Stakeholder Forum

USP Prescription/ Non-Prescription

April 11, 2022 | April 12, 2022
8:00am - 12:00pm ET
Virtual Meeting

Biographies

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

Ronald T. Piervincenzi, Ph.D., has served as Chief Executive Officer of the United States Pharmacopeia since February 2014. Dr. Piervincenzi provides strategic leadership to USP's global staff of over 1,300 across sites in the U.S. (Rockville, Frederick, D.C.), India, China, Ghana, and Switzerland, and global public health field offices, including Nigeria, Indonesia, Ethiopia, and Kenya. His transformative vision has launched key USP initiatives in bringing quality across the healthcare spectrum, upholding USP's reputation as a quality leader since its founding in 1820. Under his leadership, USP has modernized its operations and launched innovative new science, including in the areas of digital medicine, cutting-edge manufacturing technologies, and advanced biologics. USP has recently begun building a robust "capability building" services suite of offerings, including quality manufacturing consulting, donor-funded work, and education. Dr. Piervincenzi served as Chair of the Council of Experts, USP's scientific standards-setting body of 24 Expert Committees and over 750 standards-setting experts, until June 2015, when he transferred this responsibility to USP's new Chief Science Officer. Dr. Piervincenzi earned his M.S. and Ph.D. from Duke University in Biomedical Engineering, with research focused on protein engineering.

Jennifer Devine, J.D.
Senior Vice President, Documentary Standards and 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 to maximize USP's public health impact. Ms. Devine has held various jobs at USP, working on scientific, regulatory, legal, international, policy, and patient safety issues. She also held several leadership roles at the U.S. FDA, first in CDER's Office of Compliance and then as the Associate Commissioner for Global Regulatory Operations and Policy. In these positions, Ms. Devine helped shape and implement FDA's globalization strategy, providing direction and oversight as FDA worked to address the challenges of a global supply chain. 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.

Edwin L. Gump, Ph.D.
Vice President, Small Molecules

Ed Gump is currently the Vice President of the Small Molecules Department at USP, which develops USP documentary standards for prescription and Over-the-Counter (OTC) medicines. Before joining USP in 2018, Ed worked for Boehringer Ingelheim Pharmaceuticals for over 20 years, primarily in new drug development. He contributed to developing and commercializing both small molecule and biologic drugs.
Ed is an analytical chemist by training and holds a Ph.D. in Analytical Chemistry from the University of California at Riverside and a B.S. in Chemistry from the University of California at Santa Barbara.

Danita Broyles
Associate Director, Quality Assurance

Danita Broyles, M.S., Senior Market Development Manager Danita is a proud alumnus of Rust College in Holly Springs, MS, where she graduated Summa Cum Laude with a B.S in Chemistry. She then attended the University of Memphis and the University of Tennessee-Memphis Health Science Center. She obtained a dual degree M.S. in Biomedical Engineering with a concentration in Biosensors and Instrumentation from this program. Danita has worked in the pharmaceutical industry for over 17 years, starting with eight years of extensive laboratory method development and raw material release testing. Danita worked for eight years in compendial affairs roles, focusing on advocacy and compliance activities with global and national pharmacopeias. While working in the pharmaceutical industry, Danita served in and chaired or sat on the board of several industry trade association groups and USP project teams. Danita also led the development and implementation of LEAN/Six Sigma business processes to support the deployment of systems with a focus on compendial compliance. Danita then leveraged her passion for global patient safety via compendial compliance and moved to the United States Pharmacopoeia as a Senior Market Development Manager in 2019. She led and managed the market development for the USP Ingredient Verification Programs for both APIs and Excipients and worked with many excipient manufacturers through positive collaboration to obtain monograph donations to support the Up to Date initiative for Excipient monographs. Danita returned to the pharmaceutical industry in 2021, where she serves as Associate Director of Quality Assurance for Harmony Biosciences, where her primary focus is leading stability and analytical compliance activities.

