

Blacksburg Location  
2001 Kraft Drive  
Blacksburg, VA 24060



Radford Location  
20 Corporate Drive  
Radford, VA 24141

**Job Title: Quality Assurance Officer 3**  
**(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 and FDA registration. For more information, visit [www.techlab.com](http://www.techlab.com).

**Job Summary**

The Quality Assurance Officer 3 is responsible for confirming that all products meet the requirements of the TechLab quality system. This can include releasing and tracking product as well as reviewing documentation to ensure it complies with all regulatory standards. The Quality Assurance Officer 3 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 and verifying proposed changes as Document Circulation Requests (DCRs) and Sage Change Request (SCRs)
- Perform Visual Inspection of Raw Materials, Foil/Label Inspection and AQL testing of packed kits
- Perform Lot Release/Acceptance of Raw Materials, Components and Finished Products
- Ensure Non-Conformities and CAPA are identified, investigated and controlled
- Determining Quality Impact of Non-Conformities and Effectiveness of CAPAs
- Deliver New Hire Training
- Perform impact and risk assessments
- Complete projects as assigned by QA Manager or QA Supervisor.
- Approve Lot Expiration Dates
- Disposition Raw Materials, Components and Finished Products
- Approve Manufacturing/Packaging MBRs
- Approve Quality System documentation (MBRs, SOPs, TLFs)
- Approvals of DCRs, SCR and Non-Conformity Reports

- Approve risk assessments

### **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 3. 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 + 4 years of experience in GMP/FDA environment
- B.A. or B.S.+ 3 years of experience in GMP/FDA environment
- Master's Degree +2 years experience in GMP/FDA environment
- Life Science degree preferred but not required