



Compounding Quality Center of Excellence Quality Discussion

Thursday, September 24, 2026 | 2PM ET

Speaker Bios

Cindy L. Mitman, PharmD, MBA, RPh

Regulatory and Quality Head at the Global Pharmacy Reserve



Dr. Cindy L. Mitman, PharmD, MBA, RPh, BCSCP, CQA, is the Regulatory and Quality Head at the Global Pharmacy Reserve in Apex, North Carolina, where she is helping establish quality and regulatory systems for a 503B outsourcing facility designed around Blow-Fill-Seal technology. She also serves as Principal Consultant at CLM Solutions, LLC, supporting compounding pharmacies, outsourcing facilities, and pharmaceutical organizations. Dr. Mitman is a board-certified sterile

compounding pharmacist and certified quality auditor with more than 20 years of pharmaceutical experience, including at least a decade each in hospital pharmacy and sterile pharmaceutical manufacturing. Her leadership has spanned pharmacy operations, quality assurance, quality systems, regulatory affairs, facility start-up, inspection readiness, and multistate licensure. She has led regulatory inspections and contributed to ISMP initiatives that advance safe medication preparation and use. Her cross-functional career informs her commitment to ensuring patient safety and quality are an organization-wide responsibility.

Morgan Strickland, PharmD

Pharmaceutical Quality & Operations Executive



Morgan Strickland is a pharmacist with 15 years of experience in sterile pharmaceutical operations, including more than a decade leading Quality and Operations within 503B outsourcing facilities. Her experience includes building pharmaceutical quality systems, leading inspection readiness and remediation efforts, and uniting cross-functional teams to solve operational challenges. Morgan is passionate about creating a culture where quality is a shared responsibility and every department understands its role in protecting patients.

David Talmage, MBA
Global Strategic Advisor



With over two decades of experience in the pharmaceutical, biopharmaceutical, and consumer industries, David Talmage is a seasoned expert in manufacturing and quality systems. His career spans a wide range of specialties including cleanroom manufacturing operations, validation, inspection readiness, and process optimization, with a strong emphasis on efficient resource utilization and human behavior.

David has led initiatives in consent decree remediation, quality systems management, product technology transfer, and rapid site growth training. His expertise also includes pre-approval inspection readiness, commissioning and validation, and facility start-up. He is particularly recognized for his deep knowledge in aseptic manufacturing, technical training, and quality systems.

Throughout his career, David has held key roles at leading organizations such as Johnson & Johnson, MedImmune/AstraZeneca, Genzyme/Sanofi, Dendreon, and Bayer HealthCare. He holds a Bachelor of Science in Chemistry from Washington State University and an MBA with a concentration in Operations Management.

Tony Ladner, B.S., Pharm.D
Lieutenant Commander, U.S. Public Health Service, FDA



Born and raised in Minnesota. After high school, I entered the U.S. Navy as an Aviation Structural Mechanic. Upon discharge I attended flight school at Oklahoma State University then flew commercially until 2006 when I began Pharmacy School. Upon Graduation I worked as a Pharmacist at Target in Minnesota, then with the Indian Health Service at Red Lake, MN. In 2013 I was commissioned as an officer in the USPHS. I started at the FDA in November 2015 as a Consumer Safety Officer (Investigator) where I performed approximately 54 domestic and 9 international inspections including API and pharmaceutical manufacturers, P.E.T., 503A Compounding Pharmacies, 503B Outsourcing Facilities and was considered a SME for Compounding Pharmacies in the Northern Midwest region. In 2022 I transitioned to CDER Office of Pharmaceutical Quality/Office of Policy where I am a policy lead concentrating on compounding matters including Bulk Drug Substances, the forthcoming 503B Outsourcing Facilities rulemaking and Compliance Program as well as other compounding policies. I enjoy spending time with my Wife and 5 son's and participating in outdoor activities of hunting, fishing, boating and snowmobiling.

Moderator

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA



Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. Prior to accepting the Foundation post, 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, and other stakeholders with a neutral forum to address domestic and global issues. As Chief of Staff for the FDA (2007-2009), Winckler managed the Commissioner's Office, served both Republican and Democratic

commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her law degree magna cum laude from Georgetown University Law Center. She is an APhA Fellow, served as an elected member of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025) and Chair of that Board from 2019 to mid-2025. In 2023, she received the Distinguished Alumni Award of the Food and Drug Administration Alumni Association and, separately, was awarded the Osterhaus Medal for Lifetime Achievement by the Univ. of Iowa College of Pharmacy.