QUALITY ANALYTICAL DEVELOPMENT MANAGER
POSITION DESCRIPTION

☑ **Exempt**
☐ **Non-exempt**

About Us:

Bionique Testing Laboratories LLC (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 managing and training Quality team members while developing and supporting the Quality Department ensure regulatory compliance and the reliable maintenance of quality standards throughout the organization.

Key Accountabilities and Responsibilities:

- Oversee and lead a team of quality analysts in the performance of QC data review, CoA review and all related QC documents in accordance to Bionique's SOPs and processes.
- Assure that all required QC records (testing, methods, protocols, reports and raw data) are generated and approved.
- Review executed method qualification/validation packages.
- Oversees the guidelines and process recording of test results and reviews documentation by others.
- Troubleshoots and investigates trends in performance of analytical methods used for release and in-process assays
- Provides technical expertise for deviations, OOS/OOT investigations by working in concert with Operations and Quality
- Facilitates the generation of and interpretation of data and the development of process knowledge, quality attributes, and specifications
- In collaboration with the Research and Development division, responsible for assay development, assay technology transfer and assay performance monitoring program
- Responsible for overseeing the review of the reference standards and critical reagents program
- Develops, ensures the delivery of high quality-related documentation to meet global regulatory expectations for analytical methods and controls
- Delivers CMC content pertaining to mycoplasma testing for IND/BLA filings and addresses technical inquiries from regulatory agencies and clients to support clinical trial and commercial marketing applications
- Establish and enable LEAN principles across all areas of responsibility

- Builds and maintains strong working relationships with colleagues in Research and Development, Operations, Quality as well as external (client) counterparts, as applicable
- Identify process gaps, introduce innovative solutions, and lead operational excellence projects within Bionique to improve efficiency and productivity
- Supervises departmental personnel including but not limited to scheduling, time off approvals, ensuring training requirements have been met, staff development, succession planning, and performance management
- Trains and mentors less experienced Quality personnel
- Remains current in the field by review of relevant scientific literature and attendance at appropriate scientific seminars and conferences.
- Additional duties as assigned

Requirements:

- Bachelor's degree from an accredited college/university in microbiology, biology, or a relevant field
- 5+ years' experience in the biotechnology industry with increasing scientific and leadership responsibilities
- Demonstrated broad knowledge and experience in validation of test methods, general analytical analysis including compendia and alternative molecular methods, and specifications development
- Established knowledge of applicable global regulatory standards and current expectations
- Experience in validation and technology transfer of test methods
- Thorough knowledge of CGMPs (CFR/ICH/EU) and applicable international regulations and guidelines as they apply to development and manufacturing of biologics. Experience with CMC technical sections of regulatory submissions and addressing regulatory authorities on technical matters
- Strong analytical and strategic thinking
- Ability to multi-task and in a fast-paced, goal-oriented environment
- Demonstrated scientific and problem-solving capabilities and cross functional understanding
- Excellent communication skills (oral, written, presentation)
- Strong organizational and time management skills
- Highly analytical with strong attention to detail
- Works independently and proactively
- 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.