REAGAN-UDALL FOUNDATION FOR THE FDA

Managing Quality and Risk:
Compounding Quality CoE Discussion

Virtual Discussion
Wednesday, October 29, 2025
12:00PM – 1:30PM (eastern time)

Panelists & Moderator

David Short
Chief Quality Officer, QuVa Pharma, Inc.

David Short is a pharmaceutical executive with more than 30 years of experience, specializing in current Good Manufacturing Practices (cGMPs) and parenteral drug manufacturing. As Chief Quality Officer at QuVa Pharma, David brings expertise in Quality and Research & Development, having previously held leadership roles at Par, JHP, and Hospira, where he supported the production of sterile injectables. His career also includes quality leadership positions at Johnson & Johnson, Pfizer, Pharmacia, and Upjohn, overseeing the manufacturing of active pharmaceutical ingredients (API), over-the-counter (OTC), parenteral, and prescription drugs. David currently serves as Co-Chair of PDA's Compounding Interest Group and is a member of ISPE's Community of Practice for Pharmaceutical Compounding. Known for his commitment to operational excellence, David is dedicated to driving continuous improvement in processes and nurturing team development through coaching and training.

Susan Schniepp
Pharmaceuticals Quality Assurance Expert

Susan has over 40 years of quality-assurance experience in the pharmaceutical industry. She has earned several awards from the Parenteral Drug Association (PDA), including Distinguished Author Award, Distinguished Service Award, and Gordon Personeus Award. Serving as a volunteer in a number of capacities, she has served on the PDA Board of Directors from 2011 to 2013 and from 2016 to 2019 and is the immediate past chair of the board of directors. She has served on numerous planning committees, including the PDA/FDA Joint Regulatory Conference Planning Committee since 2002. She writes a column for Pharmaceutical Technology and BioPharm International every other month and also serves on both magazines' editorial advisory boards. She is currently chairing the PDA's ANSI standard on quality culture.

Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer, Reagan-Udall Foundation for the Food and Drug Administration

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her juris doctorate *magna cum laude* from Georgetown University Law Center. She is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.