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 also 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 GMP operation
- 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:

- GMP operations, 503A compounding pharmacies and 503B outsourcing facilities
- Global regulatory requirements
- Inspections, remediation and responses
- Quality systems
- Meeting with state and federal regulators

Ready to get started? Call the Eagle Client Care Team at 832.295.1276 to request a free initial consultation and discuss your operation's specific needs.

Consulting Services	$250-750/hour**
503A - USP <795>, <797> & <800>	Starting at $5,000
503B & Pharma - 21 CFR Gap Analysis Audit	Starting at $10,000
New Facility Construction Project Management	Quote dependent on scope of work requested
Mitigation, Remediation and Regulatory Response Services	$350-750/hour

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.

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EAGLE
SCIENCE-BASED SOLUTIONS

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, PhD - President

Dr. Caputo earned his PhD 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, PhD - Chief Technical Officer

Dr. Hussong earned his PhD 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.

Megan Jeffrey Liotta, MS - Vice President of Operations

Megan joined the Eagle team in 2018, and she is also currently an instructor of PCCA's Aseptic Technique Compounding Course. Previously, she served as the Quality and Regulatory Affairs Director at PCCA. Her experience includes microbial identifications based on nucleic acid technology to include both Ribotyping and DNA Sequencing. Skilled in both aseptic and environmental microbiology, Megan has experience in pharmaceutical manufacturing, sterilization, pharmacy compounding and rapid microbiological methods. Her formal education includes a Master's Degree in Biotechnology and Chemical Sciences at Roosevelt University.

Mary "Mick" Moriva - Vice President of 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 inspectionsin 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, PhD - Vice President of Scientific Affairs

Robert earned his PhD 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.

Dylan Herr - Quality Assurance and Regulatory Affairs Manager

Dylan joined the Eagle team in 2017. Prior to joining Eagle, she worked for five years as the Practice Manager and Compliance Officer of a 503A compounding pharmacy. In this role, Dylan led the development and implementation of quality systems and standard operating procedures, in addition to managing daily operations of the home infusion practice. Dylan also led the pharmacy through NABP, BOP and FDA inspections, and helped them achieve ACHC and PCAB accreditation. Her formal education includes a Bachelor's Degree in Anthropology from Dartmouth College.

Lisa Johnson - Sales, Marketing, and Business Development Manager

Lisa joined the Eagle team in November 2017 with over 20 years of experience in the pharmaceutical compounding industry. Prior to joining Eagle, Lisa spent 13 years at PCCA as a Territory Manager, where she visited pharmacies on a regular basis to keep them aware of both state and federal regulation changes. She has also worked in Sales with 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.

Stephanie Anderson - Technical Specialist

Stephanie brings a wealth of experience to the team, after having joined Eagle in April 2013 and working as a Senior Analytical Chemist. Now a Technical Specialist under Eagle's Business Development Team, she manages all stability studies, and is the liaison between the lab and our customers: writing stability study quotes, and providing associated reports including method validation, stability summary reports, and final stability reports. She has extensive knowledge of ISO 17025, USP, FDA and ICH regulations and guidelines allowing her to provide expert guidance to customers and lab personnel. Stephanie holds a B.S. in Biology from the University of Houston, and is scheduled to complete her MBA from the University of Houston – Victoria in December, 2019.

Jeff Gloyer - Engineer

Jeff joined the Eagle team in 2018. Jeff received a Bachelor's of Science in 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 industry experience from working with cleanroom spaces for both the satellite and semiconductor manufacturing industries.

Chris Trotter - Construction Project Manager

Chris joined the Eagle team in 2018. Chris worked for four years as a building condition assessor for the Department of Defense. In this role, Chris led the development and implementation of field data collection systems as well as leading teams of 10+ assessors to locations all over the world to collect data to help clients forecast building costs for renovations, maintenance and component lifecycles. His formal education includes a Bachelor's Degree in Construction Science from Texas A&M University.

