Biographies

Positron Emission Tomography Drugs: Product Quality, Regulatory Submissions, Facility Inspections, and Benefit-Risk Considerations

November 13, 2023
08:00 am to 05:30 pm

November 14, 2023
08:00 am to 12:00 pm

All times EST

FDA White Oak Conference Center
Bldg 31 Conference Center, The Great Room 1503 (B+C)
10903 New Hampshire Ave
Silver Spring, MD 20993

Keith Bowen, MS

More than 30 years' experience in global pharmaceutical development and commercial environments for various aseptically produced and solid dosage forms Spent the last 10+ years at Eli Lilly & Co. leading Quality Assurance for Lilly's PET Radiopharmaceutical affiliate, Avid Radiopharmaceuticals, Inc.

Possesses a Master of Science in Microbiology and has been previously certified by the ASQ as a Quality Auditor and Quality Engineer. During his professional history, he held various positions in QC Microbiology, manufacturing Quality Assurance, Corporate compliance, and Quality Assurance management at manufacturing site and corporate offices. He has previously worked for,

- Catalent Pharma Solutions
- Glaxo SmithKline (formerly Reliant Pharmaceuticals, Inc.)
- Merck & Co. (formerly Schering Plough Research Institute)
- Actavis (Formerly Watson Pharmaceuticals)

Sue Bunning, MA

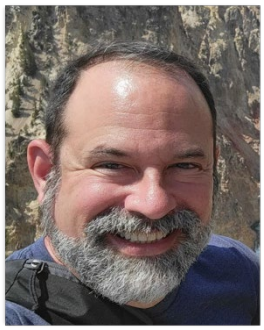
Sue has spent over thirty years working in and around nuclear medicine. Prior to joining MITA, Sue was the Director of Health Policy and Regulatory Affairs for the Society of Nuclear Medicine and Molecular Imaging (SNMMI). Before joining SNMMI, she was the Global Vice President of Government Affairs for Covidien (now Medtronic). Prior to Covidien, Sue was Director of Government Affairs for Tyco where she worked on international trade, tax, and healthcare issues. Sue started her corporate government affairs career with Mallinckrodt, (now Curium). Prior to working in corporate government affairs, Sue worked on Capitol Hill for the late Congressman Bill Emerson of Missouri. Her experience also includes working for a national political committee and as a Constituent Caseworker for the Ohio House of Representatives. A native of Cincinnati, Ohio, Sue graduated with a B.A. in Political Science from the Ohio State University and has a M.A. in International Transactions from George Mason University.

Danae Christodoulou, PhD

Branch Chief with the Office of New Drug Products, Office of Pharmaceutical Quality, CDER/FDA currently supporting radiopharmaceutical drug products. Danae has been with FDA since 1998 and served as a CMC reviewer, CMC Lead and Branch Chief. She has a Ph.D. in Inorganic Chemistry from the University of Michigan and worked previously as a senior research chemist in R&D at Johnson Matthey Inc. and the National Cancer Institute.

Jonathan Cohen, PhD

Highly experienced pharmacologist at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in the Office of New Drugs, supporting the Division of Imaging and Radiation Medicine (DIRM). Dr. Cohen received his undergraduate degree in Biochemical Pharmacology from the State University of New York at Buffalo (1995), and graduate degree in Pharmacology and Experimental Therapeutics from the University of Maryland, Baltimore (2003). Dr Cohen's graduate work characterized serotonergic signaling pathways that contribute to synaptic plasticity in the invertebrate mollusk, Aplysia californica. Following his graduate studies, he was a postdoctoral fellow at the National Institute of Health (NIH), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) where he studied cellular and molecular mechanisms of synaptic plasticity and gene regulatory networks in neuronal and glial development. Dr. Cohen has been at the FDA since 2011, previously in the Center for Biologics Evaluation and Research (CBER), in the Laboratory of Respiratory and Special Pathogens (LRSP) where he conducted regulatory science on comparative genomics of Clostridium tetani and strains producing tetanus vaccines. Since 2016, he has served as pharmacologist/toxicologist reviewer for diagnostic radiopharmaceuticals for SPECT and PET imaging, contrast agents for CT and MRI, optical imaging agents, and medical countermeasures for acute radiation exposure.



