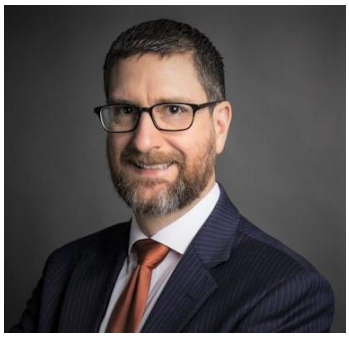
USP Open Forum

Improving the Pharma Environmental Footprint

Virtual Meeting:
February 21, 2023 • 9:00–11:00 am EST

Speaker Biographies



Darcy J. Gentlemen, Ph.D.

Senior Stakeholder Engagement Manager

Darcy is a senior manager in the stakeholder engagement department within Global External Affairs. With the objective of convening stakeholders through Sectors of the USP Convention, his portfolio includes dietary supplements, excipients, and innovation. Programming in 2022 included prospects of advanced manufacturing and supply chain resiliency, supporting healthcare practitioners' work guiding patients/consumers to choose quality products, and the interfaces of digital tools for trusted public health. Before joining USP in 2020, Darcy had several roles in science communications and/or policy, including programming public conversations between artists and scientists at the National Academies, running congressional briefings for the American Chemical Society, and serving as the managing editor for Environmental Science & Technology. He has a Ph.D. in analytical chemistry from Arizona State University and an Hon. B.Sc. in Planetary Science and also Chemistry from the University of Toronto.

Jennifer Devine, J.D.

Senior Vice President *Documentary Standards & Compendial Policy*

Jennifer Devine is Senior Vice President, Documentary Standards and Compendial Policy at USP. In this role, Ms. Devine leads activities related to the development of documentary standards for small molecules, excipients, foods, dietary supplements, and herbal medicines. She is responsible for developing and executing the strategy for the development of quality standards and helps ensure standards evolve in a manner to maximize USP's public health impact.

Ms. Devine earned her undergraduate degree at the University of Maryland, College Park, and her Juris Doctorate from Delaware Law School. She also holds a Master of Laws (LL.M.) in International Law from Georgetown University Law Center. College of Pharmacy and Health Sciences National Advisory Council, and is a member of the American Pharmacists Association (APhA), Alliance for Pharmacy Compounding (APC), American Association of Pharmaceutical Scientists (AAPS), and the National Community Pharmacists Association (NCPA).

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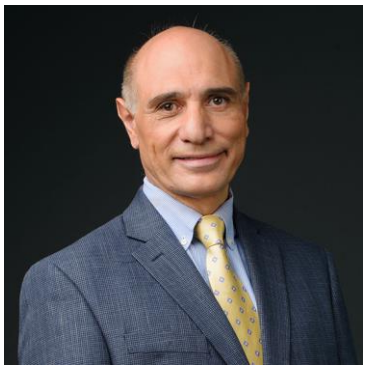

Gabriel I. Giancaspro, Ph.D.

Distinguished Scientific Fellow

Dr. Giancaspro is the Head of Compendial Policy in the Global Standards and Science Division of USP. His department is responsible for ensuring consistency in the development of all USP standards and supporting solutions. He works with other departments to develop compendial policies and approaches supporting the execution of the strategy for standards development.

Previously, he was the Vice President for Dietary Supplements and Herbal Medicines in the Documentary Standards Division at USP, responsible for the development of monographs and general chapters for botanical and non-botanical dietary supplements, safety evaluations, performance standards, and the publication of the USP Dietary Supplements Compendium and Herbal Medicines Compendium.

Before joining USP, Dr. Giancaspro's teaching and research experience including medicinal chemistry, drug analysis, and drug stability at the University of Buenos Aires Pharmacy School. He also has extensive industrial experience as the former Technical Director of Rigecin, Schwabe-Argentina, and Kampel-Martian, in charge of Regulatory Affairs, Analytical Research, Development, and Quality Control of parenterals, herbal medicines, and oncological medicines.

Dr. Giancaspro holds a Pharmacist degree and a Ph.D. in pharmaceutical sciences (medicinal chemistry) from the University of Buenos Aires, Argentina.

Lina Bader, Ph.D., PMP

Lead – Transforming Vaccination Globally & Regionally | International Pharmaceutical Federation (FIP)

Lena supports FIP to achieve the 2030 Sustainable Development Agenda through pharmacy and the FIP Development Goals. I continue to be part of the FIP leadership team and lead a number of strategic programmes that support the delivery of FIP's mission to advance the pharmacy profession nationally, regionally, and globally.