Damon Rogers - Sr. Technical Sales Specialist

Damon joined the Eagle Client Care team in November 2014. Prior to Eagle, Damon worked 20 years for two Fortune 500 companies in the capacity of a District Manager specializing in risk, process improvement, sales, and customer service. Damon brings a wealth of business acumen and leadership experience to Eagle while working closely with Eagle's Business Development, Sales & Marketing, and Consulting teams. Now as the Sr. Technical Sales Specialist at Eagle, Damon provides sales and consulting support for Eagle clients with a focus on UPS <800>, <795> and <797>. Damon studied criminal justice at Texas Southern University.

Jiyun (Jenny) Wang, MS - R & D Supervisor

Jenny joined the Eagle team in 2012. She earned her Master of Science Degree in Chemistry and Biochemistry from University of Windsor in Canada. Prior to joining Eagle, Jenny worked at Apotex Inc for a year as a chemist sampling biological samples according to the requirements of CGMP and conducting bioanalytical method validation and routine sample analysis of biological samples . At Eagle, she does extensive new analytical method development experiences for the compounded drugs and has also developed stability-indicating methods for over 100 different formulations. Jenny is very knowledgeable about the USP, ICH, and FDA regulations and guidelines.

Ashley Trueheart, MS - Microbiology Manager

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. As Microbiology Manager, she leads the microbiology department in coordinating the operations, implementing new procedures, and ensuring polices and standards are being met. She is a board certified microbiologist through the American Society of Clinical Pathologists (ASCP), as well as a certified Pharmacy Technician (PTCB).

Maria Pereira, MS - Chemistry Supervisor

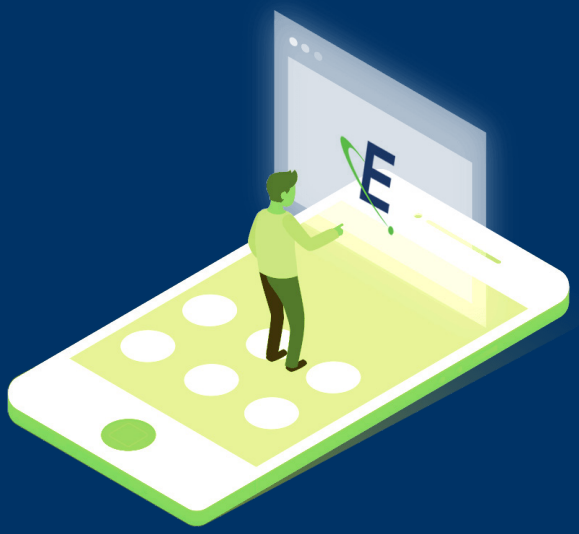
Maria joined the Eagle team in 2018. She earned her Bachelor Degree in Chemistry from Universidad Central de Venezuela and then her Master degree in Industrial Engineer from UNEXPO Venezuela, and also has an Assosicate's degree in Biotechnology from Lone Star College in Houston. Maria has been working in the pharmaceutical industry for over 10 years. At Eagle, she provides guidance to the lab personnel and making sure all the procedures and laboratory guidelines are followed. Maria has extensive knowledge in analytical chemistry and quality control.

Margaret Pereira, MS - Chemistry Supervisor

Margaret joined the Eagle team in 2018. She earned her Bachelor's Degree in Chemistry from Universidad Central de Venezuela and Master degree in Industrial Engineer with emphasis in Quality Control, Quality Assurance, Production and Project Management from UNEXPO Venezuela. Prior to working at Eagle, Margaret worked in the nutraceutical field, where she developed and validated methods for numerous formulations prepared in house. She also worked in the pharmaceutical industry, directly quality control, for over 13 years. Her expertise in analytical chemistry, USP, and GLP allows her to guide the lab personnel to ensure accurate results to the clients.

EAGLE

SCIENCE-BASED SOLUTIONS



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