Cathy S. Cutler , PhD

Dr. Cutler is Chair of the Isotope Research & Production Department (IP) at BNL. Dr. Cutler has over 30 years of experience in the development and evaluation of radiopharmaceuticals, utilizing bioinorganic and radioanalytical chemistry to develop and evaluate for both diagnosis and therapy. Her research ranges from making use of inorganic chemistry to design new metal-based radioisotopes for use in radiopharmaceuticals and targeted nanoparticles to establishing techniques to evaluate their in vivo behavior. The IP group focuses on developing methods for radioisotope production, novel separation methods to provide carrier-free isotopes, and implementing methods to provide large scale production of radioisotopes for commercial use, clinical trials, and medical applications. Dr. Cutler's current focus is on developing production and separation methods for high specific activity radioisotopes to create a suite of diagnostic and therapeutic agents that can be tailored to the individual patient's needs

David W. Dick, PhD

Clinical Associate Professor and Chief of Radionuclide Production & PET Radiochemistry in the Department of Radiology at the University of Iowa. He received his BS in Physics from Western Washington University, and his MS and PhD in Medical Physics from the University of Wisconsin-Madison. Dr. Dick is co- chair of the SNMMI Quality & Regulatory Affairs Task Force, Past President of the SNMMI

Radiopharmaceutical Sciences Council, member of the SNMMI Clinical Trials Network Radiopharmaceutical Manufacturers Committee, SNMMI Committee on Government Relations, and SNMMI Committee on Radiopharmaceuticals. He has 19 years of experience directing academic PET radiochemistry facilities in compliance with FDA regulations.

Krishna Ghosh, PhD

Medicinal Chemist with over 20 years of industry experience in Product Development, Manufacturing / Quality Assurance, Quality Control and Regulatory Affairs in biotech and pharmaceutical companies. She joined FDA in 2010 and is a subject matter expert for PET and Radiopharmaceutical drug CGMP, 21 CFR Part 11 regulations, 21 CFR Part 211 and emerging technologies with automation, Industry 4.0, cloud computing and device regulations 21 CFR Part 820. She has worked on PET drug applications since 2012 at CDER and helped to review manufacturing and facility inspections since 2013. She managed the ANDA PET drug approval program for facility inspections for about 160 PET producers from 2013- 2015 to get approximately 3000 ANDA applications approved that were submitted to FDA in 2012 according to the FR notice. She has extensive knowledge of sterile drug manufacturing and microbiological controls, Drug GMP's and ICH Q7 and conducted manufacturing facility inspections for PET and Radiopharmaceutical drugs, sterile injections and complex API in Europe, US, India and Japan as a subject matter expert and trained various ORA and CDER reviewers in complex dosage form inspections. She has been engaged with emerging technologies associated with automation, robotics and artificial Intelligence impacting data integrity and sharing her experience and knowledge with PDA, IFPAC, SQA and ISPE. She is the technical lead/chair for FDA PET drug grant project for developing a Robotic QC automation system which has been granted FDA research funding.

Christopher Ignace, PharmD, PhD

Dr Ignace has over 30 years of pharmaceutical experience encompassing new and generic drug development. Over the last 13 years with Cardinal Health, he has supported the initial filing and approval of its ANDAs. Since 2020 he is serving as scientific, regulatory, and quality liaison with drug and medical device companies seeking to develop and market their radiopharmaceutical with Cardinal.

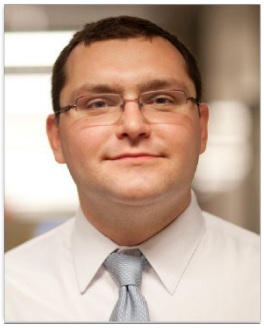
With the growing importance of theranostics, Dr. Ignace is focusing on the risk management and development optimization of new radiopharmaceuticals, as relatively new and non-US based companies with global goals seek to optimize their scientific, quality, and regulatory approaches for a US approval and successful commercial launch. The right integration of those dimensions remains challenging, yet core to developmental success.

Dr. Ignace is a French Pharmacist with a US Pharmaceutics background (PhD).

Robin Ippisch, PhD

Director of the Radiopharmaceutical Facility and the Director of Research Development in the department of Radiology and Biomedical Imaging at the University of California San Francisco (UCSF). Dr Ippisch received her bachelor's degree in Chemistry from Mills College and her PhD in Biomedical Engineering from the University of California Davis. Prior to joining UCSF, Dr Ippisch was a Research Scientist on the Radiopharmaceutical Development team at Avid Radiopharmaceuticals, where she worked on the final development and commercial technology transfers for Tauvid. At UCSF, Dr Ippisch led the pre- approval inspection for the approval of 68Ga-PSMA-11. She currently manages all aspects of the UCSF Radiopharmaceutical Facility, including the NDA/ANDA and IND portfolios.

