Bios

Michael Brent, Center for Veterinary Medicine, FDA
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Michael Brent is a Chemist in the Division of Manufacturing Technologies (DMT)/Office of New Animal Drug Evaluation (ONADE)/Center for Veterinary Medicine (CVM). Mike joined FDA as a Chemistry, Manufacturing and Controls Reviewer in 2009. He has experience reviewing a wide variety of animal drug applications for products ranging from tablets, to sterile injections, to Type A medicated articles and medicated feeds. He is the lead of the Elemental Impurities Working Group within CVM.

Mike has a background in Analytical Chemistry and Biological Chemistry. He received his Ph.D. from the University of Pennsylvania. Prior to that, he worked in analytical development in the pharmaceutical industry.

Xiaodong Bu, Merck & Co., Inc.
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Dr. Xiaodong Bu received his B.S. degree from Zhejiang University, Hangzhou China, his M. S. degree from The Ohio State University in Columbus, and his Ph.D. in Analytical Chemistry from Rutgers University under the direction of Professor Gene Hall. He is currently a Principal Scientist in Analytical Research and Development department of Merck Research laboratories located in Rahway, NJ. Xiaodong' s current responsibilities include leading the Atomic Spectroscopy group to support Merck global chemistry, as well as managing project analytical group to support Merck drug pipeline from discovery to commercialization. Xiaodong has more than fifteen years of experience in supporting drug substance process development, and strong background in automated method screening and development, stereo-chemical analysis, high-throughput analysis, and atomic spectroscopy for elemental analysis.

Danae Christodoulou, US Food and Drug Administration
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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.

George Collins, Vanderbilt Chemicals LLC
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George's education includes a BS degree in Biochemistry from UCLA. He also served as an Equine Research Animal Attendant at Ft Collins, Colorado Veterinary Teaching Hospital before joining RT Vanderbilt in 1984.

George has been VP and Mgr for the Minerals Division at Vanderbilt Chemicals LLC since 1991. He coordinates and contributes to the various mining and production activities related to producing mineral excipients as Magnesium Aluminum Silicate NF.

On behalf of Vanderbilt Minerals LLC, George has attended IPEC-Americas meetings since 2010 and currently serves as Vice Chair Compendial Review Committee, Executive Committee, and also serves on USP General Notices Team.

George enjoys skiing, taking care of his family's horses, and reading a good mystery.

Tara Lin Couch, EAS Consulting Group LLC
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Dr. Couch is a Ph.D. Analytical / Organic Chemist with exceptional analytical abilities and over 25 years of diverse laboratory and regulatory experience in academic, field, contract, and manufacturing environments. She is a sought-after expert on issues pertaining to Quality Control in both pharmaceutical and dietary supplement manufacturing. As a consultant, Dr. Couch assists with the development, improvement, and implementation of Quality Systems that are scientifically sound, efficient, practical, and compliant with FDA regulations. She also performs mock FDA inspections, gap-analyses, and contractor and laboratory audits. Dr. Couch provides GMP and laboratory trainings via seminar, webinar, and on-site presentations.

David J. Fillar, Perrigo
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David Fillar is a Quality Control Manager at the Allegan Site for the Perrigo Company. Current responsibilities at Perrigo include management of Lifecycle Analytical Services, Compendial Affairs, QC Informatics Support, Microbiology, and QC Purchased Materials. David has 25 years of experience in the Pharmaceutical Industry. Responsibilities have included Laboratory Systems, Process Validation, Environmental Monitoring, Quality Assurance, Supplier Quality Management, Operational Support, and New Products Project Management.

David holds an MBA from Grand Valley State University and a Bachelor's degree in Chemistry from Western Michigan University.

John Glennon, GlaxoSmithKline
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John Glennon has 25 years of experience in pharmaceutical analysis, focused primarily on analytical development and method transfer. This includes working at the GSK-sponsored Anti-Doping Science Laboratory during the London 2012 Olympic and Paralympic games. He is currently a member of the NPI Analytical group in GSK Global Manufacturing and Supply, and is based at the GSK manufacturing facility in Zebulon, NC. With a personal focus on Solid Oral Dose products, he is also a member of the group within GSK that sets global standards of workmanship for analytical testing. John has been working on the implementation of ICH Q3D within GSK for nearly five years. He is a member of an inter–industry consortium that is aiming to share data and align approaches to Q3D. John holds a B.Sc. in Chemistry from the University of Birmingham, UK, and an MS in analytical chemistry from North Carolina State University.

Kit Goldman, United States Pharmacopeia (USP)
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Kit Goldman joined USP as Director of Standards Development for Dietary Supplements in February 2017. Her research has ranged from basic research on photosynthetic mechanisms to research to develop safer herbicides, to studies on the mechanism of action of low molecular weight heparin. She has worked on development, launch and technical support of products from brands such as Neosporin, Bengay and Purell as well as in the development and support of Class I and Class II medical devices. Her experience also includes responsibility for manufacturing operations and supply chain.

