

JOB TITLE: LYOPHILIZATION SCIENTIST

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.

This position is a key role within the Microbiology team in the Manufacturing Department. The individual will be the subject matter expert for freeze-dry formulation and lyophilization process development of live biotherapeutic and other bacterial derived products under GLP and cGMP principles. Thorough knowledge of biopharmaceutical manufacturing technology and regulatory requirements for cGMP manufacturing will be critical to drive process development and improvement, technical transfer, and scale-up activities for manufacturing of live biotherapeutics. The position will provide technical expertise on client driven projects and subject matter expertise for a high-performance downstream processing group.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Design and develop formulation and freeze-drying cycles to optimize for bacterial viability or product stability
- Cultivation of aerobic and anaerobic organisms in biological safety cabinets and anaerobic chambers
- Support of cGMP manufacturing operations including cultivation, harvest, fills, and finish of microbial products
- Improve technical capabilities and quality practices within the department
- Serves as subject matter expert in multidisciplinary project teams and/or sub-team meetings within the company or with clients
- Lead the execution, completion and review of manufacturing documentation including manufacturing production records, quality records (deviations, CAPAs, etc) and reports
- Support deviation investigations and identifying CAPAs to resolve manufacturing related issues
- Ensure compliance with all environmental, health, safety, and cGMP regulations
- 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, pharmaceutical science, biochemical or biomedical engineering, or related biological field
- BS with 6-10 years of Biotechnology, Bioprocessing or Pharmaceutical industry experience

- or MS with 3-5 years of Biotechnology, Bioprocessing or Pharmaceutical industry experience
- or PhD with 1-3 years of Biotechnology, Bioprocessing or Pharmaceutical industry experience
- 3+ years of cGMP manufacturing experience, preferred
- 3+ years of bacterial lyophilization experience, preferred

KNOWLEDGE, SKILLS AND ABILITIES

- Excellent laboratory skills and aseptic technique
- Formulation experience with a variety of bacterial organisms including aerobic and anaerobic microorganisms
- Freeze-drying experience for maintaining viability of bacteria
- Experience with downstream processes including tangential flow filtration, depth filtration and centrifugation for concentration and purification
- Working knowledge of molecular biology methods such as PCR and ELISA (a plus)
- Ability to work both independently and as part of a multi-disciplinary 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

PHYSICAL REQUIREMENTS

- Have the physical ability to lift and carry product/equipment weighing up to 50 pounds, with or without accommodations.
- 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.