Serge Lyashchenko, PharmD



Responsible for the pharmaceutical development, clinical translation, and manufacture of novel molecular imaging and targeted radioligand therapy agents. He currently serves as Associate Attending Radio pharmacist, within Department of Radiology, at Memorial Sloan Kettering Cancer Center in New York.

Charles Metzger

Charles Metzger is the Executive Director of three organizations in the field of nuclear medicine and molecular imaging—the Coalition of PET Drug Manufacturers, the Society of Radiopharmaceutical Sciences, and the Southwestern Chapter, SNMMI. He started his own association management company in 2000; he began his career in 1996 as Associate Director of the Southwestern Chapter, SNMMI.

During the last 27 years, Charles—as he served his society leaders and members—has experienced both the gains and the pains associated with field of nuclear medicine and molecular imaging. He strives to build meaningful relationships with society leaders and members as he manages his various duties, which include assisting with regional, national and international events related to the field.

Ashley Mishoe, PharmD

A nuclear pharmacist and is currently the Vice President of Regulatory Affairs and Quality Assurance at Pharmalogic, where she oversees all regulatory compliance and quality-related aspects for the company's manufacturing facilities.

Before assuming her current position at Pharmalogic, Dr. Mishoe served as the Director of the Radiopharmaceutical Facility at the University of California, San Francisco. During her tenure there, she oversaw manufacturing operations for clinical and research radiopharmaceuticals. Additionally, she held teaching positions within the School of Medicine and School of Pharmacy and authored the Chemistry, Manufacturing, and Controls section for UCSF's New Drug Application for 68Ga-PSMA11, the first FDA-approved PSMA PET agent.

Dr. Mishoe earned a Bachelor of Science in Psychology and a Bachelor of Science in Health Sciences, with a minor in music, from Clemson University. Her academic journey continued at the Medical University of South Carolina, where she attained her Doctorate in Pharmacy. While at MUSC, she furthered her qualifications by completing the Authorized Nuclear Pharmacist training certificate and an Interprofessional Education Fellowship.

Beyond her academic and professional roles, Dr. Mishoe actively contributes to the pharmaceutical community. She serves as a member of the United States Pharmacopeia Expert Panel for Small Molecules and maintains active memberships in both the American Pharmacists Association and the Society of Nuclear Medicine and Molecular Imaging, where she was selected as the Henkin Government Relations Fellow in 2018.

Currently, Dr. Mishoe is involved with numerous committees and councils, including the Radiopharmaceutical Sciences Council, the Government Affairs Committee, the FDA Task Force, the Committee on Radiopharmaceuticals, the Coalition on PET Drugs, and the Medical Imaging and Technology Alliance.

Michael Nazerias, MS

Michael has worked in the PET drug regulatory environment since 2000. He has held various RA/QA roles for Siemens Molecular Imaging and PETNET Solutions. He was involved in the development, submission, and approval of the first ANDA for [F-18]FDG, as well as ANDAs for sodium [F-18]fluoride and [N-13]ammonia. Michael has submitted over 10 PET Drug INDs and gained approval of several PET NDAs in the US and Market

Authorizations in the EU. He has worked on FDA inspectional responses and been involved in USP standards for PET drugs. Michael is currently Vice President of Regulatory Affairs & Quality Assurance for PETNET Solutions, Inc.

Michael is a past CORAR Board Member and current Chair of the MITA PET Regulatory Committee as well as a participant on the Coalition of PET Drug Manufacturers.

Jiulian Nwoko, BA, BS

Director of Contract Manufacturing at SOFIE, having joined in 2017. He supports the ongoing development of pharmaceutical products in the clinical space as well as assisting contract partners in the validation of their products for the commercial space. He has a great deal of experience in the qualification of commercial products as well as the optimization of the manufacturing and product release environments. He is a graduate of West Virginia University with degrees in Chemistry and Physics

Reiko Oyama, MS, RPh, BCNP

Reiko Oyama is the Director of the Nuclear Pharmacy at Washington University School of Medicine (WUSM) Cyclotron Facility and Nuclear Pharmacy, and also serves as the Quality Assurance (QA) Manager and Pharmacist-In-Charge. She is a Board-Certified Nuclear Pharmacist (BCNP) with over 20 years of experience in PET radiopharmaceutical production.

