Natural colorants for use in foods, dietary supplements and drugs and participated as one of IACM's NGO representatives at the Codex Committee on Food Additives (CCFA) for several years.

SPEAKERS:

Brian Carlin, Ph.D., Owner
Carlin Pharma Consulting LLC
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Brian Carlin, the Excipient Iconoclast, is the owner of Carlin Pharma Consulting LLC, advising on product robustness and quality risk mitigation in the face of Special Cause Variation. He was Director QbD/Regulatory at DFE Pharma and Director Pharma Open Innovation/R&D at FMC.

He was a formulation Team Leader at SmithKline Beecham & new product development Pharmacist at Richardson Vicks. He is a Fellow of the Royal Pharmaceutical Society and holds honorary Professorships at DeMontfort University and University of Maryland.

He is a past chair of the IPEC Americas QbD and Excipient Composition Committees and a coauthor of the 2020 IPEC QbD Guide. He was the recipient of the 2014 IPEC One World Award for Regulatory Excellence, and the 2012 IPEC Foundation Award for Industry Research Achievement.

He serves on the USP Excipient Test Methods Committee and the ICH Q13 working group on Continuous Manufacturing.

He has a doctorate in Interfacial Rheology from London University, and a degree in Pharmacy from the University of Aston in Birmingham.

Shivkumar Chiruvolu, Ph.D., Senior Director, Business Development
Applied Materials
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Dr. Chiruvolu is a veteran technology executive experienced in leading large teams in public companies and start-ups. He has 25+ years of experience in leadership roles in business and corporate development, and technology development, new company creation and scaling including at Nanogam, NeoPhotonics, Teijin, Kodak and Applied Materials. He has led investments into startups in areas of nanotechnology, biopharma, energy storage startups and 3D printing, including setting up strategic partnerships.

Dr. Chiruvolu holds a Ph.D. in chemical engineering from University of California, Santa Barbara.

Stephen Conway, Ph.D., Global Pharmaceutical Commercialization
Merck & Co., Inc
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Stephen currently directs the Sterile Packaging Development Group with responsibility for design and commercial development in support of new vaccine, biologic and parenteral small molecules and combination products. For the last six years, Stephen has also led the cross-functional Development and Commercialization team of scientists and engineers executing process design, commercial readiness, and regulatory support for Merck's first implementation of Continuous Manufacturing for drug products at the Cramlington, UK, facility, including participation in pre-competitive collaborations and numerous Agency engagements. Stephen has also served as Technical Operations lead for Bulk Pharmaceutical and Packaging processes at the Cramlington site, supporting a diversified portfolio of products, and as a leader in the Center for Materials Science and Engineering in West Point, PA and Rahway, NJ. Here, he supported drug product materials characterization for the small molecule development portfolio using a variety of physical methods. He has extensive experience of collaboration with both upstream formulation R&D partners and downstream commercial operations. Before that, he worked in Technical Operations and Process Engineering roles at several of Merck's API manufacturing sites in the US, Puerto Rico, and the UK.

Stephen obtained degrees at the University of Birmingham (UK), the Massachusetts Institute of Technology, and Rutgers, The State University of New Jersey, all in Chemical Engineering. Under Professor B. J. Glasser, he completed his PhD thesis on "Instability and Segregation in Bounded Particulate Shear Flows".

Charlie Cunningham, Technical Director, NALAN
Colorcon Inc.
ccunningham@colorcon.com

Charlie Cunningham is Colorcon's Technical Director for the North America and Northern Latin America regions and is responsible for technical support of film-coating processes and solid oral dose formulation using immediate and modified release technologies supplied by Colorcon.
In his 29 year career at Colorcon, Charlie has focused on coating process applications and the scale-up and optimization of aqueous film-coating processes. Charlie has published numerous articles in the areas of immediate release and delayed release film coating technologies as well as solid oral dose formulation and excipient technologies. He holds four patents related to novel film-coating and excipient formulations.

