RESEARCH SCIENTIST 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 develops, designs, validates and conducts complex analytical testing methods, assays and research projects or experiments. In cooperation with the R&D Director, prepares protocols and reports for validation studies in compliance with Global Health Authority guidance and industry best practices. Oversees the execution of studies by scientists and supporting departments, ensuring successful and timely completion per client agreements and established protocols. Liaison with the GMP Testing department to transfer qualified and/or validated methods and optimize assays for further development.

Key Accountabilities and Responsibilities:

- Assays to be developed primarily include qRT-PCR and emerging methods. Secondarily, cell culture-based assays may be developed.
- Prepare protocols and reports for validation studies in compliance with global health authority guidance and industry best practices.
- Coordinate the execution of validation studies with analysts and supporting departments, ensuring successful and timely completion of validation activities per client agreements and the established protocol.
- Responsible for maintaining detailed laboratory records of all activities.
- Directly interact with our clients, providing project updates and reports and interact with BTL management at all levels.
- Provide leadership to, and mentoring of, junior members of the department and direct reports.
- Ensure all activities are conducted in compliance with the appropriate regulations and are aligned with regulatory agency and industry expectations.
- Effectively collaborate with a fully integrated R&D team to facilitate the success of projects.
- Liaising with the GMP Testing department to transfer qualified and/or validated methods and optimize assays for further development.
- 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
- Anticipates and proactively addresses issues and handles ambiguity with comfort
- May perform director-level tasks in absence of Director of R&D
- Subject matter expert in respective field
- Manages, trains and educates others

Requirements:

- PhD from an accredited college/university in Cell Biology, Microbiology, Biochemistry or related field; Bachelor's or Master's degree considered with extensive industry experience may be considered
- 3+ years of relevant biopharmaceutical industry experience and a background in molecular biology, particularly qRT-PCR required
- Extensive knowledge of analytical assay development, qualification, validation, and tech transfer requirements to comply with current regulatory and industry standards.
- Experience in project management and oversight for analytical assay development and validation
- Proficient in relevant analytical methodology, emerging new technologies, troubleshooting and problem solving.
- Familiarity with general laboratory automation and LIMS/information technologies is highly desirable
- Working knowledge of Current Good Manufacturing Practices (CGMP).
- Excellent written and oral communication skills and proven ability to work well as a member of a multidisciplinary team.
- Familiarity with Microsoft Word, PowerPoint, Excel; Sigma Plot or GraphPad Prism is essential ·
- Demonstrated capacity to work in a fast-paced environment with strong attention to detail
- Ability to handle multiple tasks and projects under deadline pressure
- Creative and able to adapt quickly to change
- Strong organizational and time management skills
- A results-oriented team player

Physical Requirements:

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

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.

Any questions about job listings can be directed to careers@bionique.com