Danita enjoys working in many philanthropic activities in her spare time. She has been the current Chairperson for the past ten years of LEAD Scholarship Foundation, Inc.; a 20-year-old nationally recognized 501(c)3 nonprofit that provides scholarship and mentoring opportunities to high school

seniors who have overcome adversity. Danita enjoys event planning to raise money for various charities. She has worked with different organizations to produce pageants, balls, banquets, fashion shows, casino nights, golf outings, etc., as fundraisers to help those in need. Danita is the proud wife of a navy veteran(GO NAVY). She enjoys spending spare time with her many nieces and nephews, discussing Marvel movies, Star Wars, or performing science experiments.

Naiffer Romero, MSc, MPH
Sr. Manager Scientific Affairs LATAMSr. Manager Scientific Affairs LATAM

Naiffer has more than 18+ years of pharmaceutical industry experience. In his 10+ years tenure with USP, he has served several roles: Lead scientist in the dosage form performance laboratory, reference standard development team, Manager in charge of LATAM Compendial engagement and education, responsible for stakeholders and national regulatory bodies engagement. Naiffer is also a certified USP Education instructor.

Most recently, Naiffer joined USP's Scientific Affairs performance cell, where he leads scientific outreach and engagement for LATAM & U.S. on key national health priority topics. His combined pharmaceutical expertise includes Analytical Development, salt and polymorph selection, Development of dissolution methods, IVIVC modeling, and impurity analytical strategy. Naiffer also serves as a member of USP's Nitrosamine Steering Committee and community host to 'Nitrosamine Exchange,' a knowledge community in All-things Nitrosamine.
Naiffer also liaises technical discussion on pharmacopeial collaboration, including International meetings of World Pharmacopeias (part of WHO).

Frank A White III (Trey), Ph.D.
Senior Director, Digital Platforms & Delivery

Frank (Trey) White joined USP over six years ago and brings more than 25 years of diverse experience in laboratory research, informatics, I.T., and product development as Senior Director, Digital Platforms & Delivery, in the Digital and Innovation group.
His role at USP includes developing, coordinating, and oversight of the strategy for delivering our documentary standards to customers and stakeholders through new platforms and business models. Since 2021, he is also the Chair of the Data Integration Office, whose focus is to improve data quality and interoperability at USP.
Dr. White received his Ph.D. in Molecular and Cell Biology from The Pennsylvania State University. His research focused on gene sequence and expression analysis of the J.C. virus.
Jessica Simpson, MPH

Senior Manager, Executive Secretariat

Jessica Simpson has been with USP for 14 years, working with the volunteers and stakeholders throughout her time. She earned her B.S. in Biology from James Madison University and her Masters of Public Health from Johns Hopkins. Prior to working at USP, she did immunology research at the National Cancer Institute.

Christine E. Feaster
Vice President, Global Commercial Operations

Christine E. Feaster is Vice President, Global Commercial Operations.
In this role, Mrs. Feaster is responsible for all global commercial activities. She has a keen awareness of the public health impact of all strategies and plans that effectively enables her to prioritize this aspect of her team's work. Mrs. Feaster is responsible for building and shaping a world-class team with a global mindset and oversees the strategies for Strategic Customer Development, Key Account Management, Channel Strategy, Customer Experience and Service, Commercial Effectiveness, as well as the North American Region strategy. Mrs. Feaster's role is to improve customer insights for meaningful and fuller engagement and improve public health through USP's products and services worldwide.
Before assuming her current role, Mrs. Feaster held various leadership positions at USP, including the Head of Chemical Medicines and Dietary Supplements Strategic Marketing and Program Operations and the Global Quality Assurance department.

Mrs. Feaster has over twenty years of leadership experience in the highly regulated pharmaceutical, biologics, and dietary supplement industries. Before joining USP, Ms. Feaster held various executive positions, most recently as Chief Operating Officer and various Quality leadership roles at Baxter, NABI, and Nutramax Laboratories. Mrs. Feaster earned her Bachelor of Arts from Notre Dame of Maryland University in Biology and Philosophy and attended the University of Pennsylvania, Wharton School of Business, Executive Programs.