Kit received her B.S. from Duke University, her Ph.D., from The University of Michigan and conducted post-doctoral research at the University of Illinois.

Ravi Harapanhalli, Amneal Pharmaceuticals
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Dr. Ravi Harapanhalli has been serving as Senior Vice President of Global Regulatory Affairs at Amneal Pharmaceuticals in Brookhaven, NY since last two years. In this capacity he oversees all regulatory affairs activities including submission of ANDAs, 505b2 NDAs, and regulatory meetings with FDA and other Health authorities. He advises scientific teams on complex regulatory and technical issues facing high-barrier generics including combination products and complex drug substances. Earlier, he worked at PAREXEL International for seven years, which included 4 years as Vice President of Technical Affairs; and he provided high level consultations to pharmaceutical/biopharmaceutical industry. Prior to that, he was at US FDA for over 11 years in the Office of New Drug Quality Assessment and worked through the ranks from being a CMC Reviewer to finally serving as Branch Chief in the last four years until July 2008. During his tenure at FDA he supervised and reviewed various dosage forms and complex drug substances and combination products including modified-release dosage forms, implants, transdermals, MDIs/DPIs, liposomes, suspensions/dispersed systems, synthetic APIs, therapeutic proteins/peptides/MAbs, oligonucleotides, iron complexes, radiopharmaceuticals, etc. Before joining FDA, he was in academics for 8 years and in pharmaceutical industry for 3 years. He frequently presents at national/international conferences; has published over 35 peer-reviewed articles, and holds four patents on tumor targeting and therapy from Harvard Medical School. He is a Diplomat of American Board of Science in Nuclear Medicine and holds a Ph.D. in Synthetic Organic Chemistry from IIT Bombay.

James Harrington, RTI International
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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.

Sven-Erik Hillver, Medical Products Agency (MPA)
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Hillver is Senior Expert at the Department of Pharmaceutics and Biotechnology at the Medical Products Agency, Uppsala, Sweden. He holds a Pharmaceutical Sciences Licentiate degree focused on organic synthesis and NMR spectroscopy from the University of Uppsala. In 1989 he joined the Medical Products Agency as a quality assessor and since 2003 he is one of the Agency's Senior Experts. He is a member of the CHMP/CVMP Quality Working Party (QWP) since 2006 and among other roles, he has been the Quality representative of the EU in the ICH Expert Working Group Q3D Guideline for Elemental Impurities.

Akihiko Hirose, National Institute of Health Sciences
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Dr. Akihiko Hirose is a Director of Division of Risk Assessment at National Institute of Health Sciences, Japan. He received a Ph.D. in physiological medicine from Tohoku University in 1990. He is an expert in risk assessment of industrial chemicals, contaminants in drinking water and food. He is mainly working on the chemical risk assessment of industrial chemicals as an expert member for the committee under the Japanese Chemical Substance Law. He is also an expert member of the Expert Committee of Chemicals and Contaminants in the Japanese Food Safety Commission, and a member of the committee for the rolling revision of drinking water quality standards in Ministry of Health Labor and Welfare (MHLW). He is currently researching on the development of the chemical impurities risk assessment methodology by using QSAR systems and TTC concept, and on the development of the evaluating methodology for health effects by manufactured nanomaterials exposure. As for the fields on the drug quality controls, he has been the MHLW/PMDA topic leader for the ICH Q3D and Q3C expert working groups.

Alison Ingham, Health Canada
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Alison Ingham obtained her B.Sc. (Chemistry and Biochemistry) at the University of the Witwatersrand in South Africa and her Ph.D. in Bioinorganic Chemistry from the University of Victoria, Canada. After graduation she lectured at the University of Ottawa, before joining Health Canada. During her tenure at Health Canada, Alison has been involved with assessing the certification process at the European Directorate for the Quality of Medicines, and was appointed an Assessor by EDQM in 2006. She was the Manager of Product Assessment in the Nutrient and Isolates Division at the Natural Health Products Directorate. Currently she is a Manager in the Bureau of Pharmaceutical Sciences of the Therapeutic Products Directorate of Health Canada where her responsibilities include assessment of generic drugs as well as guidance development.

Elisabeth Kovacs, Apotex
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Graduated from University Babes-Bolyai, Cluj Napoca Romania. Employed by Apotex for over 33 years in roles of increasing responsibilities focused on analytical R&D methods and specifications development, support to product development in the form of dissolution/drug release, compatibility studies. Also interaction with various regulatory agencies on policy and regulation development in form of industry feedback though organizations such as Association of Affordable Medicines AAM (formerly GPhA).