Pedro Durão, Ph.D., PAT Scientist
Hovione
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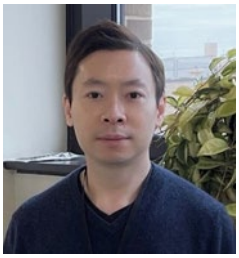
Pedro Durão is a PAT Scientist at Hovione since 2020 and he has been involved in the development and implementation chemometric models based on PAT tools on multiple chemical and pharmaceutical processes. Since 2018, his focus has been in the implementation of PAT tools in pharmaceutical continuous projects.

He is a pharmacist (University of Coimbra - Portugal, 2007), MSc in Pharmaceutical Engineering (Instituto Superior Técnico – Portugal, 2010) and holds a PhD in Chemical Engineering (Université de Sherbrooke – Canada, 2017) in the PAT field.

Douglas B. Hausner, Ph.D., Senior Manager, Continuous Manufacturing Business Development
Thermo Fisher Scientific
doug.hausner@thermofisher.com

Doug is the Senior Manager for Continuous Manufacturing at Thermo Fisher Scientific, leading the solid dose program. He is a subject matter expert in continuous manufacturing. Prior to joining Thermo Fisher Scientific, Doug spent 9 years leading the development of continuous manufacturing technology at Rutgers University and the NSF Engineering Research Center, C-SOPS. Doug has a PhD in Physical Chemistry from Temple University.



Raimundo Ho, Ph.D., Principal Research Scientist and Materials Science Center of Excellence Lead
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Raimundo Ho, Ph.D. is currently Principal Research Scientist and Materials Science Center of Excellence Lead at AbbVie Inc. He joined the Solid State Chemistry group in Abbott/AbbVie in 2011, and has more than 11 years of experience in CMC development of pharmaceuticals spanning across pre-clinical development to commercialization. He received his Masters in Chemical Engineering in 2005 and Ph.D. in 2009 from Imperial College London. He has been an active member of the IQ Co-processed API Working Group since 2019. Together with partners in industry and academia, the IQ Co-processed API Working Group collaborate to raise awareness of new co-processed API technologies and to engage regulatory agencies around the world on regulatory strategies for bringing these new technologies forward into commercial manufacturing. Raimundo has extensive experience in solid form development, materials science at the drug substance/drug product interface including characterization, process development and physical property control to enhance drug product processing and manufacturing. He has contributed to more than 25 scientific publications, 3 patents and a number of book chapters in the field of chemical engineering.

Yong Hu, Ph.D., Branch Chief, Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ/CDER/Food and Drug Administration
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Dr. Yong Hu is a Branch Chief in the Office of Pharmaceutical Manufacturing Assessment (OPMA) under the Office of Pharmaceutical Quality (OPQ) in CDER/FDA. He has been with the FDA for more than thirteen years, with the initial six years in the former Office of New Drug Quality Assessment (ONDQA). Dr. Hu has extensive experience in leading and performing quality and manufacturing assessments for both new and generic drug applications, including various continuous manufacturing and oral inhalation product applications. Dr. Hu has served as an FDA Liaison on the USP Physical Analysis Expert Committee since 2017. He currently represents OPMA on the OPQ working group for Guidance for Industry: Metered-Dose Inhalers and Dry Powder Inhalers. Prior to his FDA career, Dr. Hu worked as a formulation scientist and team lead in GlaxoSmithKline for eight years, responsible for leading human drug formulation development, manufacturing process development and scale up, clinical supplies manufacturing, and technology transfer to commercial manufacturing. He was also responsible for managing the inter-departmental interfaces between Chemical and Pharmaceutical Development and driving team activities for CMC technical development for both APIs and drug products. Dr. Hu's professional experience also includes four years of teaching and research as a lecturer at the Tsinghua University in Beijing, China. Dr. Hu received his Ph.D. in Industrial and Physical Pharmacy and M.S. in Biological Sciences both from Purdue University, and B.S. in Biochemistry from Nankai University, China.

