

Blacksburg Location
2001 Kraft Drive
Blacksburg, VA 24060



Radford Location
20 Corporate Drive
Radford, VA 24141

Job Title: Quality Assurance Officer 2
(Effective: 05/17/2024)

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 2 is responsible for ensuring that all TechLab® Inc. products meet the requirements of the quality system. This can include tracking product and reviewing documentation to ensure it complies with regulatory standards. The Quality Assurance Officer 2 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 (DCRs) and Sage Change Request (SCRs)
- Perform Visual Inspection of Raw Materials, Foil/ Label Inspection and AQL testing
- Ensure Non-Conformities and CAPA are identified, investigated and controlledInitiate Non-Conformity documentation and determine the Quality Impact.

- Determining Quality Impact of Non-Conformities and Effectiveness of CAPAs
- Deliver New Hire Training
- Complete projects as assigned by QA Manager or QA Supervisor

- Approve Lot Expiration Dates
- Disposition Pre-Raw/Raw Materials, Components and Finished Goods
- Approve Manufacturing/Packaging MBRs
- Approve Quality System documentation (MBRs, SOPs, TLFs)
- Approve DCRs and SCRs

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 2. An employee in this position must be able to lift upwards of 30lbs. A typical workweek 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 or Associate's Degree + 3 years of experience in GMP/FDA environment

B.A. or B.S.+ 2 year of experience in GMP/FDA environment

Master's Degree +1 year experience in GMP/FDA environment

Life Science degree preferred but not required