Memberships: AAM: Member of the Science and Regulatory Advisory Working Group, USP-AAM Task Force, USP: Expert Panel on Analytical Method life Cycle, Expert Panel on General Chapter <467> Residual Solvents, CSPS (Canadian Society of Pharmaceutical Scientists) Board of Directors, AAPS IVIVR Focus group Steering Committee

Nancy Lewen, Bristol-Myers Squibb
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Nancy Lewen is a research Fellow and supervisor of the atomic spectroscopy laboratory at Bristol-Myers Squibb (BMS) in New Brunswick, NJ. She has nearly 30 years of experience in the analysis of pharmaceuticals for metals/elemental impurities. 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 10 years, and is the current chair of the USP Chemical Analysis Expert Committee. Nancy has served on various USP sub-committees for more than 10 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.

Joy E. Mason, Eli Lilly and Company
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Joy Mason is a Quality Consultant in Compendial Affairs at Eli Lilly and Company, with 28 years of experience in pharmaceutical quality systems, microbiological testing, project management, change management, and six sigma initiatives.

Joy received her Bachelor's degree in Microbiology at Miami of Ohio, and her Master's degree in Pharmaceutical Sciences at Butler University in Indiana. She received her six sigma black belt certification from Purdue University in Indiana in 2013. She has completed four six sigma initiatives to support laboratory operations. She has also coordinated the implementation of several large-scale Compendial changes for Lilly labs.

Timothy McGovern, Food and Drug Administration
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Tim is an Office Associate Director for Pharmacology/Toxicology in FDA CDER's Office of New Drugs where he interacts with nonclinical review teams in the review of IND, NDA, and BLA submissions, advises Office Directors on nonclinical issues, and is involved in development of policy and guidances related to nonclinical and regulatory issues. Tim is currently the Rapporteur for the ICH Q3C and Q3D Expert Working Groups and is FDA liaison for USP expert panels on biocompatibility and residual solvents. He has published in the areas of inhalation toxicology, carcinogenicity testing, evaluation of genotoxic impurities, and evaluation of leachables and extractables.

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

She is a co-recipient of the United States Pharmacopeia (USP) award for Innovative Response to a Public Health Challenge and currently leading revision of USP Elastomers chapter. She is also Chair of the PQRI 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

Helmut Rockstroh, Roche
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Dr. Helmut Rockstroh is the head of Global Pharmacopoeial Affairs at F. Hoffmann-La Roche Ltd and has held that position since 2009. Dr. Rockstroh has over 25 years of experience in Quality Management and Standards. He has served as a Delegate to the United States Pharmacopoiea Expert Committee: General Chapters, Chemical Analysis (2015) and European Pharmacopoeia's Expert Group 12 (General Methods) and Swiss Pharmacopoeia Expert Group for Drug Products (Small Molecules) (2010). Dr. Rockstroh received his PhD. (Dr. rer Nat) in Physical Chemistry from the University of Freiburg, Germany.

Christian Sampaolesi
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Head of New Dossiers Section since March 2017, the group in charge of the evaluation of new dossiers at the Certification of Substances Department (DCEP) of the EDQM. He holds an MSc in Regulatory Affairs Sciences for Medicines and a BSc in Industrial Chemistry. After 5 years working with the pharmaceutical industry he joined in 2009 a European National Competent Authority as Quality Assessor, a position he held for 3 years. From 2010 to 2012, he was a nominated member within the Joint CHMP/CVMP Quality Working Party at the EMA. He works with the Certification of Substances Department of the EDQM since June 2012.

David R. Schoneker, Colorcon
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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.

Orit Schwartz, Teva Pharmaceuticals
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Orit Schwartz is heading the Global Quality Program Management group for Teva Pharmaceuticals, involved in some of the key programs such as Data Integrity, Elemental Impurities and others.

Prior to this, Orit worked in Teva's division of Global Specialty Medicines and filled diverse roles, primarily responsible for Operational Launch Management, Projects Management and Supply Chain Management related with some of Teva's key assets such as Copaxone® 40mg/ml, Treanda®, Granix® and Lonquex®.

Before joining Teva in 2010, Orit worked for about 14 years in global technology companies and held various positions, mostly in the management of Supply Chain organizations.

Orit holds a B.Sc in Industrial Engineering from Tel-Aviv University and an MBA with honors from Ben-Gurion University.

