4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements
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Bios

MODERATOR/WORKSHOP ORGANIZING COMMITTEE CHAIR

David R. Schoneker, President/Owner
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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 43 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.

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 serving as the Vice Chair for Science and Regulatory Policy, where he is actively involved with the development of Regulatory, Safety, Excipient GMP and Supplier Qualification related guidelines to improve Excipient Acceptability, Safety and Global Supply Chain Security.

Mr. Schoneker also Co-Chairs IPEC's QbD/Product Development Committee, Composition Committee and IID Working Group and is a member of the Board of Directors of the IPEC Foundation. He is the Global Expansion Coordinator for the IPEC Federation and has been critically involved in the development of many of the IPEC 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:

Sophie Bertilsson, Ph.D., Chemistry and Pharmaceutical Assessor
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Sophie Bertilsson is a chemistry and pharmaceutical assessor at the Swedish Medical Products Agency, which she joined in 2017. Prior to this she worked at AstraZeneca for 16 years in various roles within the chemistry, pharmaceutical development and regulatory field. Sophie is the EC quality representative in the ICH Expert Working Group for the next impurity guideline to be developed - ICH Q3E – covering Extractables and Leachables.

Sophie has a background in organic chemistry and received her PhD from University of Uppsala, Sweden in 2001.

William Dale Carter, Head of Quality, Business Line Silica, Region Americas
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Dale Carter is the Head of Quality for the Business Line Silica in the Region Americas for Evonik. He is responsible for product quality and compliance with IPEC/PQG GMPs for the manufacturing of Silica products at facilities in the United States and Brazil. Dale is a former Board member of EXCiPACT and a member of the NSF Joint Committee for Pharmaceutical Excipients that wrote the ANSI/NSF/IPEC/363 Good Manufacturing Practices for Pharmaceutical Excipients. He is a Past Chair of International Pharmaceutical Excipient Council of the Americas and currently serves as Vice Chair Membership. Dale received an MS in Chemistry from North Carolina State University and a BS in Chemistry from Davidson College. He is an ASQ Certified Quality Auditor. Prior to joining Evonik/JM Huber Dale worked for Pfizer, The Coca-Cola Company, and Archer Daniels Midland Company.

Stephen W. Erickson, Ph.D., Senior Research Statistician
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Since 2015, Steve Erickson has served as Senior Research Statistician at RTI International in Research Triangle Park, North Carolina. He has broad experience as a consulting statistician in several fields including analytical sciences, biostatistics, statistical genetics, and genomics. He currently serves as lead biostatistician for the coordinating center of the National Cancer Institute's Pediatric Preclinical Testing Consoritum (PPTC) and as co-principal investigator for the data coordinating center of CDC's Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet). Since joining RTI, he has collaborated on multiple projects with its Analytical Sciences Department (ASD).

Dr. Erickson received his doctorate in statistics from UCLA in 2006.

Xiaoyi Gong, Ph.D., Director of Chemistry
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Dr. Xiaoyi Gong, Director of Chemistry in Merck and Co., Inc., leads a team of analytical chemists focusing on development, registration and commercialization of novel drug products. He is a recognized expert of international regulatory guidelines for pharmaceutical development. Currently he serves as the co-chair of the Working Group of ICH Q3D Guideline for Elemental Impurities for International Consortium for Innovation & Quality in Pharmaceutical Development (IQ), and is member of multiple drug development oversight committees internally at Merck.

Xiaoyi is also a leading expert of new analytical technologies in the pharmaceutical industry. He has led multiple technical functions focusing on applying state-of-art analytical techniques for analytical method screening and development, high-throughput analysis, elemental analysis, labelled compound analysis, and structural characterization of metabolites. He pioneered the development and implementation of a number of new analytical technologies across these fields. Xiaoyi chaired the Analytical Workgroup of the New Technologies Review & Licensing Committee at Merck that coordinates acquisition, evaluation, and implementation of new analytical technologies for the global Merck organization.

