**Job Title: Equipment Engineer**

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 Equipment Engineer who will be responsible for providing engineering, validation and maintenance support to process manufacturing equipment, facility, and utilities to ensure our manufacturing production operations run smoothly daily.

**ESSENTIAL DUTIES AND RESPONSIBILITIES**

- Provides engineering, validation and maintenance support to the process manufacturing equipment, facility, and utilities at a site; equipment may include major processing equipment such as bioreactors, tangential flow filtration, chromatography, filling equipment, support systems such as incubators, freezers bio-safety cabinets, offline bench-top instruments, or facility/utility systems.
- Ensures new equipment is appropriately designed/qualified and existing processes run in a compliant manner through equipment life cycle. Help define and optimize equipment qualification strategy.
- Owns and manages changes to the process equipment to maintain equipment in a validated state.
- Investigates any equipment or process deviations and developing corrective actions to prevent re-occurrences. Able to provide industry wide expertise for complex equipment and process investigations.
- Participates in all external and internal audits of the manufacturing facilities and process equipment as SME and responds to any observations received.
- Develops and implements equipment reliability and maintenance strategies that are compliant, effective and cost appropriate.
- Applies knowledge of engineering principles and best practices to ensure robust solutions.
- Independently leads or provide SME support on capital related projects.
- Establishes equipment specifications in standard documentation – User Requirements (URS), Functional Specification (FS) and Detail Design Specifications (DDS).

- Works closely with operations and manufacturing sciences to evaluate new product introductions and facility fit evaluations.
- Leads to define and advance facility and equipment changes in line with 5- and 10-year strategic plans.
- Leads evaluation of new technologies and equipment platforms for manufacturing.
- Translates current and future processes into the facility and equipment requirements at a manufacturing site.
- Maintain and assure compliance with the Validation Master Plan, Calibration Program, regulatory requirements, and site policies.
- Drafting, authorize and execute validation protocols and support validation and technical assessments for quality.
- Prepare validation summary reports for executed protocols.
- Conduct deviation investigations, such as validation failures, complaints and hold investigations to identify and implement the appropriate corrective actions.
- Provides accurate budget estimates for capital equipment and projects.
- Troubleshoot technical issues and execute corrective actions.
- Complies with all safety regulations and current Good Manufacturing Practices (GMPs).

**REQUIRED EDUCATION**

- 5+ years of relevant experience and a BS in engineering (Mechanical Engineering preferred)
- 5+ years working in validation and equipment support in the pharmaceutical and/or biotech industry, or equivalent combination of education and experience.

**KNOWLEDGE, SKILLS AND ABILITIES**

- Previous experience in biotech or pharmaceuticals industry desirable.
- IQ, OQ, PQ experience.
- Excellent technical writing skills – experienced writing and executing effective validation plans, SOPs, risk assessments, summary reports, and final reports.
- Demonstrates a working knowledge of process engineering system, methods, and procedures.
- Demonstrates a working knowledge of current GMPs and safety regulations.
- Demonstrates a strong verbal, written, and interpersonal communication skills.
- Proficient in Microsoft Office applications.
- Strong analytical and problem-solving skills.

**PHYSICAL DEMANDS**

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable

accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee is regularly required to walk; use hands to finger, handle, or feel; reach with hands and arms, talk, and hear. The employee is required to stand; climb or balance and stoop, kneel, crouch. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, color vision, peripheral vision, depth perception and ability to adjust focus. Must have ability to handle more than one task at a time and must work at a rapid pace while maintaining attention to detail.

**WORK ENVIRONMENT**

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. This job is performed in a temperature controlled facility without exposure to extreme hot or cold temperatures. Generally, this job is performed in a sanitized laboratory setting and routinely uses standard medical and research equipment such as centrifuges, biosafety cabinets, microscopes, incubators, pipettes and computers. While performing the duties of this job, the employee is frequently exposed to blood, viruses, bacteria, body fluids and other hazardous material. Employees entering and leaving the laboratory must wear appropriate clothing and protective equipment. The noise level in the work environment is usually moderate.