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
- 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.
Eagle consultants have over 150 years of extensive experience in:

- CGMP operations, 503A compounding pharmacies and 503B CGMP outsourcing facilities
- 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 and consulting services, pricing, and assistance with submitting a sample via EagleTrax.

Consulting Services
503A - USP <795>, <797> & <800>
503B CGMP & Pharma - 21 CFR Gap Analysis Audit
New Facility Construction Project Management
Mitigation, Remediation and Regulatory Response Services and more

11111 S. Wilcrest Dr. #S1000 Houston, TX 77099 | 800.745.8916 | eagleanalytical.com

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

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 product. 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 microbiologyexperience, 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.

Megan Jeffrey Liotta, MS - Vice President of Consulting

Megan joined the Eagle team in 2018 after being the Quality and Regulatory Affairs Director at PCCA for over 10 years. Recognized by most as the instructor of PCCA's Aseptic Technique Compounding Course, Megan brings to the team her decades of experience with microbial identification methodologies (e.g., Ribotyping and 16S sequencing), as well as her industry experience in pharmaceutical manufacturing, sterilization, pharmacy compounding and rapid microbiological methods. She received her master's degree in Biotechnology and Chemical Sciences from Roosevelt University in Illinois.

Mary "Mick" Moriva – 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.

Robert E. Byrne, 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 University of Chicago. Robert has built 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 University of Phoenix.

Jay Patel, Ph.D. – Director of Chemistry

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 crossindustry experience from working with cleanroom spaces for both the satellite and semiconductor manufacturing industries.

Jacqueline Esqueda, PharmD – Senior Business Development

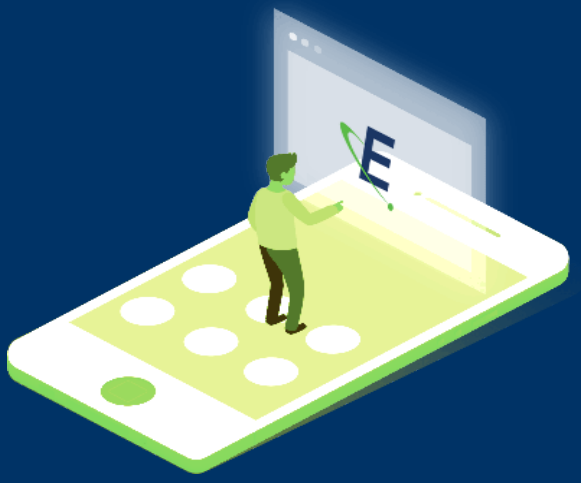
Dr. Jacqueline Esqueda received a Bachelor of Science in Chemistry and later received a Doctor of Pharmacy from the Feik School of Pharmacy in San Antonio. Prior to joining the Eagle Team, she worked as an R&D Scientist for a contract drug manufacturing organization where she was responsible for analytical 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.

Frank Allen, BS, PMP – Director of Operations

Frank Allen joined the Eagle team in February of 2021 as the Director of Operations. Frank comes to Eagle with over 20 years of experience in the Engineering and Operations in the Food and Beverage and Pharmaceutical Industry. Frank has a bachelor's degree in Chemical Engineering from the University of Missouri – Columbia. He has a diverse background in executing and managing capital projects as well as supervision and oversight in a production environment.

Ashley Trueheart, MS - Director of Product Design and Development

Ashley joined the Eagle team in 2015. She earned her master's degree in Biological Science specializing in Molecular Biology from the University of Houston. Prior to joining Eagle, she worked in food microbiology gaining experience in PCR assay testing of detection of major pathogens and environmental samples. Before becoming Eagle's Director of Product Design and Development, she was Eagle's Microbiology Manager. She is a board-certified microbiologist through the American Society of Clinical Pathologists (ASCP), as well as a certified Pharmacy Technician (PTCB).



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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