

## **JOB TITLE: FERMENTATION MANAGER - BIOTECH**

List Biological Laboratories, Inc. is a privately held company located in Campbell. The company is a leading contract development and manufacturing organization for bacterial derived products for early clinical trials including live biotherapeutic products derived from the rapidly growing exciting field of microbiome therapeutics. 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 congenial small company environment and the convenience of working in the South Bay Area.

We are seeking a talented and motivated Fermentation Manager to lead the fermentation production activities for reagent grade and GMP manufacturing of bacterial products including live biotherapeutic products, bacterial toxins, lipopolysaccharides, and other bacterial produced proteins. Thorough knowledge of biopharmaceutical manufacturing technology and regulatory requirements for cGMP manufacturing will be critical to develop and provide oversight for technical transfer, scale-up, process improvements, and GMP manufacturing from 10L, 40L, 100L, and 500L scale. The individual will have a broad knowledge of existing and new fermentation platform processes including aerobic, anaerobic, single use bioreactors, fed-batch, and high density fermentation processes and upstream harvest processes including tangential flow filtration, depth filtration, and centrifugation. The position will provide technical expertise on client driven projects and provide leadership to build a high-performance fermentation department.

### **ESSENTIAL DUTIES AND RESPONSIBILITIES**

- Successfully lead the development, scale-up and fermentation production of bacterial products, both for reagent grade and cGMP manufacturing products
- Improve technical capabilities and quality practices within the department
- Supervise, mentor and provide necessary training for development of fermentation 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
- Provide technical recommendations for evaluating process data, troubleshooting and root cause analysis as well as providing strategic recommendations leading to improved economics and process robustness
- Support deviation investigations and identifying CAPAs to resolve manufacturing related issues
- Broad use of expertise and knowledge to solve complex non-routine technical problems
- Lead improvements in process and methods
- Coordinate and facilitate communication across multi-disciplinary groups

- Ensure compliance with all environmental, health, safety, and cGMP regulations
- Position requires work with Select Agents and Toxins in which access is covered under Federal policies
- Contributes to building a culture that encourages continuous learning, improvement, and innovation, and encourages and mentors team members to expand their technical skill base

#### **QUALIFICATION AND EXPERIENCE**

- BS/MS/PhD in biology, microbiology, biochemical or biomedical engineering, or related biological field
- 5 -10 years of relevant industry experience
- 3+ years of cGMP manufacturing experience
- Proven track record of effective management

#### **KNOWLEDGE, SKILLS AND ABILITIES**

- Fermentation experience with a variety of bacterial organisms including aerobic and anaerobic microorganisms
- Experience with upstream harvest processes including tangential flow filtration, depth filtration and centrifugation
- Experience with single-use bioreactors a plus
- Highly independent and self-motivated and integrates well within a team
- Strong ability to troubleshoot technical problems
- Good organizational skills with ability to meet deadlines and prioritize work on multiple projects
- Excellent oral and written communication skills
- Dedicated, hard-working and dependable
- Must be able to acquire security background clearance from FBI and CDC

\*\*If hired, List Labs will require that you provide evidence of your legal right to work in the United States. List Labs will not sponsor applicants for work visas at any time during recruitment or employment.

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