

Curriculum Vitae

PROJECT MANAGER KELLY FAHRBACH

Phone: 419-693-5307

Summary of Qualifications

Kelly is in her sixth year of skilled microbiology and chemistry laboratory experience in the pharmaceutical and medical device industries; focusing on bioburden and sterility assurance testing, limulus amebocyte lysate (LAL) testing for detection and quantification of bacterial endotoxin on medical devices, and environmental monitoring. She has generated reports of test results, maintained precise documentation, followed many standard operating procedures, charted shelf life data of bacteria created inhouse, and generated protocols for client-specific projects. She has experience in laboratory settings, including basic chemistry and microbiology laboratories, basic microbial techniques and identification of microbes, and executing proper sterile technique. She is the in-house environmental monitoring subject matter expert (SME).

Professional Experience

PROJECT MANAGER, LexaMed, Ltd.

Kelly provides laboratory testing services for clients in the pharmaceutical and medical device industries. Her responsibilities include:

- Specializes in microbiological testing including cleanroom sterility testing, limulus amebocyte lysate (LAL) testing, bioburden enumeration testing, and environmental monitoring.
- Performs Ethylene Oxide BIER unit exposures, analyzes data and generates reports.



Kelly Fahrbach Project Manager

- Experience in quality assurance tasks such as helping maintain company quality systems such as CAPA programs, document control, and maintaining laboratory records and files.
- Authors and reviews Standard Operating Procedures and protocols.
- Exercises proper aseptic technique, thorough documentation, and completes reports and protocols in a detailed and timely manor.

LABORATORY CONSULTANT, MICROBIOLOGY, LexaMed, Ltd.

- Authors, reviews, and approves company and client protocols and reports.
- Performs the testing of products for sterility, bioburden, LAL and environmental monitoring as well as other test methods as required.
- Assures all sample testing data is accurate and conducted in strict adherence to SOPs, cGMPs/QSRs, and FDA regulations.
- Consults on operations and procedures involving environmental monitoring, that includes viable and or non-viable monitoring at clients site.

Education

- ♦ B.S., Biology, University of Toledo, *Toledo, OH*
- ◆ Transfer coursework, focus on Biology, Monroe Community College, Monroe, MI