Xiaoyi obtained a Ph.D in Analytical Chemistry from Iowa State University in 2000. His research interests are in modern analytical instrumentation, detection techniques, separation science, chirality, high-throughput analysis, and elemental analysis. In addition to over 50 publications in peer reviewed scientific journals and multiple patents, Xiaoyi has been recognized with the following distinctions: R&D 100 Award (2000); Inventors Award, Iowa State University (2011); Merck Presidential Award for Green Chemistry (2011) for promoting SFC technologies at Merck; Special Achievement Awards, Merck Research Laboratories (2012, 2014) for championing new analytical technology evaluation and implementation, and global deployment of next generation HPLC technology at Merck.

James Harrington, Ph.D., Research Chemist
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Dr. James Harrington graduated with a B.S. in Chemistry from the University of North Carolina at Wilmington in 2004 and a Ph.D. from Duke University in 2010 in the area of bioinorganic chemistry. Following a postdoctoral appointment at North Carolina State University's Department of Soil Science, he served in the U.S. Environmental Protection Agency (EPA), measuring toxic metal bioavailability in support of the Superfund program. After an appointment at Catalent performing elemental impurity testing in pharmaceutical products and packaging materials, he joined RTI's Analytical Sciences Department (ASD), where he is a Research Chemist contributing to environmental exposure and public health research with university collaborators. He has also contributed to numerous bioanalytical research projects for NIEHS's National Toxicology Program (NTP) in the area of metallomics and inorganic speciation. He has over 40 publications in the areas of inorganic analytical methods and biogeochemistry of trace metals and an adjunct appointment at the NCSU Department of Crop and Soil Sciences. His research interests include bioinorganic chemistry, environmental health, and analytical method development.

Laurence J. Harris, Ph.D., Director
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Dr. Laurence J. Harris Joined Pfizer in Sandwich, UK in 1999 as a process development chemist in Chemical Research and Development (CRD) where he led project teams, API technology transfer, new API technology and Green Chemistry implementation programs. In 2008 he joined the Analytical Research and Development (ARD) department in a team leader role before moving into the GMP Analytics function of ARD. He is currently a Director within the Global GMP Analytics function with responsibilities for stability testing, drug product release, excipients and packaging component release. Since 2014 he has been leading efforts within Pfizer Worldwide Research and Development to implement ICH Q3D into the development workflow. This role has resulted in him becoming a key contributor to the cross industry consortium working towards the delivery and use of the Lhasa Elemental Impurities Excipient Database in ICH Q3D risk assessments. In 2019 and '20 he has been the industry co-chair for the Lhasa / industry consortium. During 2020 he has also been working with Lhasa to build a cross industry nitrites in excipients database in support of drug product nitrosamine assessments.

Galina Holloway, Senior Scientist Liaison
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Galina Holloway joined USP in 2006 and is a Senior Scientific Liaison responsible for development, modernization, and revision of Excipient Monographs and General Chapters. Before Dr. Holloway joined the Excipients group, she was a senior group leader at USP Research and Development Laboratory where she led a group of highly qualified scientists in development and validation of analytical procedures for drug substances, drug products, food ingredients, excipients and dietary supplements.

Dr. Holloway has 25+ years' experience as an analytical chemist both in the US and Russia. She has headed a research laboratory on water quality for the Russian Academy of Sciences, been a senior analytical chemist for a major international pharmaceutical company and laboratory director of an independent tobacco products testing laboratory.

Over the past several years, Dr. Holloway has been leading the work of USP expert volunteers on defining excipient composition and organic and inorganic impurities. This work has resulted in publication of a Stimuli article "The complexity of setting compendial specifications for excipient composition and Impurities" and a USP General Announcement "Draft Roadmap for addressing element-specific chapters and tests in excipient monographs."

Dr. Holloway holds a Ph.D.in Chemical Enzymology and a M.S. in Organic Chemistry from Moscow State University, Russia.