Pauline Janssen, MSc, Product Application Specialist
DFE Pharma
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Pauline Henrica Maria Janssen is a Product Application Specialist at DFE Pharma. She has been working on application development of excipients based upon fundamental knowledge of excipients and powder physics. She joined DFE Pharma beginning of 2017 and worked as a product developer and application specialist on multiple OSD and DPI projects. Pauline holds a Master's Degree (cum laude) in Physical Chemistry from the Radboud University in Nijmegen, with an additional specialization in Science, Management and Innovation.

Krizia M. Karry, Ph.D., Head of Global Technical Marketing of Pharma Solutions
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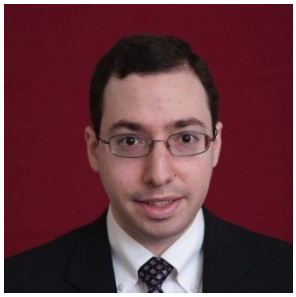
Krizia Karry, is the Head of Global Technical Marketing of Pharma Solutions at BASF. Her group is responsible for generating application data and defining the portfolio's value proposition in support of mid to long-term growth. Krizia has over 10 years of technical experience in the pharmaceutical industry, having worked at Pfizer, Bristol-Myers Squibb, AstraZeneca and Eli-Lilly. Her focus areas include continuous manufacturing processes; support to real-time release applications; development, implementation and validation of PAT tools; and formulation optimization. Krizia has a PhD in Chemical and Biochemical Engineering from Rutgers University, and a Masters in Pharmaceutical Engineering.



Scott M. Krull, Ph.D., Chemical Engineer, Office of Testing & Research
Food and Drug Administration
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Scott Krull is a Chemical Engineer in the FDA's Office of Testing and Research, and first joined the FDA as an ORISE Fellow in September 2017. During his time with the FDA, Scott's research has focused on emerging technology for pharmaceutical products, including continuous manufacturing and orally disintegrating films. He has also investigated process monitoring and control strategies for continuous manufacturing. Scott earned his bachelor's degree in Chemical Engineering from The Cooper Union in 2011 and his Ph.D. in Chemical Engineering from the New Jersey Institute of Technology in 2017. Scott will be presenting today on leveraging residence time distribution models to understand ingredient and process impacts in continuous manufacturing.

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

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

Christine M. V. Moore, Ph.D., Executive Director
Organon
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Dr. Christine Moore is a founding member of Organon where she leads Global External Advocacy and Policy, providing oversight for review and implementation of new GMP-related policy. Christine started her career as an API process development engineer at Pfizer and Searle/Pharmacia, then moved to US FDA where she led the offices responsible for small molecule new drug review and manufacturing process assessment, and most recently returned to industry to advance regulatory policy and innovation at Merck and now Organon. Christine is a global thought leader in scientific and regulatory approaches for advancing pharmaceutical manufacturing technologies including continuous manufacturing, process analytical technologies, and portable/point of care manufacturing. She holds a PhD in chemical engineering from Massachusetts Institute of Technology and a BS in Chemical Engineering from Northwestern University.

R. Christian Moreton, Ph.D, Partner
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Dr. Moreton has been a partner at FinnBrit Consulting since 2007, providing consulting and advisory services in formulation and process design, development and scale up, and in aspects of excipients. Prior to FinnBrit Consulting, he spent approximately 35 years working mainly as a formulation scientist in large and small innovator companies, and in generic companies in the United Kingdom, Sweden, Canada and the United States. Dr. Moreton has worked on formulation development projects for tablets, capsules, oral liquids, parenteral solutions, creams, ointments, transdermal delivery and suppositories. He has also worked in QA, QC and Regulatory Affairs for an excipient and drug delivery company. Dr. Moreton is a visiting tutor at the Manchester University (UK) on their Pharmaceutical Industry Advanced Training (PIAT) distance learning program covering oral solid dosage forms.