She received a B.S in Pharmaceutical Sciences in Japan. After obtaining her Japanese pharmacist license, she held several QA pharmacist and staff pharmacist positions in both the private sector and hospital settings. In the latter, one of her responsibilities was compounding Total Parental Nutrition in a clean room. After moving to the United States in 2000, she joined the Cyclotron Facility at WUSM in 2003 and then obtained a Missouri pharmacist license and BCNP certification. She also completed her M.S. in Radiopharmaceutical Sciences in 2017. She has significant experience in sterile pharmaceutical preparation and expertise in aseptic training and operation.

Timothy Pohlhaus, PhD

A Senior Policy Advisor in CDER/OC/OMQ at the FDA. In his 14 years in CDER's Office of Compliance, he has played significant roles enhancing establishment surveillance programs, assessing facilities for pre-approval/pre-license purposes, advising on CGMP compliance actions, and developing CGMP guidance and policy. He has focused on biotechnology, positron emission tomography, and other sterile drug manufacture.

Sally W. Schwarz, RPh, MS, BCNP

An Emeritus Professor of Radiology at Washington University School of Medicine in St. Louis, MO. She is a Board-Certified Nuclear Pharmacist. She served on the United States Pharmacopeia Expert Committee for 10 years and was involved in writing the revised USP Chapter <823>. She served as the Nuclear Pharmacy advocate on the US NRC Advisory Committee for the Medical Use of Isotopes (ACMUI) for 6 years She is a member of the Society of Radiopharmaceutical Sciences (SRS) and received the 2017 SRS Distinguished Service Award. Sally is a Past President of SNMMI, and was the first pharmacist, and 4th woman of 65 SNMMI Presidents to hold this position. She received the ACS Chemical Sciences and Technology Award in 2019. In 2022, SNMMI named an Award in her honor, the Sally Schwarz Award for her work in Radio pharmacy.

Peter J. H. Scott, PhD.

Prof. Peter Scott obtained his PhD in organic chemistry from Durham University in the UK. He then moved to the US for postdoctoral research in organometallic chemistry at SUNY Buffalo, and radiochemistry at the University of Michigan. Peter worked for Siemens Molecular Imaging after his postdoc where he led radiochemistry at their Los Angeles Technology Center. He started his independent faculty career at University of Michigan in 2009, where he is Professor of Radiology, Chief of Nuclear Medicine and Director of PET Radiochemistry. Scott's group is involved in all aspects of Radiopharmaceutical Sciences including i) developing new methods for radiolabeling bioactive molecules, ii) designing and translating new radiotracers for PET imaging, iii) cGMP radiopharmaceutical manufacture and iv) using artificial intelligence to imagine the radiochemistry laboratory of the future. Peter has published over 160 papers and is as an inventor on multiple patents. He has received numerous awards for his research, including the 2023 Sam Gambhir Trailblazer Award from SNMMI.

Henry F. VanBrocklin, PhD, FSNMMI, FSRS

Professor and Director of Radiopharmaceutical Research in the Department of Radiology and Biomedical Imaging at the University of California San Francisco (UCSF). His work in the field spans many radiopharmaceutical science disciplines from short-lived radioisotope production to the development of new strategies for labeling biomolecules with imaging and therapeutic isotopes. His current research interests include

design of imaging agents targeting cancer cell surface markers, preparation of probes for neurodegenerative disorders including AD and ALS, the application of imaging in drug development and elaboration of zirconium- 89 labeled antibodies for various applications including rheumatoid arthritis, HIV reservoir detection and Long COVID. He has interacted with the FDA on Radiopharmaceutical Regulation since 1993 and participated in Coalition activities since its inception in 2011.

Nicholas A. Violand, BS

Nicholas A. Violand is an Investigator/Drug National Expert within ORA Headquarters' Division of Pharmaceutical Quality Programs. He began his career with FDA in 2008 as an Investigator in the New Jersey District, which is now part of the Office of Pharmaceutical Quality Operations, Division I. Focusing primarily on drug CGMP and pre-approval inspections both domestically and internationally, as well as inspections of compounding pharmacies in the State of New Jersey, he has experience with a wide variety of sterile and non-sterile dosage forms, and his work has resulted in many significant regulatory actions. He became a Drug Specialist in 2014, training and mentoring newer Investigators, and a Drug National Expert in 2018, where he continues inspectional work and a focus on training and inspection-related projects. Mr. Violand received a B.S. in Biotechnology from the School of Environmental and Biological Sciences at Rutgers University.

