

- 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 will perform routine mycoplasma testing (cell-based and/or molecular biology assays) of manufactured in-process, commercial and clinical products according to CGMP regulations and associated standard operating procedures. Training and duties will include performance of procedures and operations directly relating to mycoplasma protocols in compliance with CGMP standards. These may include but are not limited to aseptic technique, direct culture procedures, subculture procedures, microscopy, DNA extraction, real-time PCR, media preparation, record keeping, and laboratory maintenance activities.

Key Accountabilities and Responsibilities:

- Perform lab activities including but not limited to:
 - Prepare, inoculate (using aseptic technique), and monitor broth and agar cultures and evaluate them for mycoplasma growth
 - Perform fluorescent microscopy to identify mycoplasma growth in mammalian cell cultures
 - Maintain mammalian cell cultures
 - Perform DNA extractions and real-time PCR analysis to test for the presence of mycoplasma DNA
 - Perform routine monitoring, maintenance, and cleaning of instruments and equipment
 - Prepare and maintain required frozen stock mycoplasma control organisms
 - Document all laboratory activities accurately and completely
- Drive performance improvement experiments.
- Support Quality Control and Quality Assurance activities.
- Ensure proper level of laboratory supplies and reagents.
- Maintain laboratory in an audit readiness stage and CGMP compliant manner at all times.
- Review data for conformance to CGMP specifications and assist with investigation of



laboratory deviations.

- Troubleshoot as needed.
- Assist in data trending and data review, investigations, as well as participate in non-routine R&D projects.
- Responsible for collecting and entering data from electronic systems.
- Contribute to creating and revising standard operation procedures.
- Ensure quality and safety of testing operations. Follow established safety and environmental guidelines and procedures for all work performed.
- Additional duties as assigned

Additional Accountabilities and Responsibilities

- Performs job responsibilities as directed and completes tasks as assigned
- Keeps manager informed of progress and communicates effectively with colleagues as necessary to achieve assigned tasks and goals
- Ability to adhere to a standard timeline and escalate actions appropriately for resolution in a timely manner

Requirements:

- BS/BA in cell biology, microbiology, biochemistry, or related scientific field highly preferred. Equivalent combination of education, training and experience may be substituted.
- Laboratory experience working in CGMP microbiology or cell culture lab, or experience in a regulated environment is preferred.
- Knowledge and experience with aseptic techniques desirable.
- Team-oriented individual with excellent communication skills
- Must be able to pay attention to details
- Enthusiasm for learning and contributing to improved patient outcomes
- Ability to work weekends on a rotating basis

Physical Requirements:

- Ability to lift up to 50 pounds and stand for prolonged periods.

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.