Nancy Lewen, Partner
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Nancy Lewen has nearly 30 years of experience in the analysis of pharmaceuticals for metals/elemental impurities, along with several years of experience performing metals analysis in the environmental industry. Her experience is extensive in the use of ICP-OES, ICP-MS, flame and graphite furnace AA, laser ablation ICP-MS and various sample preparation techniques. She also has experience with XRF. Nancy has taught numerous short courses on the use of atomic spectroscopy for pharmaceutical applications and has published several papers on the topic, as well.

Nancy has served as the chair of the USP elemental impurities advisory panel for more than 15 years, and is the current chair of the USP Chemical Analysis Expert Committee. Nancy has served on various USP sub-committees for more than 15 years. She is a co-recipient of the USP award for Innovative Response to a Public Health Challenge, and also a co-recipient of the USP award for Outstanding Contribution to the Standards-setting process. Nancy is also the recipient of the BMS Chemistry Leadership Award, the BMS award for Outstanding Contribution to Analytical Chemistry, and a co-recipient of the NJ Biomedical Research Association award for Outstanding Women in Science.

She currently is a partner in Owasso Pharamcon LLC, a consulting firm dedicated to sharing expertise and knowledge regarding metals analysis in pharmaceuticals, as well as the application of physics and biomedical engineering in the pharmaceutical industry.

Denise McClenathan, Ph.D., Principal Scientist
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Denise is currently Principal Scientist and Group Leader in Procter & Gamble's Global Elemental Analysis Capability. She joined P&G as a Scientist in 2004 after receiving a B.A. in Chemistry from Saint Mary's University of Minnesota and a Ph.D. in Analytical Chemistry from Indiana University. At IU, Denise researched plasma source time-of-flight mass spectrometry, studying with Professor Gary Hieftje. At P&G, she is responsible for strategies to address an array of complex elemental analysis problems, across all of P&G's consumer products programs, from upstream innovation projects through marketed-product compliance needs. Denise is currently a member of the Technical and Analytical Challenges Team sponsored by IPEC and her research interests include instrumentation and methodologies for elemental analysis, spanning microwave digestion, ICP-OES, and ICP-MS, as well as validation strategies. Denise is the author of 16 publications and patents.

Vishakha Metkar, Senior Manager Regulatory Affairs
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Vishakha Metkar is a Senior Manager Regulatory Affairs at Colorcon Asia Pvt. Ltd- India. Her responsibilities include coordination of regulatory functions in the region to achieve regulatory acceptance of Colorcon products in target markets and interaction with Indian FDA & Food Safety and standards Authority of India (FSSAI) for matters involving various required Product approvals / Licenses for Manufacturing & Distribution activities of Colorcon in South Asia.

Also monitors excipient & color regulations activities in South Asia & Southeast Asian countries to provide help with regulatory assessment of Colorcon products supplied in these regions. Provides guidance on filing requirement in US /EU / JP / China related to Colorcon products.

As a Regulatory Affairs head since 2005 she has been involved in all Regulatory projects at Colorcon and has an expertise with interpretations of various regulations / guidelines for Excipients. Has expertise with Indian regulations for Excipients and Food additives.

Was involved in formation of IPEC India & is a member of their Managing committee; Chairman for its Regulatory Affairs Committee and Vice Chairman for the PR & Communication committee. She is actively involved with initiating and planning of all events of IPEC India & regularly represents IPEC India at their events and joint events with various trade organizations in India presenting on various Excipient regulations/guidelines. She represented IPEC India at ExcipientFest Americas 2016 in Baltimore as a presenter on 'Current Regulations & Emerging challenges for Excipient Regulations in India'.

Vishakha obtained a Master's Degree in Analytical & Medicinal Chemistry from SNDT- Mumbai University & is active in the field of Excipients for nearly 30 years since 1989 (24 yrs at Colorcon). Her past experience involves working for Pharma, Contract Analytical Laboratories and Excipients companies as head of Quality & Regulatory Affairs.