Dr Moreton holds a B.Pharm. (Nottingham University, UK), a M.Sc in Pharmaceutical Analysis (University of Strathclyde, UK) and a Ph.D in Pharmaceutics (University of Wales College of Cardiff; now Cardiff University, UK).

Venkatesh Natarajan Ph.D., Principal Engineer
Amgen
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Venkatesh Natarajan is Principal Engineer at Amgen in Cambridge, MA, where he is responsible for supporting and guiding the robust evaluation, development and GMP implementation of manufacturing technologies. Prior to Amgen, he was Principal Engineer at Biogen where he was responsible for evaluating new technologies, process and capacity modeling, de-bottlenecking of manufacturing facilities and process economics modeling. Venkatesh started his career at Millipore as an Applications Engineer, where he worked on generating Applications data and developing best practices for all downstream products. He received his Ph.D. in Chemical Engineering from Rensselaer Polytechnic Institute in Troy, NY, where he studied optimization of ion exchange chromatography for purification of proteins.

Bart Nitert, Ph.D., Principal Scientist Oral Solids Development
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Bart Nitert is Principal Scientist Oral Solids Development within Janssen R&D, Johnson & Johnson. In this role, he is involved in strategic and scientific development of the continuous manufacturing platform within Janssen. He holds Master degrees in Pharmacy and Pharmaceutical Engineering from University of Groningen, The Netherlands and a PhD degree in Chemical Engineering from The University of Sheffield, United Kingdom. In his professional career he worked for generic and non-generic companies in various functions covering formulation and process development of oral solid dosage forms, manufacturing support of commercial products, and leading drug product development projects.

Thomas O'Connor, Ph.D., Deputy Director, Office of Testing and Research
OPQ/CDER/U.S. Food and Drug Administration
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Thomas O'Connor, PhD is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA. Tom has been at the FDA since 2013 serving in various roles including as a chemistry reviewer in the Office Generic Drugs and a team leader in the immediate office of the Office of Pharmaceutical Quality. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Tom earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Suneel Rastogi, Ph.D., Product Marketing Director
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suneel_rastogi@amat.com

Involved in developing strategies for pharmaceutical regulatory and market acceptance of novel technologies adopted from semiconductors industry.

Over 20 years of extensive pharmaceutical industry experience in effectively managing internal and external development projects. Core competencies include various aspects and stages of product development including pre-formulation, materials characterization, formulation and process development, quality by design, stability, scale-up, technology transfer, regulatory submission and commercial launch of dosage forms. Strong scientific and strategic expertise with in-depth understanding of analytical, quality, regulatory, physicochemical characterization, biopharmaceutics and clinical aspects of product development. Managed 100+ projects at various stages of product development including solid and liquid orals, injectables, rectal gels, nasal sprays, ophthalmic and topical products. Successfully developed a variety of conventional and complex modified release dosage forms including high market value blockbusters with greater than $B yearly sales. Expertise in combining efficiency with speed with good science, compliance and quality through well rounded experience in small and large organizations such including Forest Laboratories (legacy Abbvie), Mallinckrodt, Impax (legacy Amneal), Leading Pharma and Navinta.

Ph.D. in Pharmaceutics from University of Minnesota.

