Compliance Through Science

EAGLE CONSULTING SERVICES

Regulatory requirements from State Boards of Pharmacy, the FDA and the DEA can be confusing and difficult to understand. That's why, in addition to science-based testing and data interpretation solutions, Eagle offers consulting services to meet your operational and regulatory needs. Our scientific experts excel at helping you define your pharmacy's challenges, risks, and opportunities, then discover and implement cost-effective, science-based solutions. With their guidance, you'll feel confident with your compliance.

The services we offer include:

- Facility Design Review — CGMP, USP <795>, USP <797>, and USP <800>
- Operational Flow Analysis and Procedural Review
- Quality Systems Development
- Gap Analysis Audit — USP or 21 CFR
- Standard Operating Procedures Development and Implementation
- Mitigation, Remediation and Regulatory Response Services

We are committed to providing you with:

- Cost-effective regulatory solutions
- Support to pharmacies and CGMP operations
- Solutions that are science-based to meet your specific needs

Our consulting team consists of industry experts dedicated to providing science-based compliance solutions.

- Pharmaceutical manufacturers, pharmacies, medical device companies, and other highly regulated industries
- Global regulatory requirements
- Inspections, remediation, and responses
- Quality systems
- Meeting with state and federal regulators

Ready to get started? Contact Client Care at 1.800.745.8916 for the most up-to-date information on our testing, technical, and consulting services, pricing, and assistance with submitting a sample via EagleTrax.

Consulting Services		
CGMP Quality Systems Development	Environmental Monitoring Program Development	Mitigation, Remediation and Regulatory Response Services
Cleaning Validation	Equipment Qualification	Process Validation
Disinfectant Efficacy Testing (DET)	Facility Design Review	SOP Development and Implementation
Due Diligence Analysis	GAP Analysis/Third-Party Audit	Training

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All pricing in U.S. Dollars and subject to change at any time.

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Our Consulting Team

We've brought together the industry's best and brightest minds to provide you with unparalleled expertise.
Meet the team:

Ross A. Caputo, Ph.D. – President and Chief Executive Officer

Dr. Caputo earned his Ph.D. in Microbiological Physiology and Immunology from Miami University in 1976 and has over 30 years of experience in the FDA-regulated pharmaceutical industry on sterilization research and aseptic processing focusing on process optimization and control. He has authored more than 50 publications and owns 15 patents, all related to infection control, sterilization processes and the production of sterile products. Throughout his career, Dr. Caputo has been an active participant and committee member of organizations such as AAMI/ISO and PDA, which are charged with the development of standards for the regulated marketplace.

David Hussong, Ph.D. – Chief Technical Officer

Dr. Hussong earned his Ph.D. in Microbiology from the University of Maryland (UM). He has 46 years of professional microbiology experience, including 30 years with the Food and Drug Administration (FDA), during which time he led the microbiology inputs to the 2004 Guidance on aseptic processing, and was a lead editor for the 1994 Guidance for sterile product application information. Dr. Hussong is currently the chair of the USP Microbiology Expert Committee for the 2015-2020 cycle. He has been a member of the Parenteral Drug Association since 1993 and the American Society for Microbiology since 1975.

Robert E. Bryne, Ph.D. – Vice President of Scientific Affairs

Dr. Byrne earned his Ph.D. in the Department of Chemistry at the University of Notre Dame in 1980. He continued his academic studies as a Post-Doctoral Research Fellow and as a Research Associate/Assistant Professor at the University of Chicago. Robert has an extensive industrial background in R&D and Operations. At Baxter Pandex Diagnostics, Robert was responsible for protein purification and characterization of natural and recombinant proteins and synthetic peptides, which were used in the development of infectious disease immunoassays. He has also managed GMP/GLP laboratory operations and has also contributed quality and regulatory consulting services in the medical device, drug and vaccine industries.

Lisa Johnson, BS – Vice President of Marketing and Business Development

Lisa joined the Eagle team in November 2017 with over 20 years of experience in the pharmaceutical compounding industry. Her previous experience prior to her long tenure at PCCA included sales at Spectrum Pharmacy Products and Meridian Pharmaceuticals Lisa has a strong understanding of the marketplace and regulations specific to compounding pharmacies. Her formal education includes a bachelor's degree in business and marketing from the University of Phoenix.