She was a Quality Assurance head at Colorcon from 1997 until 2005 during which she successfully developed their QMS and steered their ISO 9001–1995, 2000 & 2005 certifications; was a certified lead auditor for ISO and authored the Quality Manual for Colorcon India. She has managed numerous customer & regulatory audits and very actively involved with all validations & their approvals of their new plant in GOA in 2003.

She has a vast experience in Analytical testing of various drugs & dosage forms, API (bulk Drugs), Excipients, Cosmetics, and highly skilled in sophisticated instrumental analysis, micro biological testing including sterility / antibiotic assay & pyrogen toxicity. Is a qualified & certified Competent person for Chemical & Instrumentation by Maharashtra state FDA- Mumbai.

She also has a deep experience with manufacturing of Aluminium hydroxide paste/ powder and water soluble dyes – like Sunset Yellow FCF/ Tartrazine/ Ponceau 4R/ Carmoisine / Erythrosine / Brilliant Blue and Lake colors.

Thanh Nguyen, Ph.D., Senior XRF Applications Scientist
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Thanh Nguyen has worked at Rigaku Americas Corp. for the past 7 years as a Senior XRF Applications Scientst. In her current role, she has performed method development of customer-based applications on a wide variety of materials (i.e. pharmaceuticals, thin films, alloys, state-of-the-art textiles, foods, plastics, cements, etc). In addition, she also provides hands-on onsite as well as remote trainings for customers in North America, South America, and Asia. Previous to joining Rigaku, Thanh had 15 years experience in the pharmaceutical R&D industry at Merck, Merial (now Boehringer Ingelheim Animal Health) and Encysive Pharmaceuticals as a lead bioanalytical chemist in DMPK. Thanh holds a Ph.D. in Analytical Chemistry from the University of the Sciences in Philadelphia and a BS in Chemistry from Texas A&M University.

Yoshiaki Ogasawara
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Yoshiaki Ogasawara studied Chemistry at the Seikei University in Tokyo and received a Master's degree in Physical Chemistry from the university. After graduation, I worked 15 years as a researcher of pharmaceutical development for a pharmaceutical company in Japan, where I was a manager of the section of solid dosage form development and my team launched many drug products to the market. In 1992, I moved Colorcon-Japan as a Technical manager, where I was in charge of all technical and regulatory matters. Also, I headed Colorcon-Japan's plant construction project (Pharma GMP plant under JP contract manufacturing law), and completed it in 2000. After plant construction, I managed QA/QC and Regulatory section as well as Technical, and contributed a lot to the company's growth in Japan. After retirement from Colorcon JP in 2014, I worked for Nippon Gohsei (now Mitsubishi Chemical Corp.) as a senior technical manager and guided key persons in pharmaceutical excipient regulation and pharmaceutical technology.

On behalf of above two companies, I had attended IPEC Japan committees since 1998, and served as chairs of the 1st committee (the JPE related matters), Master File committee and Regulatory committee.

Ulrich Rose, Ph.D., Head of Division, European Pharmacopoeia
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Dr. Rose is pharmacist by training and obtained his PhD in pharmaceutical chemistry in 1985. Before joining the EDQM in 1991 he was assistant professor and lecturer for pharmaceutical analysis and physico-chemistry at the University of Mainz in Germany.

Until 2011 he was responsible for the establishment and monitoring of Ph. Eur. reference standards in the European Pharmacopoeia laboratory. Moreover, he was involved in the elaboration and revision of Ph. Eur. monographs. After that he became co-ordinator and auditor for EDQM's Mutual Joint Audit program. Within this function he audited the Official Medicines Control Laboratories in and sometimes outside Europe. Since 2014 he is head of division A and deputy head of the European Pharmacopoeia department where he is overlooking the monograph work on chemically defined active substances, herbals, finished products and general methods and is involved in the international harmonisation of pharmacopoeias.