Laura R. Wasil, PhD

Senior Pharmaceutical Quality Assessor (Microbiology) in the Division of Microbiology Assessment I within the Office of Pharmaceutical Manufacturing Assessment at the U.S. Food and Drug Administration, where she reviews sterility assurance and product quality microbiology information in New Drug, Abbreviated New Drug, and Investigational New Drug applications. She received her Bachelor of Science degree in Microbiology from the University of Pittsburgh in 2004, and her Doctor of Philosophy degree in Infectious Diseases and Microbiology from the University of Pittsburgh Graduate School of Public Health in 2012. She has also served as a lecturer in the topics of molecular biology and genetics at the University of Pittsburgh School of Health and Rehabilitation Science, Department of Physician Assistant Studies since 2012. Laura has been involved in the review of applications for traditional and complex Positron Emission Tomography (PET) drug products since joining the U.S Food and Drug Administration in 2017 and serves as a subject matter expert in sterility assurance for these products.

Jill Wilson, BA, RAC

Vice President, RA/QA at Ionetix, joining in 2018 and leading the development of the QA program and first FDA submission. Prior to joining Ionetix, she spent 17 years in the PET industry at SOFIE (formerly Zevacor/IBA Molecular). Ms. Wilson has written and submitted multiple PET ANDAs from submission through approval. She has extensive experience in lifecycle management and has directly participated and overseen well over 30 FDA inspections. Ms. Wilson has a BA in Consumer Affairs from Montclair State University and maintains a RAC certification.

Daniel Yokell, PharmD

Dr. Yokell joined Telix Pharmaceuticals in September 2021. Currently, he is Global Head of Diagnostic Neurooncology, overseeing the late stage development of Telix's assets in this area. Previously within Telix he was the Director of Global Regulatory Affairs Strategy, overseeing the global regulatory strategy for Telix's portfolio of diagnostic and therapeutic radiopharmaceuticals. He is a board- certified nuclear pharmacist, and was previously at Massachusetts General Hospital, Gordon Center for Medical Imaging and Harvard Medical School for over 12 years. During his tenure at MGH, Dr. Yokell was the Associate Director of the Gordon Center PET Core, overseeing the cGMP PET drug manufacturing facility which produced a wide variety of PET radiopharmaceuticals supporting MGH's clinical and clinical research programs. He also had an active research program in developing novel radiopharmaceutical synthesis and quality control methods.

Leo Zadecky, RPh, MS

Captain Leo Zadecky serves as the Senior Review Officer with the FDA's Drug Shortage Staff. Senior Regulatory Review Officer with the FDA's Drug Shortage Staff. After five years of practice in ambulatory and specialty pharmacies, he joined the United Public Health Service and the FDA in 2003 as a Regulatory Management Officer in the Office of Generic Drugs. Additionally, Capt. Zadecky served two years as a Chief Pharmacist Federal Medical Center Devens in the Bureau of Prisons and has served as an Investigator and Supervisor in the FDA's Office of Regulatory Affairs. Since July 2014, Capt. Zadecky has been with the Drug Shortage Staff. In his current role, he interacts daily with various divisions in the FDA, federal agencies, patient advocacy groups, and drug manufacturers to mitigate and prevent critical drug shortages. He received his Bachelor of Science in Pharmacy from Duquesne University in 1998 and a Master of Science in Regulatory Affairs from Northeastern University in 2018.

Steve Zigler, PhD

Steve Zigler began working in PET at the hodist Medical Center in Peoria, Illinois, in the early 1990s. At Peoria, he helped established one of the first PET centers dedicated to clinical patient care and played a leading role in the development, submission, and FDA approval of the first NDA for [F-18]FDG.

Since 1996, Steve has worked for PETNET Solutions, a

Siemens company. At PETNET, he has led various departments, including Q&R, Technical Development, Engineering, and new product development. His work has focused on process development, standardization, documentation, training, validation, technology transfer, and the commercialization of new PET radiopharmaceuticals.

Steve is currently Co-director and a board member of the Coalition of PET Drug Manufacturers. He has served three five-year cycles as a volunteer member of the USP Committee of Experts focused on public standards for PET radiopharmaceuticals.