Job Title: Microbiology Manager

List Lab's mission is to "harness bacteria's potential for a healthier world." We are a premier contract development and manufacturing organization for bacterial derived products for early clinical trials including live biotherapeutic products derived from the rapidly growing microbiome field. Live biotherapeutic products, an exciting new therapeutic, are a novel approach to disease treatment and have significant potential to improve patient lives. List Labs also specializes in the production of both native and recombinant bacterial proteins and toxins used for research and development.

List Labs offers a dynamic and congenial company environment and the convenience of working in the South Bay Area.

The Microbiology Manager provides oversight and leads Microbiology strain transfer, technology transfer, media development, lyophilization development, process development, and cGMP manufacturing of master and working cell banks. This position will work directly on client driven projects for the development of live biotherapeutic products derived from the microbiome.

The Microbiology Manager contributes primarily to the execution of new Microbiology platform processes for external customer projects based on in-depth knowledge and hands-on experience.

The position manages the relationship with other Manufacturing/Production Departments, including coordination, communication, and technical oversight to ensure timely delivery of quality products pursuant to Quality Control standards and company goals / timelines. The position participates in the preparation, review and approval of Microbiology related protocols, technical reports, batch records and SOPs.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Serving as the primary point of contact to the Production leadership to support technology transfer of strains, media, cultivation, and lyophilization processes
- Lead the Microbiology team to develop robust, reproducible, and scalable manufacturing processes for bacterial cultivations and preservations
- Leads and supervises cGMP manufacturing of master and working cell banks, deviation investigation, batch review and release for in-house and outside customer campaigns
- Improve technical capabilities and quality practices within the department
- Supervise, mentor, and provide necessary training for development of Microbiology staff
- Lead the execution, completion and review of manufacturing documentation including batch production records, quality system documents and reports

- Serves as subject matter expert in multidisciplinary project teams and/or sub-team meetings within the company or with clients
- Analyzing, interpreting, and presentation of process data and experimental results
- Provides technical recommendations for evaluating process data, troubleshooting and root cause analysis as well as providing strategic recommendations leading to improved economics and process robustness
- Supporting deviation investigations and identifying CAPAs to resolve manufacturing related issues
- Contributing to and supporting lab organization, improving lab efficiencies, and reducing costs
- Collaborating with Production leadership in developing project plans and schedules and ensuring the tasks are executed accordingly to the specific campaign requirements and/or commitments
- Supporting and maintaining safety and security
- Work with counterparts in Fermentation, Process Development, Quality, Purification, etc. to facilitate technology transfer and project success

QUALIFICATION AND EXPERIENCE

- BS/MS/PhD in biology, microbiology, biotechnology, biochemical or biomedical engineering, or related biological field
- Minimum 8+ years with a BS or 7+ years with a MS as an Associate III
- BS 8 years of Biotechnology, Bioprocessing or Pharmaceutical industry experience with a minimum of 3 years of managerial experience
- or MS 7 years of Biotechnology, Bioprocessing or Pharmaceutical industry experience with a minimum of 2 years of managerial experience
- or PhD 2 year of Biotechnology, Bioprocessing or Pharmaceutical industry experience with a minimum of 1 year of managerial experience
- 3+ years of cGMP manufacturing experience

KNOWLEDGE, SKILLS AND ABILITIES

- Hands on experience and expertise with a variety of bacterial organisms including aerobic and anaerobic microorganisms
- Media, cultivation, cryopreservation, lyophilization and process development experience
- Expertise with standard microbiological assays including colony forming units, optical density, total cell counts, colony morphology, cell morphology, etc.
- Aseptic technique, microscopic methods, and strain characterization experience
- Experience with use of anaerobic chambers is a plus
- Experience with small scale parallel bioreactors systems is a plus

- Experience with upstream harvest processes including tangential flow filtration, depth filtration and centrifugation
- Demonstrated ability to lead teams and mentor professionals
- Excellent interpersonal and communication (both oral and written) skills.
- Ability to function in a fast-paced dynamic team environment and balance prioritize multiple projects.
- Ability to work effectively both independently and as part of a multi-disciplinary team
- Willing to work with a flexible schedule and extended hours when needed
- Self-motivated; energetic individual demonstrating personal initiative
- Strong analytical and organizational skills, and a can-do attitude
- Laboratory skills and the ability to be hands-on.

PHYSICAL REQUIREMENTS

- Have the physical ability to lift and carry product/equipment weighing up to 50 pounds
- Be able to wear appropriate personal protective equipment (PPE), including powered air purifying respirators (PAPRs)
- Keep current on appropriate vaccinations (e.g. tetanus, diphtheria and pertussis [Tdap])
- Be comfortable handling BSL1, BSL2 and BSL3 organisms with appropriate safety precautions