Wyatt J. Roth, Ph.D., Senior Director
Eli Lilly and Company
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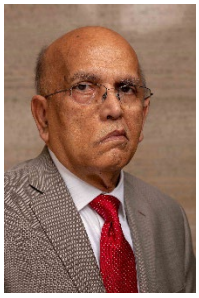
Wyatt Roth is a senior director within the Synthetic Molecule Design and Development organization at Eli Lilly and Company, Indianapolis, IN. He received B.S. degrees in Pharmaceutical Sciences and Agricultural and Biological Engineering from Purdue University in 2008, and earned his Ph.D. in Industrial and Physical Pharmacy from Purdue University in 2012. After joining Lilly, Wyatt led continuous manufacturing (CM) feasibility and process optimization studies which influenced the decision to build Lilly's first GMP drug product CM facility. Since that time, he has served as the lead development scientist for Lilly's first two assets which used a CM. Wyatt has expertise in control strategy development and technical transfer from development to commercial manufacturing sites for continuous direct compression manufacturing processes culminating in the approval of Lilly's first drug product which uses a CM platform.



Abu T. Serajuddin, Ph.D., Professor of Industrial Pharmacy
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Abu Serajuddin, PhD, is Professor of Industrial Pharmacy at St. John's University, Queens, New York, USA. Prior to joining academia in 2008, he worked in the pharmaceutical industry for 32 years in scientific and managerial positions at Sanofi-Aventis, BMS, and Novartis. In his latest positions in the industry, he served as Executive Director and the US Head of Pharmaceutical R&D at Novartis Pharmaceutical Corp. During the past 13 years at St. John's, he has built a world-class teaching and research program dedicated to the development of drug delivery systems and pharmaceutical processing technologies. He has published over 125 scientific papers and book chapters, and he is a co-inventor in 13 issued patents. He also made over 150 invited presentations in national and international conferences. He served in many leadership positions in the AAPS and received several of its major awards, including AAPS Fellow (1998), AAPS Research Achievement Award in Formulation Design & Development (2010), AAPS Research Achievement Award in Manufacturing Science & Engineering, and AAPS Lipid-based Drug Delivery Outstanding Research Award (2015). He received the Ralph Shangraw Memorial Award in 2016, which is the highest scientific recognition given by the International Pharmaceutical Excipients Council (IPEC). For his academic and research excellence as a member of the faculty, St. John's University bestowed him the University Medal for Outstanding Achievement in 2019.

Changquan Calvin Sun, Professor of Pharmaceutics
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Dr. Sun is Professor of Pharmaceutics in the Department of Pharmaceutics, University of Minnesota, USA. Dr. Sun's research focuses on formulation development of tablet products through appropriate application of materials science and engineering principles, including 1) crystal and particle engineering for superior pharmaceutical properties, e.g., powder flowability, tabletability, dissolution, and stability; 2) pharmaceutical unit operations, e.g., blending, granulation, and tableting. He has published more than 220 papers in these areas with more than 10,200 citations (H-index = 54).

Dr. Sun currently serves on the editorial advisory boards for AAPS Open, CrystEngComm, Int. J. Pharm., J. Pharm. Sci., Mol. Pharmaceutics, and Pharm. Res. He is an editor of Chemical and Pharmaceutical Bulletin and Crystals. He has served on the Expert Committee in Physical Analysis of the United States Pharmacopeia since 2010. Dr. Sun is an AAPS Fellow and a Fellow of Royal Society of Chemistry. He has received a number of awards, including the 2019 Ralph Shangraw Memorial Award by International Pharmaceutical Excipient Council (IPEC) for his outstanding research contributions in the study of excipients or excipient-related technology over a number of years.

Kevin Thurow, Global Improvement Leader
IFF Pharma Solutions
kevin.thurow@iff.com

Kevin Thurow has more than 13 years manufacturing experience with a wide variety of roles including production engineering, manufacturing representative for large capital projects, and operations leadership. Previous employers include Johnson & Johnson, Dow Chemical, DuPont, and now IFF. Currently he is the Global Improvement Leader for the METHOCEL™ product line with IFF. In this role he supports the multiple METHOCEL™ manufacturing sites globally scope capital and non-capital projects that will improve the productivity, quality, and process safety of our assets. Kevin holds a Bachelor's Degree in Chemical and Biomolecular Engineering from The Georgia Institute of Technology. He currently resides in Midland, Michigan with his wife, two year old daughter, and two dogs.