Mark Wiggins, Ph.D.
Owner and Compendial Consultant

Mark Wiggins is the Owner and Compendial Consultant with Global Pharmacopoeia Solutions LLC, which he formed after more than 30 years of experience in the pharmaceutical industry. He was previously Director of Compendial Affairs at Merck, with more than 15 years' experience submitting new and revised monographs to pharmacopeias and reviewing and responding to proposed

compendial changes from around the world. He also has experience in the testing and release of excipients for use in formulation design, scale-up, and clinical supplies in support of new product R&D, and in the synthesis and characterization of active pharmaceutical ingredients for use in the treatment of HIV/AIDS, cancer, diabetes, hypercholesterolemia, and depression. Mark has been an active participant in pharmaceutical industry associations in the U.S. and abroad and represented PhRMA on the ICH Q4B activities to harmonize general chapters in the pharmacopeias. He has been an invited speaker at international meetings in the U.S., U.K., Europe, India, Japan, Korea, and China, including the Ph. Eur. workshop "Quality of Medicines in a Globalized World." Mark holds B.S. and M.S. degrees in Chemistry from Trinity University and the University of Wisconsin.

Mark is co-authored a comprehensive series of twelve articles on pharmacopeia compliance that have been published as online regulatory sourcebooks for the journals Pharmaceutical Technology and BioPharm International

Joe Albanese, Ph.D.
Managing Director and Consultant

Joe Albanese is the Managing Director and Consultant with Albanese Consulting LLC, which he formed after more than 29 years of experience in the pharmaceutical industry. He recently retired from Janssen Pharmaceuticals (part of Johnson and Johnson), where he held positions in R&D, Supply Chain, and Quality in both Small Molecule and Biotherapeutics Development and manufacturing. As part of his duties, Joe was responsible for the compendial vigilance process for all Janssen products ensuring compliance with all major global and national pharmacopeias. He actively served in industry working groups such as the PhRMA Limited Duration Key Issues Team for compendial issues with USP, the EFPIA Biotherapeutics subteam for the elaboration of biotherapeutic compendial standards. He was a member of the USP General Notices Project Team. He is currently active in the industry trade organizations NJPQCA, Midwest Compendial Discussion group, and PDA that influence global health and compendial authorities. Joe received a B.S. degree. in Chemistry from Elizabethtown (P.A.) College and Ph.D. degree in Chemistry from the University of Delaware.

Joe is co-authored a comprehensive series of twelve articles on pharmacopeia compliance that have been published as online regulatory sourcebooks for the journals Pharmaceutical Technology and BioPharm International

Andrea Torbey (Coming Soon)

Senior Program Manager

Kay Marie Whiten, M.S.
Vice-Chair, Stakeholder Engagement Planning Committee

Kay M. Whiten grew up in Wisconsin, graduating with a B.S. in Chemistry from Carroll College in Waukesha, Wisconsin, where she met and married her husband. After college, she was employed at the Food and Drug Administration as a Control Analyst with the Antibiotic Certification and Testing Group in Washington, D.C. She then moved to New York City, working as a Quality Control Analyst for Lederle Laboratories in Pearl River, NY, while studying at Long Island University in Brooklyn, NY, receiving a Master of Science in Chemistry. At Lederle Laboratories, Kay transitioned to become a Technical Writer, where she began her review of USP publications. During this time, she served the Rockland subsection of the New York Section of the American Chemical Society as a Board member and President. Kay moved to Barr Laboratories in Pomona, NY, first as a Senior Technical Writer and later as a Technical Group Leader. She supervised the input of specifications and methods for launching their first SQL*LIMS platform. After Teva Pharmaceuticals acquired Barr, Kay managed the update of specifications and methods for changes in the USP monographs and general methods. She assisted in correspondence with the USP to comment on USP Pharmacopeial Forum's proposed changes. As Manager, first of Technical Writing and then USP Compliance Support, Kay reviewed and interpreted changes in USP publications, explained their impact to the company at region-wide focus groups and teleconferences, and corresponded with the USP. Kay was recognized in 2019 by the USP for her years of collaboration in standards-setting. Kay has lived in Bronx, NY, for 28 years, where she is close to her twin daughters and two grandsons. She is currently on the Board of Directors and serves as secretary of the Westchester Chemical Society, a subsection of the New York Section of the American Chemical Society.