As Lead for Equity, sustainability policy, and development, I'm charged with developing, leading, and delivering activities that facilitate the implementation of all the FIP DGs with measurable outputs, with

a specific focus on equity, sustainability, and access.

She also provides focused support, policy analysis, and development for the goals around equity and sustainability, as well as the related goal of access. She has a key role in the evaluation of the implementation of the FIP global roadmap and in advocacy and outreach activities relating to the Goals.

Isamir Martinez, Ph.D., PMP

Scientific Alliances & Business Engagement Manager | American Chemical Society, Green Chemistry Institute (ACS-GCI)

Dr. Isamir Martinez is currently the Scientific Alliances and Business Engagement Manager at the ACS Green Chemistry Institute®, leading efforts to enable the implementation of green chemistry and engineering throughout the global chemical enterprise by working with the ACS GCI Industrial program, engaging stakeholders and other strategic collaborative programs. Extensive scientific background in organic chemistry, medicinal/process/pharmaceutical chemistry, biocatalysis, chemical sourcing, and green chemistry. Before joining ACS, I worked at Neurogen Corporation, Pfizer Pharmaceuticals, and consulted for several years, building alliances, managing projects, and developing business with biotechs and Contract Research Organizations (CROs). She has also taught organic chemistry courses at Quinnipiac University & University of Connecticut. Throughout her career, Isamir gained broad experience developing, implementing, and promoting innovative technologies while managing projects in a cross-functional, multidisciplinary, and global team environment.
Isamir holds a Ph.D. in Organic Chemistry from the University of Connecticut and a B.S. in Chemistry from the University of Puerto Rico. After her Ph.D., she served as a Dreyfus fellow at Connecticut College. She has a Master's Certificate in Applied Project Management, is PMP certified, and has been an ACS member since 1994.

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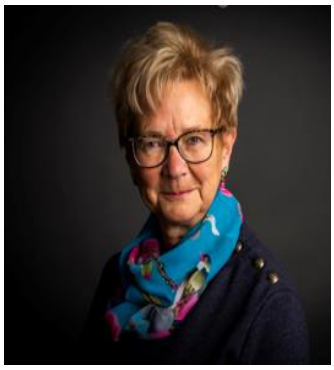
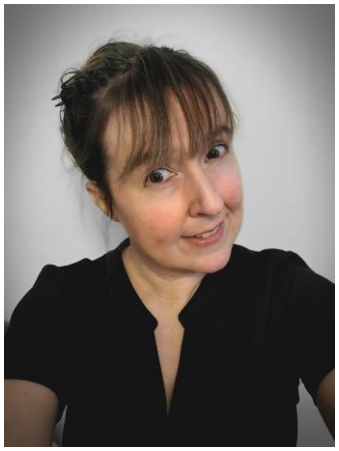


Jane Weitzel, Ph.D.

Chair of USP's Expert Committee on Measurement and Data Quality

Jane Weitzel has worked in analytical chemistry for over 40 years in the pharmaceutical and mining industries. She was elected to the USP Council of Experts as chair of the 2020-2025 General Chapters–Measurement and Data Quality Expert Committee. Recently she has been focusing on implementing the new USP General Chapter <1220> Analytical Procedures Life Cycle, and this includes using measurement uncertainty to support implementing green chemistry initiatives.



Danielle Seiler

Director, Proof of Concept Lead

Danielle leads the proof of concept (PoC) function within Digital & Innovation (D&I), which entails managing and developing a portfolio of early-stage projects through research and evaluation and working with the Senior VP, D&I, to shape and stand up the PoC team. She identifies and investigates promising technologies and trends. Investigation will include conducting preliminary research of new D&I projects to inform potential organizational applications and fit and developing strategic plans to further assess the potential for broader organizational strategic investment. Danielle manages a diverse portfolio, working both within D&I and in close collaboration with stakeholders across the organization according to the needs of the specific initiative.

Susan Moini, Ph.D.

Director of Analytical Development Laboratory

Susan oversees USP analytical development laboratory to develop and validate analytical procedures for USP/NF monographs. Her group works on a wide range of projects, including small molecules, excipients, and dietary supplements. The project's goal is to fulfill the USP initiative for modernizing outdated monographs by eliminating hazardous reagents and applying newer and more efficient analytical technologies. This initiative has significantly enhanced the testing quality and reduced the solvent consumption for hundreds of monographs. Before USP, Susan worked in varying positions at Wyeth and Pfizer's R&D departments.