QUALITY ASSOCIATE - 1
POSITION DESCRIPTION

☐ **Exempt**
☑ **Non-exempt**

About Us:

Bionique Testing Laboratories, Inc. (Bionique) has been a leading global provider of mycoplasma testing services for the biopharmaceutical industry for over 30 years. Bionique offers the full breadth of services from lot and Final Drug Product release testing per regulatory guidelines to a GMP compliant Real-Time PCR assay to support clients' needs from concept to clinical trials and commercialization for biopharmaceutical and cell therapy products. Bionique's experience and expertise extends to development and validation of rapid microbiological methods to support abbreviated release timelines. Additional services such as regulatory and compliance consultancy add to Bionique's unique position in this niche analytical testing space. Located in Saranac Lake, NY, Bionique is an FDA registered and GMP compliant contract testing facility. Bionique aims to offer unsurpassed quality mycoplasma testing services to meet the specific scientific and regulatory needs of each client and partner.

Summary:

This position is responsible for document control and retention of data associated with mycoplasma testing. Assigned projects are multifaceted and this position works independently. The Quality Associate contributes to process improvement and best practice initiatives. This position assures tasks are completed in a timely manner and follows up with other departments as needed.

Key Accountabilities and Responsibilities:

- Assists with GMP training requirements of laboratory staff
- Drafts, edits, approves, and maintains SOPs and/or appendices
- Participates in continuous improvement initiatives
- Coordinates biennial SOP review for staff
- Maintains prep sheets and worksheets
- Trains departmental staff
- Generates reports as needed, including but not limited to CAPA Response Reports
- Assists in the CAPAs of internal audit
- Assists with preparation of and may represent Quality during external client audits
- Liaise with regulatory bodies and participates in regulatory audits
- Supports the Supplier Management Program
- Manages OOS/deviation events when necessary
- Maintains Quality System Tracking Database
- Coordinates FDA Registration
- Maintains Quality archives
- Reviews tracking and trending analytical data
- Reviews/audits assigned daily reports including but not limited to:
    - Protocols
    - Non-conforming event reports

- Additional duties as assigned

Additional Accountabilities and Responsibilities

- Performs jobs responsibilities with minimal direction and completes tasks as assigned
- Proactively communicates progress and furthers understanding amongst colleagues and supervisors
- Highly organized and delivers on commitments without reminders
- Driven to continuously improve individual work and departmental processes
- Handles recurring issues with comfort and escalates new ones appropriately
- Has a basic working knowledge of industry standards
- Accurately performs quality reviews of items as requested
- May serve as a delegated backup for senior staff when requested
- Strong critical thinking and problem-solving skills required
- Subject Matter Expert in equipment and facilities Validation/Qualification

Requirements:

- Bachelor's degree from an accredited college/university in a relevant field; experience or combination of experience with degree may be substituted for Bachelor's degree requirement
- Ability to handle multiple tasks and projects under deadline pressure
- Able to adapt quickly to change
- Strong organizational and time management skills
- Highly analytical with strong attention to detail
- Excellent verbal and written communication skills
- A results-oriented team player
- Proficient with Microsoft Office Suite or related software

Physical Requirements:

- Prolonged periods of sitting on a chair, working at a desk and working on a computer and/or telephone
- Must be able to lift up to 25 pounds

Bionique is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, gender, sexual orientation, gender identity, gender expression, national origin, age, disability, genetic information, marital status, pregnancy status, amnesty, covered veteran, or any other protected status or characteristic protected by applicable federal, state, and local laws.