



Job Title: Quality Assurance Officer 1
Effective:

Company Overview

TECHLAB®, Inc. was founded in 1989 by scientists from the Virginia Tech Anaerobe Lab, one of only three institutions in the world dedicated to the study of anaerobic organisms. In the late 1970's and early 1980's, research headed by Dr. Tracy Wilkins began on *Clostridium difficile* and its toxins.

Today the company is poised for high growth through private equity funding and develops, manufactures and distributes intestinal diagnostics worldwide retaining an emphasis on science and collaborations with universities. Products are focused in the areas of intestinal inflammation, antibiotic associated diarrhea and parasitology. Research continues on markers of intestinal inflammation, the toxins of *Clostridium difficile*, amebiasis and vaccine development. TECHLAB®, Inc. has ISO 13485 certification along with FDA registration. For more information, visit www.techlab.com.

Job Summary

The Quality Assurance Officer 1 is responsible for ensuring that all TechLab® Inc. products meet the requirements of the quality system. This can include reviewing and tracking product as well as reviewing documentation to ensure it complies with regulatory standards. The Quality Assurance Officer 1 reports to the Quality Assurance Manager or the QA Supervisor.

Work Activities

- Issuing and reviewing MBRs in support of Production schedule
- Issuing/confirming Lot Expiration Dates of Raw Materials, Components and Finished Products
- Create, review and apply QA Release Labels
- Review QC results detailed per SOPs, RMSs and PRSs
- Ensure approved documents (MBRs, SOPs, TLFs) are issued and controlled
- Ensure Controlled Records are controlled and easily retrievable
- Initiating proposed changes as Document Circulation Requests and Sage Change Requests
- Perform Visual Inspection of Raw Materials, Foil/Label Inspection and AQL testing
- Ensure Non-Conformities and CAPA are identified, investigated and controlled
- Initiate Non-Conformity documentation and determine the Quality Impact.
- Approve Lot Expiration Dates
- Approve Raw Materials for Release
- Approve Manufacturing/Packaging MBRs
- Complete projects as assigned by QA Manager or QA Supervisor

Tools and Equipment Used

Ensur document processing system
Microsoft Office Suite

Job Context

TechLab® maintains a climate controlled environment for the job of Quality Assurance Officer 1. An employee in this position must be able to lift upwards of 30lbs. A typical workday is Monday through Friday 8:00 to 4:30 or 8:30 to 5:00. Overtime is occasionally necessary with or without advance notice.

Minimum Qualifications

High School Diploma +2 years of experience in GMP/FDA environment

Associates Degree + 1 year of experience in GMP/FDA environment

B.A. or B.S.