Job Title: Quality Assurance Specialist II

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 Quality Assurance Specialist to support our Quality and Compliance Department. This position will be primarily responsible for GMP product support, and administering quality systems such as supplier qualification, deviations, CAPAs, and change control. This position will also perform quality reviews for site documents and executed GMP records, perform gap assessments, provide guidance to operations staff to drive GMP compliance, support inspections, and perform other duties as needed.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Provides Quality support for GMP production activities, including line clearances, document reviews, deviation support, etc. Identify and escalate quality/compliance issues to Production and Quality leadership.
- Performs verification of data and records to authorize lot disposition, Certificate of Analysis/Testing approval, labeling or other approvals.
- Provide QA guidance and input to deviation investigations, root cause analysis, and verification of data and records to authorize closure of deviations, CAPA, and change control.
- Track and issue monthly status reports for deviations, CAPA and change control. Collect metrics to assist with monitoring Quality Systems (deviations, CAPA and change control, external and internal audits).
- Maintain master list of supplier audits, schedule, responses and status, and administer changes to the ASL based on supplier assessments or requests from stakeholders.
- Work with area management to develop criteria for performing GAP assessments and developing closure plans as needed.
- May assist with other related duties as defined by QA Management.

QUALIFICATION AND EXPERIENCE

- BS/BA in a scientific discipline preferably in biological sciences or related field with 2-5 years of related experience or MS with 0-3 years of related experience.
- Relevant experience working in the quality systems aspects of Biotechnology or Pharmaceutical industry.
- Direct experience conducting documentation review and GMP compliance gap assessments.

KNOWLEDGE, SKILLS AND ABILITIES

- Must have excellent attention to detail and the ability to consistently meet high quality standards.
- Excellent verbal, written, and interpersonal communication skills and the ability to work collaboratively across departments.
- Must possess good organizational and time management skills. Must be systematic in obtaining and using information.
- Must be able to work independently but able to identify problems and know when to solve proactively and seek advice.
- Must be able to work under tight deadlines while delivering a high-quality output.
- Strong knowledge of cGMP (e.g. FDA, EU and ICH) requirements and the ability to interpret them.
- Ability to assess compliance risks and to recommend corrections to quality system to minimize them.
- Must be proficient with computer applications (i.e. Microsoft Office products and Adobe Acrobat).

PHYSICAL REQUIREMENTS

- Prolonged periods of sitting at a desk and working on a computer.
- Must be able to lift up to 15 pounds at a time.
- Must be able to enter cleanrooms and stand for 2-4 hours.
- Specific vision requirements including reading of written documents, and use of computer screen.
- Document storage and retrieval may require lifting boxes of documents, carrying documents from one place to another and storing boxes on shelves or in file cabinets.
- Should have good keyboarding skills and manual dexterity.
- Handling documents requires repetitive motion using a variety of scanning and computer equipment.

Compensation and Benefits

- The anticipated base salary range for this position is $75,000 - $105,000 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.