Mark G. Schweitzer, Ph.D., Global Head AS&T and Scientific Initiatives
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Dr. Schweitzer is the Global Head, Analytical Science & Technology, Novartis Quality. In this role, he is responsible for the development and implementation of strategic initiatives in pharmaceutical analytical chemistry, technology development, and analytical process improvements across Novartis. During his career spanning over 35 years, Dr. Schweitzer has led analytical and formulation development groups for several major pharmaceutical companies (Abbott/AbbVie, Searle/Pharmacia/Pfizer) and private research organizations supporting pharmaceutical and agricultural product development. He has successfully delivered analytical support across the range of development programs, from early stage/FIH to technology transfer to manufacturing. Dr. Schweitzer received his Ph.D. in Chemistry from The Ohio State University in 1984. He is active in several external organizations including PhRMA, ICH, and USP. He served as the Vice Chair and Chair of the Analytical Technical Group within PhRMA; served as the rapporteur for ICH Q3D: Elemental Impurities Expert Working Group through step 2b; is currently the PhRMA topic lead for the ICH Q3D(R1) Expert Working Group; and served as the Vice Chair of the USP Chemical Analysis Expert Committee from 2017 to 2018. He currently is a member and Vice-Chair of the USP General Chapters-Chemical Analysis Expert Committee (2020-2025 cycle).

Donna Seibert, Ph.D., Senior Manager
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Donna S. Seibert, PhD is Sr. Manager in Analytical Research and Development in Consumer Self Care at Perrigo Company, a leading global healthcare supplier that develops, manufactures and distributes OTC and generic prescription pharmaceuticals, infant formulas, self-care, and nutritional products. Seibert has over 18 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. She also serves on the USP OTC Methods and Approaches Expert Committee. Seibert holds a BA in Chemistry from Transylvania University and a Ph.D. in Analytical Chemistry from Wayne State University.

Janeen Skutnik-Wilkinson, Director Global Regulatory CMC Intelligence & Policy
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Ms. Skutnik is the Director of Global Regulatory CMC Intelligence and Policy at Biogen, where she is responsible for developing Biogen positions, working with trade associations, managing global regulations and intelligence. She is also the current Chair of IPEC-Americas. Her former positions include: Associate Director Quality Intelligence at Biogen, Vice President at NSF DBA; and Director /Team Leader of Quality & Regulatory Policy at Pfizer. She has over 25 years experience and expertise in compendial activities, quality and regulatory policy, and has held a variety of positions with responsibilities in documentation, change control, analytical method validation and product launch. Ms. Skutnik earned a Bachelors of Science from the University of Connecticut in 1994. She is a member of the ICH IWG for ICH Q3D Elemental Impurities, and was also on the EWG for Q3D. She was the Chair of PhRMA's Compendial Liaison Team (2000-2012); and the PhRMA Topic Leader for the ICH Topic - Q4B Regulatory Acceptance of Pharmacopoeial Interchangeability. She is the IPEC Delegate to the ICH Assembly and ICH Informal Quality Discussion Group.

Andrew Teasdale
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Andrew Teasdale PhD has over 25 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. In his current role he chairs AstraZeneca's Impurity Advisory Group. Dr Teasdale has published a number of papers relating to extractables and leachables, mutagenic impurities and other impurity related matters. He is currently the chair of the Extractables and Leachables safety Information exchange (ELSIE) and also led a number of industry expert groups; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), Product Quality Research Institute (PQRI) . Andrew has also represented EFPIA in both ICH Q3C and Q3D Expert working groups. He has also advanced a number of key scientific advancements in the control of impurities as the inventor of the purge factor concept and the instigator of the development of Elemental Impurities database for excipients. With over 50 scientific papers, he has also written 2 books:

Genotoxic Impurities – Strategies for Identification and control. Editor A Teasdale. Publisher Wiley. ISBN 978-0-470-49919-1

ICH Quality Guidelines – An Implementation Guide. Editors A Teasdale, D Elder, R W Nims. Publisher Wiley. ISBN 978-1-118-97111-6.