Mary "Mick" Moriva, BA – Subject Matter Expert on Quality Assurance and Regulatory Affairs

Mick brings extensive experience to the Eagle team as a quality assurance professional with over 20 years' experience in the areas of quality assurance, quality management systems and regulatory inspections in the medical devices, biotech, compounding pharmacy and nutraceutical industries. Mick is a subject matter expert in all areas of quality control and quality assurance. While at Pharmaceutical Systems Incorporated, Mick was responsible for training pharmacy clients in the requirements of USP <795> and <797> as well as aseptic processing techniques. Mick's formal education includes a degree in professional management from Lake Forest School of Management.

Jay Patel, Ph.D. – Director of Analytical Sciences

Dr. Patel joined the Eagle team in 2021 and has extensive experience in analytical chemistry and synthetic organic chemistry. Previously, he was the Manager of Research & Development and Quality Control at WDPrx, where he successfully managed multiple NDA/ANDA projects from their inception to commercial launch by navigating them through the rough waters of regulatory agencies. Prior to his work at WDPrx, He spent time in academia as a Research Scientist at The University of Texas Medical Branch, and as an Adjunct Assistant Professor of Chemistry at Fordham University and St. John's University.

Jeff Gloyer, MS – Principal Engineer

Jeff joined the Eagle team in 2018. Jeff received a Bachelor of Science in Engineering and a Master of Systems Engineering from Arizona State University. He has experience working in multidisciplinary teams to implement the engineering design process. Jeff led projects in many different sectors, including the energy, automotive, semiconductor, aerospace, robotics, and pharmaceutical industries. He brings cross-industrious experience from working with cleanroom spaces for both the satellite and semiconductor manufacturing industries.

Jacqueline Esqueda, PharmD – Senior Business Development

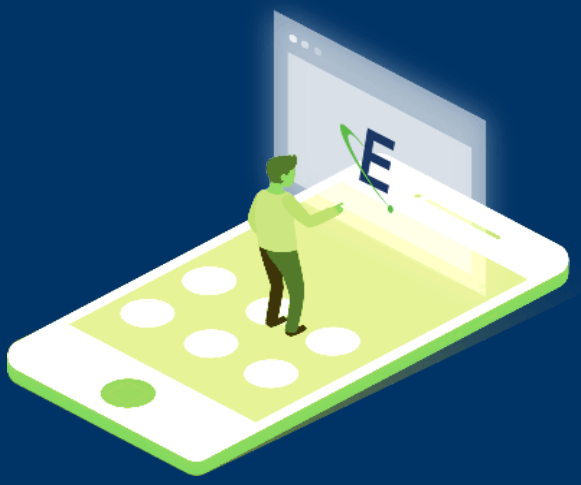
Dr. Jacqueline Esqueda received a Bachelor of Science in Chemistry and later received a Doctor of Pharmacy from the Feik School of Pharmacy in San Antonio. Prior to joining the Eagle Team, she worked as an R&D Scientist for a contract drug manufacturing organization where she was responsible for analytical method development, formulation development, and process development from the laboratory through the manufacturing scale. As a pharmacist, Jacqueline was responsible for the startup and production operations of a 503B outsourcing facility including but not limited to the development and implementation of all SOPs, formulations, processes, and the training of all staff in both sterile and non-sterile drug production.

Melissa Stappen – Microbiology Manager

Melissa Stappen joined the Eagle team in 2022 as the Microbiology Manager. Melissa comes to Eagle with over 30 years of experience in the pharmaceutical, medical device, and biotech industry. Prior to the pharmaceutical industry, Melissa started her career in the clinical laboratory/healthcare provider setting. During her career she has provided support to quality assurance, quality control, and compliance departments regarding quality systems, investigations, and endotoxin testing.

Yu-Ting Wu, Ph.D. – Bio-Technology Laboratory Manager

Dr. Yu-Ting Hu earned her master's degree in Systematic Bacteriology and a Ph.D. in Environmental Microbiology from the Institute of Microbiology, Chinese Academy of Sciences. She completed her postdoctoral research at Cornell University in Metabolic Engineering and Protein Engineering. Her expertise involves microbiology, biochemistry, and molecular biology. Before joining Eagle, Dr. Hu worked in academia and industry for many years as an associate professor, chief scientist, and director at prominent research institutes and at Fortune 500 enterprises. She has extensive hands-on experience in pharmaceutical and biotech R&D and product industrialization.



Ready to Get Started?

Call the Eagle Client Care Team at 800.745.8916 to request an initial consultation and discuss your operation's specific needs.

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