Antonio Hernandez-Cardoso, M.Sc.
Senior Principal Scientist

Since July 2005, Antonio Hernandez-Cardoso has worked at USP providing general scientific support within the Global Science and Standards Division (GSSD), specifically in the General Chapters Department, coordinating the volunteer experts' works for the development and revision of general chapters by supporting Expert Panels and Subcommittees of the Physical Analysis-, Chemical Analysis-, Dosage Forms-, and Measurement and Data Quality- Expert Committees.

Antonio brought fourteen years of experience in pharmacopeial topics working with the Mexican Pharmacopeia as Associate Director in the Development of its Allopathic, Homeopathic, and Herbal Pharmacopeias and special publications for Medical Devices and Drugstores.

Also, he taught compendial topics to the pharmaceutical industry and several subjects on pharmaceutical sciences at the National Autonomous University of Mexico for over twelve years.

Jose Zayas, Ph.D
Member, Stakeholder Engagement Planning Committee

Jose Zayas, Ph.D., has worked in the pharmaceutical industry for over 35 years, covering all areas from Product Development to Manufacturing Operations. Throughout his career, he managed several remediation projects for companies that were under consent decree. During his tenure in the industry, he worked for SmithKline and Cardinal Health and hosted or participated in over 45 general GMP and pre-approval (PAI) inspections with successful results.
Most recently, he was Vice-President of Quality & Regulatory Affairs at Ionetix Corporation, dealing with a startup that required product development, CMC, and regulatory submission of an expanded access IND, as well as an ANDA. Jose is an expert in quality systems, technology transfer, analytical methods development and validation, and all CMC-related items, as well as manufacturing compliance. He has provided training to the industry in the U.S., as well as in Latin America and the Caribbean. Finally, he founded two contract testing and development laboratories servicing the pharmaceutical industry.
Jose has authored over a dozen publications across multiple disciplines and is the author of a patent and several patent applications. He holds a Ph.D. in organic chemistry from The Ohio State University and completed his postdoctoral in organic chemistry at Princeton University.

Alice Tira
Vice President, Global Quality Systems at United States

Alice M. Tira is Vice President, Global Quality Systems at USP. She oversees all aspects of USP's Global Quality Management System, including the certification to ISO 9001 and ISO 17025. Ms. Tira has over twenty years of leadership experience in the development, implementation, and success of quality programs. Before joining USP, she served as site head of the Quality Assurance department at Valeant Pharmaceuticals (previously Biovail Corporation). During her time at Valeant, Ms. Tira was responsible for overseeing the management of all Quality Assurance activities, spanning from product development to commercial manufacture of pharmaceutical solid dosage forms. Her experience

includes knowledge and expertise in U.S FDA regulations, cGMPs, ICH, ISO 9001, ISO 17025, and ISO 17034. Ms. Tira earned her Bachelor of Science Degree in Environmental Health/Science from Louisiana State University.