Philip Travis, BSc., Associate Director
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Philip Travis is an Associate Director for Merck and Co. Inc., Compendial Compliance and Advocacy Group located in Rahway, New Jersey USA. He holds a BSc from the Pennsylvania State University. He began his career in the pharmaceutical industry as an analytical chemist supporting release testing for Excipients, Active Pharmaceutical Ingredients, and Drug Products. Since 2002, he has been extensively involved in the development and application of global Pharmacopeial requirements for both Merck and Pfizer. He has worked with industry and lead activities to promote the development of appropriate public standards through the New Jersey Pharmaceutical Quality Control Association; European Federation of Pharmaceutical Industries and Associations; International Pharmaceutical Excipients Council; and Consumer Healthcare Products Association. He Chairs the USP Compendial Process Improvement Project Team.

Matthew D. Vera, Ph.D., Quality Assessment Lead (acting)
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Matthew Vera completed his B.S. in chemistry at Lebanon Valley College, and was a Fulbright Scholar in chemistry at the University of Munich. He subsequently returned to the U.S. and earned a Ph.D. in organic chemistry from the University of Pennsylvania. After completing his degree at Penn, Matt worked as a research scientist in the pharmaceutical industry in the areas of new drug discovery and medicinal chemistry.

Matt joined the FDA Office of Generic Drugs in 2010 as a CMC review chemist, focusing on the quality assessment of drug master files (DMFs) and generic drug applications (ANDAs) for immediate-release solid oral dosage forms. In 2015, Matt became an acting Quality Assessment Lead in the OPQ Office of Lifecycle Drug Products. Additionally, Matt frequently serves as Application Technical Lead (ATL) in OPQ's team-based interdisciplinary review system for product quality assessment. Matt's scientific interests are in the areas of chemical and degradation behavior of drugs as well as formulation development. Matt currently serves in the ICH Q3D expert working group.

Francine Walker, Technical Director
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Francine Walker is the Technical Director of SGS Chemical Solutions Laboratory. She has more than 25 years of experience in the analysis of metals using a variety of instrumental and wet chemistry techniques including AA, GFAAS, ICP-OES, and ICP-MS. Francine has implemented and administered quality systems for a variety of laboratory and manufacturing facilities to meet the requirements of ISO 9001, ISO 17025 and FDA cGXP guidelines. She has assisted industries in the areas of food safety compliance, vendor specification development, site and quality audits, and regulatory compliance permitting. Francine is a trained quality auditor and authored applications in support of a variety of quality systems. Francine received her BS degree in chemistry from the University of Pittsburgh.

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Glenn Williams currently leads the X-ray Fluorescence applications group at Rigaku Americas Corporation located in Houston, Texas. He has been with Rigaku for the last 8 years where he has specialized in X-ray Fluorescence Spectrometry including the development of applications and new technologies. Previous to joining Rigaku, Glenn worked for 15 years in the pharmaceutical industry in solid-state characterization groups (including Pfizer Central Research in Groton, CT and GlaxoSmithKline in King of Prussia, PA). He obtained his Ph.D. in Physical Organic Chemistry from SUNY Buffalo and has over 20 years' experience in materials characterization and analytical chemistry.

Priscilla Zawislak, Global Regulatory Affairs Advocacy Manager
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Priscilla has over 35 years' experience in Regulatory Affairs and Quality for excipients, food additives and ingredients for personal care products. Currently with DuPont Nutrition & Biosciences [formerly The Dow Chemical Company], she is the Global Regulatory Affairs Advocacy Manager for the pharmaceutical business and 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 DuPont).

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 Immediate Past Chair of IPEC-Americas and has been an active member of IPEC-Americas committees since 2001 and is a member of the IPEC Americas Executive Committee.

She is a member of the USP Excipients Project Team, the General Notices Project Team, the Compendial Process Improvement Team and a delegate to the USP Convention.

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