

Impurities and Contaminants

in Dietary Ingredients and Dietary Supplements

April 21, 2022 • 10:00am – 12:00pm ET

Virtual Meeting

Speaker Biographies

RICHARD KO, Pharm.D., Ph.D.

Member, Dietary Supplements Admission Evaluation and Labelling Expert Committee

Dr. Richard Ko, the founder of herbal Synergy, received his undergraduate degree in biochemistry from the University of California, Berkeley, and his Doctor of Pharmacy and Doctor of Philosophy from the University of Southern California, Los Angeles. His doctoral dissertation was on pharmacokinetic drug interactions. He was a Research Scientist (Food and Drug Scientist) at the California Department of Health Services, Food and Drug Branch, for 16 years. In his government role, he was actively involved in regulating dietary supplements and investigating herbal products related to injury and death. He has published peer review articles and has made numerous presentations in the dietary supplement area. He currently serves on the USP Botanical Dietary Supplements and Herbal Medicines Expert Committee. Dr. Ko is fluent in English and Chinese.

KIT GOLDMAN, Ph.D.

Senior Director, Dietary Supplements and Herbal Medicines

Currently, Senior Director leading the Dietary Supplement and Herbal Medicine Science Team, 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 low molecular weight heparin. She has worked on the development, launch, and technical support of products from brands such as Neosporin, Bengay, and Purell and 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 postdoctoral research at the University of Illinois.

MICHAEL BRADLEY, M.S.

Member, Non-Botanical Dietary Supplements Expert Committee

Michael Bradley, Vice President of Global Quality with GNC Holdings, LLC, has over 30 years of experience in the FDA-regulated Industries for Pharmaceuticals, Dietary Supplements, Conventional Foods, and Cosmetics. His current responsibilities include Quality Control, Quality Assurance, and Regulatory Affairs. He is responsible for the design, development, and overall administration of the GNC's Corporate Quality Management System.

His regulatory expertise includes GMP regulations for Foods, Dietary Supplements, and Drugs, labeling

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regulations for Food, Drugs, and Cosmetics, and a working knowledge of FDA administrative and regulatory practices.

He has expertise in Analytical R&D for Foods, Dietary Supplements, and Pharmaceuticals. His expertise also includes Product Development, and he has participated in the development and commercialization of Dietary Supplements and Conventional Foods. Before joining GNC, his previous roles included Scientific Affairs, Regulatory Affairs, Quality Control, Quality Assurance, and Analytical Validation. He has expertise in applying Official Compendial Standards and Methods, including AOAC, USP-NF, FCC, ASTM, USFDA-BAM, JECFA, and APHA.

Mr. Bradley is certified by the American Society for Quality in Quality Management, Quality Auditing, and HACCP Auditing standards.

Mr. Bradley is also certified by the Regulatory Affairs Professional Society in Regulatory Affairs principles.

Mr. Bradley received his Bachelor of Science and Master of Science degrees in Food Science from the University of Massachusetts at Amherst.

JAMES P. KABABICK

Member, Botanical Dietary Supplements and Herbal Medicines Expert Committee

James P. Kababick is the founder and Director of Flora Research Laboratories, LLC (FRL), specializing in the research and analysis of botanicals, dietary supplements, and related compounds. Following his botanical microscopy training at FDA, he spent many years as an adjunct faculty at Bastyr University, where he taught botanical drug identification by microscopy and thin-layer chromatography. He continues to provide education in dietary supplement quality control testing to students of the Botanical Medicine Department through their field learning program. In addition to his work at the private research & testing lab and university, he serves on multiple expert committees for AOAC, USP, NIH, AHPA, and others.

