Job Title: Manufacturing Associate II/III, Upstream

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.

We are seeking a talented and motivated Manufacturing Associate II/III, Upstream to join our Upstream team and will perform fermentations and harvest methods for the manufacture of bacterial toxins, proteins, lipopolysaccharides, recombinant proteins, and live biotherapeutics for both reagent grade and cGMP products. This position works closely with other scientists in the QA/QC and production teams.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Cultivation of aerobic and anaerobic microorganisms by batch and fed-batch fermentations in stainless steel and single use bioreactors.
- Support development, scale up, and cGMP production activities including cultivation and harvest of microbial products.
- Cell separation methods including centrifugation, depth filtration and tangential-flow filtration (for concentrating and diafiltering).
- Media and solution preparation.
- Follow, review, and author technical documentation including reports and standard operation procedures (SOP).
- Draft Master Product Records, address feedback and release it into QMS.
- Lead fermentation development, technical transfer, scale-up, process improvements and cGMP manufacturing from 10 L, 40 L, 100 L, and 500 L scales.
- Design technical protocols, conduct studies, and write study reports.
- Serve as a subject matter expert in multidisciplinary project teams and/or sub-team meetings within the company or with clients.
- Use broad expertise and knowledge to solve complex non-routine technical problems.
- Perform data analysis of lot records or complex problems and provides summaries to supervisors.
- Implement improvements to technical methods/protocols and manufacturing and quality practices based on accumulated scientific knowledge/concepts and understanding of regulatory guidance.
- Lead multiple projects.
- Lead and support deviation investigations and identify CAPAs to resolve manufacturing related issues.

- Responsible for record completion.
- Responsible for quality and timely results.
- Coach and mentor less experienced staff.
- Maintain safety training and regulatory compliance training.
- Contribute to hazardous waste collection and autoclaving programs.
- May assist in other related duties as defined by management.

QUALIFICATION AND EXPERIENCE

- BS Degree in Microbiology, Biology, Biotechnology, Biochemical Engineering, Chemical Engineering or related field with 5-8 years of related experience or MS with 3-7 years of related experience
- Fermentation experience in a pharmaceutical or biotechnology setting is required.
- Fermentation experience with a variety of microbial organisms, including aerobic and anaerobic bacteria is preferred.
- Working knowledge of routine microbiological methods and principles.
- Proficiency with GLP and cGMP procedures.
- Minimum of 3 years' hands-on experience with bioreactor operations, preferably pilot scales
- Expert knowledge on bioreactor functionality, automation, control, engineering, and critical parameters for scale up.
- Solid understanding of bacterial or cell physiology

KNOWLEDGE, SKILLS AND ABILITIES

- Specialized knowledge of scientific principles and methods related and relevant to job
- Working knowledge of cGMPs and manufacturing processes to support deviation investigations and identifying CAPAs to resolve manufacturing related issues
- Excellent interpersonal and communication (both oral and written) skills
- 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
- Demonstrates self-motivation, energy, and proactive initiative
- Strong analytical and organizational skills with a can-do attitude

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
- While performing the duties of this job, the incumbent may be regularly required to stand, sit, talk, hear, reach, stoop, kneel, and use hands and fingers to operate a computer, keyboard, telephone, and laboratory equipment.

COMPENSATION AND BENEFITS

- The anticipated base salary range for this position is $65,000 - $95,000 per year based on a variety of factors, including but not limited to, internal equity, experience, education, specialization, skills, abilities, and training relevant to the role.
- The title may be assessed one level lower or higher, accordingly.
- Benefits include medical, vision, dental, vision, and group-term life insurance, 401(k) retirement plan with a 4% employer match, vacation, and holidays.
- The above salary range represents the Company's good faith and reasonable estimate of the range of possible compensation at the time of posting.

**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.

Apply: applicant@listlabs.com