Bionique® Testing Laboratories, Inc.
156 Fay Brook Drive
Saranac Lake, NY 12983
518-891-2356 | 518-891-5753

Position Title: Research Scientist

The R&D Department is seeking a talented and innovative Scientist to join our growing team at Bionique Testing Laboratories' facility in Saranac Lake, NY. The successful candidate will assume responsibility for developing and validating analytical testing methods for the detection of mycoplasma to support preclinical, clinical, and commercial development of biotherapeutics inclusive of cell and gene therapies.

Duties include:

- Assays to be developed primarily include qRT-PCR and emerging methods. Secondarily, cell culture-based assays may be developed.
- In cooperation with the R&D Director, 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.
- Author, review, and finalize validation reports, IND sections, and responses to regulatory agency questions regarding mycoplasma testing methods.
- Maintain detailed laboratory records of all activities.
- Directly interact with our clients, providing project updates and reports.
- Interact with management at all levels.
- Provide leadership to, and mentoring of, junior members of the department with the potential for 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 CGMP Testing department to transfer qualified and/or validated methods and optimize assays for further development.
- Additional duties and responsibilities as required.

Qualifications:

- Highly organized individual with 3-10 years of relevant Biopharmaceutical industry experience and a background in Molecular Biology, particularly qRT-PCR.
- PhD in a relevant biological discipline. Master's or Bachelor's degree in a relevant field with extensive industry experience may also be considered.
- Extensive knowledge of analytical assay development, qualification, validation, and tech transfer requirements to comply with current regulatory and industry standards.
- Proficient in relevant analytical methodology, emerging new technologies, troubleshooting and problem solving.
- Experience in project management and oversight for analytical assay development and validation.
- 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.