Katherine Ulman, Owner and Primary
KLU Consulting, LLC
kathyulman@yahoo.com

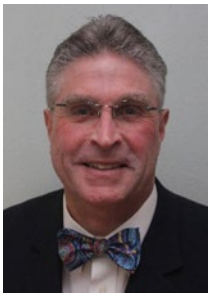
Katherine Ulman is the owner and Primary for KLU Consulting, LLC. She retired from Dow Corning Corporation after more than 40 years of employment. While at Dow Corning she held positions as a global regulatory compliance manager for their Healthcare business as well as regulatory manager for their Healthcare Industries Materials Site. She has published and presented several papers in her field, is an adjunct professor of Chemistry at the South Dakota School of Mine and Technology and a member/consultant for IPEC-Americas. Ulman earned her Bachelor of Science degree in chemistry from the South Dakota School of Mines and Technology in 1976.

Priscilla Zawislak, ***Vice President***, IPEC Federation
Vice Chair, Science and Regulatory Policy, IPEC-Americas
Global Regulator Affairs Advocacy Manager, IFF
priscilla.zawislak@iff.com

Priscilla has over 35 years' experience in Regulatory Affairs and Quality for excipients, food additives and ingredients for personal care products. Currently with IFF (International Flavors & Fragrances, formerly DuPont Nutrition & Biosciences), she is responsible for regulatory advocacy for excipients, APIs and food additives. Prior positions included Global Regulatory Affairs Manager for Ashland Specialty Ingredients' Pharmaceutical and Nutrition business where she was responsible for regulatory compliance for food additive and excipient products, and Quality Manager at FMC Health and Nutrition (which is now part of IFF).

Priscilla is currently Vice-President of the IPEC Federation, a global organization consisting of regional IPECs in the US, Europe, China, Japan and India. She is also the Vice Chair of Science and Regulatory Policy for IPEC-Americas and is also a past Chair of the organization. She has been an active member of IPEC-Americas committees since 2001, is a member of the IPEC Americas Executive Committee and a member of the Board of Directors of EXCiPACT®.

Priscilla earned her degrees in Biological Sciences and Chemistry from the University of Delaware.



Joseph Zeleznik, Technical Director, North America
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Joseph Zeleznik is Technical Director, North America for IMCD US Pharma. In this role, he has responsibility for product and technology training, conducting customer seminars, and advising with formulation development through excipient and process selection. Mr. Zeleznik also collaborates to develop prototype formulations, demonstrating the benefits of IMCD's products and technologies. He works closely with IMCD's many principals to promote product awareness and coordinates joint meetings in those efforts. Mr. Zeleznik currently serves as a member of IPEC-Americas' Executive Committee as Chair-elect. He has contributed to the development of several IPEC Guides. Prior to joining IMCD US, Mr. Zeleznik served as Manager, Technical and Regulatory Affairs at MEGGLE USA, Inc., where he provided formulation and product application guidance and had quality and regulatory oversight for MEGGLE USA's North American lactose manufacture. Mr. Zeleznik served as Associate Director, R&D with JRS PHARMA and Research Manager with Penwest Pharmaceuticals Co. Mr. Zeleznik has nearly 30 years' experience in the pharmaceutical industry, specializing in the development and application of high functionality excipients, focusing on co-processed and other novel excipients. Mr. Zeleznik received his B.S. and M.A. degrees in Chemistry from the State University of New York, College at New Paltz. Mr. Zeleznik has contributed to articles published across various industry journals. He was a contributing author to the Handbook of Pharmaceutical Excipients, 8th Ed. published in 2017 and participated in the development of the NF co-processed excipient monograph, Silicified Microcrystalline Cellulose. Mr. Zeleznik is an avid outdoorsman, enjoying camping, hiking, biking, and wildlife photography and has been an active as a cub scout and boy scout leader with Boy Scouts of America for many years.