Currently, his work is focused on the utilization of modern analytical technologies in the investigation of dietary supplements and other agricultural products. He is the pioneer of the field called “Phytoforensic Science.” Phytoforensic Science involves utilizing numerous technologies from microscopy to mass spectrometry to detect adulteration and contamination in the global food supply chain with a special focus on dietary supplements. He has developed and presented the Standardized Phytoforensic Approach (SPA) and the Crossover Analytical Technique (CAT) to address strategic approaches to clandestine adulteration and DNA identity issues, respectively. In 2010 James was named “Fellow of AOAC.” Fellow of AOAC is awarded to scientists for meritorious service to the

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scientific society and their field of science. It is the second-highest honor the organization bestows upon scientists. James is also a renowned expert in the detection of clandestine pharmaceutical adulteration of dietary supplements. He developed expanded screening panels for PDE-5 inhibitors (E.D. drugs), weight loss drugs, steroids, sedative drugs, and synthetic cannabinoids (SYNCAN panel). He appeared on the Dr. Oz Show to help educate consumers about the growing clandestine adulteration problem with tainted dietary supplements. He served as the vice-chair of the USP Screening for Undeclared Drugs and Drug Analogs (SUDDA) Expert Committee, joining experts globally to apply the phytoforensic approach to address methodology approaches for investigating clandestine adulteration of dietary supplements.

He served as the Vice-Chair (2020-2021) & member (currently) of the 2020-2025 USP Botanical Dietary Supplements & Herbal Medicines Expert Committee, the USP Joint Standard Settings Subcommittee, the Subcommittee on Modern Analytical Methods, the USP Dietary Protein working group, and the Saw Palmetto Modernization working group. His collaborations include developing databases and spectral libraries for rapid identification of botanicals, compounds, and clandestine drugs, presenting lecture series, and teaching hands-on training courses in the phytoforensic sciences. He is the co-author of several papers related to dietary supplement adulteration, chemical profiling of botanicals, and collaborative studies and was the co-developer of the AOAC Validation of Dietary Supplement Analytical Methods, Validation of Quantitative Chemical Test Methods, and BSI-NIH funded Method Development and Validation of Dietary Supplement Analytical Test Methods training courses which he taught for many years. James routinely assists various federal agencies in collaborations, including the various FDA field offices, the FDA Office of Criminal Investigation, the FDA Forensic Chemistry Center, U.S. Department of Justice, US Customs and Border Enforcement, as well as the DEA, BATFE, and various state agencies throughout the country. He has served as an expert witness for the United States Department of Justice and various state justice departments.

BINU KOSHY, Ph.D.

Senior Scientist II, Dietary Supplements and Herbal Medicines

Binu Koshy joined USP as a Scientific Liaison in 2019. Before joining USP, Binu worked at Tishcon Corp., an FDA-inspected dietary supplement manufacturing facility in Salisbury, Maryland, under various capacities. He joined Tishcon as a Senior Microbiologist and was later promoted to Q.C. Lab manager and then to Director, Quality Control, responsible for managing the Quality unit. He has vast experience in product formulation and testing dietary supplement products. After joining USP, he worked in the dietary supplements group on developing new and modernizing existing USP monographs, especially probiotics and proteins.

Binu received his Ph.D. in Biological Sciences from the Indian Institute of Science (IISc), India. He completed his postdoctoral research in IISc, where he studied the differential gene expression pattern in *Candida albicans* and *Saccharomyces cerevisiae* under stress conditions using Microarray.

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AMY L. ROE, Ph.D., DABT, ATS

Dietary Supplements Admission Evaluation and Labelling Expert Committee Member

Dr. Roe has 22+ years of experience as a practicing toxicologist in government, pharmaceutical, and consumer product industries through positions at the FDA and The Procter & Gamble Company. Her professional experience is in general, descriptive, and regulatory toxicology, as well as specialized expertise in drug/xenobiotic metabolism and pharmacokinetics. Her industry experience is quite broad and includes toxicology support of drugs, medical devices, herbal/dietary supplements, foods, and water filtration devices. As a project leader, she has led multi-disciplinary drug development teams. Dr. Roe is a board-certified toxicologist (DABT) and a Fellow of the Academy of Toxicological Sciences (ATS). She is well-recognized externally in her field, as evidenced by her service on a number of professional boards and committees, including USP Dietary Supplement Admission Evaluation & Labeling Expert Committees and Probiotic Expert Panel, SOT Regulatory & Safety Evaluation Specialty Section (Past-President), Food Safety Specialty Section (Vice-President Elect) and an NIH/NCCIH Expert Advisory Panel related to natural product-drug interactions. Dr. Roe is currently serving as co-chair of the hepatotoxicity/ADME sub-committee of the HESI Botanical Safety Consortium. She also serves on the Editorial Board of Applied In Vitro Toxicology.