Amanda Guiraldelli, Ph.D.
Scientific Affairs Manager - U.S. Pharmacopeia

Amanda Guiraldelli has been with USP since 2012 and holds the position of scientific affairs Manager and principle scientist in the compendial science group-general chapters. She is the scientific liaison to the USP Measurement and Data Quality Expert Committee, where she works to develop and revise USP standards. Previously, Amanda worked as a senior scientist at the USP reference standard laboratory for eight years with characterization of compendial standards. She is visiting professor at the University of Campinas (UNICAMP) Brazil at the Institute of Chemistry. She is a frequent speaker and instructor on topics related to analytical procedure life cycle and Analytical Quality by Design (AQbD). Amanda is a specialist in chromatography, mass spectrometry, and chemometrics and has over 12 years of experience in pharmaceutical R&D areas. Before joining USP, she was an R&D scientist in the pharmaceutical industry and visiting scientist at TU Berlin in Germany and Leiden University in the Netherlands (Center for Proteomics and Metabolomics), working on protein characterization by LC-HRMS and method development using UHPLC-HRMS. Amanda graduated in pharmacy biochemistry and holds a Ph.D. in analytical chemistry from the University of São Paulo (metabolomics by UHPLC-HRMS, GC-MS, and 1H NMR and chemometrics).

Mark Argentine, Ph.D.
Senior Research Advisor in the Product Research and Development

Dr. Argentine is a Senior Research Advisor in the Product Research and Development division of Lilly Research Laboratories, Eli Lilly and Company. He received a B.S. in chemistry from the College of William and Mary in Virginia and a Ph.D. in analytical chemistry from the University of Massachusetts, Amherst. He joined Eli Lilly and Company in 1993 and has been involved in analytical control strategy development and commercialization of synthetic and semi-synthetic drug substances and drug product materials for the past 28 years. Current responsibilities and interests continue to include the development of analytical control strategies for pharmaceutical commercialization as well as the regulatory and quality aspects of drug development. Additionally, he serves as working group chair to the I.Q. Consortium on Analytical Quality by Design/Analytical Method Lifecycle Working Group.

Horacio Pappa
Senior Director of the General Chapters

Dr. Pappa has been with USP since 2003. He is currently the Senior Director of the General Chapters Department, Science division of the USP. He provides scientific leadership to a team of scientific liaisons responsible for the activities of seven different expert committees that cover the majority of the USP General Chapters. Horacio earned his Ph.D. in Pharmaceutical Chemistry from the University of Buenos Aires. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to Chromatography and Validation. Before joining USP, he worked in the pharmaceutical industry in QA/QC. Horacio held the position of Assistant Professor of Quality Control in the Faculty of Pharmacy at Buenos Aires University and Executive Secretary of the Argentine Pharmacopeia from 1997-2001. He is a Quality Engineer certified by the American Society for Quality.

Yun (Jenny) Wang, Ph.D.
Chemist, Division of Lifecycle API

Jenny is an FDA liaison of the USP Expert Panel for the new USP General Chapter <1220>. She has been a CMC assessor in the Office of Pharmaceutical Quality in CDER since 2013. Before joining the FDA, Jenny worked as an analytical chemist for over 13 years in branded and generic pharmaceutical companies. Jenny graduated from the University of Miami with a Ph.D. in Chemistry.

Steven Walfish, MS, MBA
Senior Principal Scientist

Steven is Senior Principal Scientist at United States Pharmacopeia (USP), responsible for the Statistics Expert Committee. Before this role, Mr. Walfish was Principal Statistician at Becton Dickinson in Franklin Lakes, NJ, responsible for supporting continuous improvement efforts and process development for worldwide operations. Mr. Walfish has held roles at G.E. Healthcare, Human Genome Sciences, and Chiron. Steven was President of Statistical Outsourcing Services, a consulting company that provides statistical analysis and training to the FDA-regulated industries.

Steven brings over 30 years of industrial expertise in the development and application of statistical methods for solving complex business issues. Steven has experience applying statistical methods to analytical method verification and validation, and stability analysis.
Mr. Walfish holds a Bachelor of Arts in Statistics from the University of Buffalo, a Master of Science in Statistics from Rutgers University, and an Executive MBA from Boston University.

Anne M. Cook
QA Advisor – Compendial Affairs

- Graduated in 1986 from Western Kentucky University with an ACS Bachelor's degree in Chemistry
- She started the same year with Eli Lilly and Company, where she has worked for almost 34 years
- Her career has included many opportunities, including excipients and chromatography testing per the USP and various Quality Assurance roles, becoming a Compendial Affairs QA Consultant in 2016.
- She took up running six years ago and ran her first marathon last year.