Mark Schweitzer, Novartis
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Dr. Schweitzer is the Global Head, Analytical Science & Technology, Novartis Technical Operations 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 30 years, Dr. Schweitzer has led analytical and formulation development groups for several major pharmaceutical (AbbVie, Searle/Pharmacia/Pfizer) and private research organizations supporting pharmaceutical 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 a several external organizations including PhRMA, ICH, and USP. He served as the vice-chair and chair of the Analytical Technical Group within PhRMA and was the rapporteur for ICH Q3D: Metal Impurities Expert Working Group through step 2b of the development of the guideline and is currently the PhRMA topic lead for the ICH Q3D Expert Working Group and the Vice-Chair of the USP Chemical Analysis Expert Committee.

Donna Seibert, Perrigo
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Ms. Paskiet has over twenty years of experience in packaging analysis related to product failures, de-formulation and migration studies. She has served as a project advisor in support of qualification studies associated with packaging and delivery 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 Expert Committee member. She serves as Vice Chair of Product Quality Research Institute (PQRI) Development Technical Committee (DTC) and Chair of Parenteral and Ophthalmic Drug Product Leachables and Extractables Working Group. Ms. Paskiet is also on the faculty of the Parenteral Drug Association Training Institute and author/co-author of papers related to pharmaceutical packaging.

Timothy Shelbourn, Eli Lilly and Company
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Timothy Shelbourn is a Research Scientist at Eli Lilly and Company in Indianapolis. He heads the atomic spectroscopy laboratory in the Pharmaceutical Research and Development division. Tim received his B.S. degree from the University of Nebraska, his M.S. degree from Roosevelt University in Chicago, and his MBA from Webster University in St. Louis. Tim has 32 years of experience in atomic spectroscopy including atomic absorption, ICP atomic emission, ICP mass spectrometry, X-ray Fluorescence, as well as laser ablation and HPLC hyphenated ICP-MS. Since 2005, Tim has served on the USP Chemical Analysis Expert Committee and is currently the process owner for the elemental impurities compliance strategy for Pharmaceutical Research and Development at Eli Lilly. Since 2015, Tim has co-chaired the IQ Consortium Elemental Impurities Implementation Working Group.

Bruno Spieldenner, European Directorate for the Quality of Medicines and Healthcare (EDQM)
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Studied Physics and Chemistry at the University of Strasbourg and in 2006 he graduated a Master's degree in analytical chemistry and spectroscopy from the University of Marseille, in France.

After that he worked during 7 years as a laboratory engineer for a pharmaceutical company in Switzerland, where he was in charge of LC-MS/MS method development for both small and large molecules. There he got familiar with a broad set of analytical procedures used in quality control of medicinal products.

Since 2013, he joined the European Pharmacopoeia department of the EDQM in Strasbourg, where he is involved in the modernisation of texts on general methods and the implementation of the ICH Q3D Guideline.

William Stevens, Merck & Co. Inc.
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Bill has worked in analytical chemistry in Pharma for 26 years. His work has largely included methods development and product development for drug product in both early and late phase. He has had the good fortune to contribute to dossiers for several market approved programs for oncology, cardiovascular and diabetic therapies. Bill was the department lead for the Merck Elemental Impurities team for new drug products at Merck. This team has experienced several new regulatory filings after the implementation of ICH Q3D.

Francine Walker, Chemical Solutions Ltd.
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Francine Walker has over 25 years of laboratory, quality control, and manufacturing experience and is currently the Technical Director of Chemical Solutions – an independent laboratory specializing in heavy metal and elemental testing. 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. Ms. Walker has extensive experience in the analysis of metals using a variety of instrumental and wet chemistry techniques including AA, GF-AAS, ICP-AES, and ICP-MS. Francine is also a trained quality auditor and authored applications in support of a variety of quality systems. Francine has assisted industries in the areas of food safety compliance, vendor specification development, site and quality audits, and regulatory compliance permitting. Francine has presented numerous seminars and is a member of the many industry committees. Ms. Walker received her BS degree in chemistry from the University of Pittsburgh.

Janeen Skutnik Wilkinson, Biogen
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Ms. Skutnik is the Sr. Mgr Regulatory (GMP) Intelligence and Compendial Affairs at Biogen. In this role she is responsible for Review of regulations and guidances, globally that impact Biogen as well as many external engagement activities. Her former positions include: Vice President of Health Sciences at DBA, .Director /Team Leader of Quality & Regulatory Policy at Pfizer, responsible for working with various trade associations and also developing Pfizer Positions on Quality and CMC issues. She has over 20 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 EWG for ICH Q3D Elemental Impurities. 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 a member of the PDA Regulatory Affairs and Quality Advisory Board, and a co-leader of the PDA Pharmacopoeial Interest Group. Ms. Skutnik is the past-President of the International Pharmaceutical Excipients Council Federation, a Past Chair of the International Pharmaceutical Excipient Council of the Americas and served as Chair of the International Pharmaceutical Excipients Association's (IPEC) Compendial Review/Harmonization Workgroup (1999 - 2007).