Job Title: Director/ Sr. Director, Quality Systems and Compliance

List Lab's mission is to "harness bacteria's potential for a healthier world." We are a growing and profitable premier contract development and manufacturing organization (CDMO) for bacterial derived products for phase 1 and phase 2 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. We also specialize 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 currently seeking a Director/Sr. Director, Quality Systems and Compliance, to fulfill a critical role in the Quality Department to ensure compliance to cGMP and other applicable regulatory requirements, as well as managing the Quality Assurance, Analytical Development, and Quality Control departments.

This leadership role provides strong strategic direction for the application of List Labs' Quality Management System (QMS) expectations in support of manufacturing of List Labs' products. In this key position, the individual will develop, implement, manage, and maintain GxP (cGMP, GCP, and GLP) quality systems and will work across all disciplines to ensure that List Labs' operations as a Contract Development and Manufacturing organization (CDMO) maintains regulatory compliance with local, state, federal, and international regulatory agencies.

This role will be responsible for implementation/ deployment and improvement of current and future Quality Assurance systems and compliance of our contract development and manufacturing (CDMO) site, quality control, product disposition, audits, documentation control and review, internal and external GMP audits, technical documents, and evaluation and recommendations for improvements to GMP systems.

Key Responsibilities

- Responsible for List Labs' QMS program and its continuous improvement while keeping current with emerging and changing regulations, guidance documents and industry best practices and expectations
- Provide cross functional quality leadership and act as a GxP compliance subject matter expert
- Evaluate business goals, identify improvement opportunities, utilize critical thinking, and apply problem-solving techniques to improve and sustain product quality and process effectiveness in the overall QMS lifecycle to support the company's vision
- Provide trend analyses, and KPI/metrics to senior management

- Expertise on quality assurance and quality control concepts relating to biologics manufacturing
- Responsible for all Quality Operations functions including batch disposition, lot rejection and acceptance, and resolution of CAPA and deviations
- Implement necessary regulatory changes and updates to regulatory and compliance approaches appropriate for a CDMO biologics manufacturing site
- Provide technical guidance and training / mentoring to other QA employees and cross-functional teams
- Develop and implement departmental and divisional policies and procedures
- Reviews production batch records and associated data for product release. Ensures completeness and accuracy of information contained in all documents, document files, databases, and documentation systems.
- Serve as client contact for quality and regulatory compliance related to development and manufacturing activities
- Oversee and guide the strategy and direction of quality control and validation activities
- Oversee audits/inspections including audit preparation, execution, reporting and follow up to any findings.
- Provide expertise and guidance in interpreting governmental regulations, agency guidelines, and internal policies to assure compliance and effectiveness
- Maintains, enforces, and measures quality assurance processes including CAPA and non-conformance process to correct deficiencies and formulate improvements.
- Support Regulatory submissions and on-going regulatory compliance for product development process for List products and client products
- Review and sign off on product and manufacturing changes for compliance with applicable regulations
- Oversee risk management
- Oversee the company's training program for List Labs' staff to maintain compliance with regulations and SOPs
- Build a positive quality culture

Requirements and Qualifications

- Bachelor's degree in a relevant scientific or technical discipline. An advanced degree and directly relevant professional certification are desirable.
- Minimum of 15 years of experience in the biotechnology, pharmaceutical, and/or CDMO manufacturing industry. At least 10 years must have been at the senior management level with direct QA oversight experience over QA/ QC activities.
- Management experience for a contract development and manufacturing (CDMO) site is a must
- Working knowledge of GLP and cGMP regulations 21 CFR Part 11, 210, 211, 600 & EU guidelines and good documentation practices.
- Internal and external GMP auditing experience.

- Sound knowledge in ISO standards and applicable US and International Regulatory requirements for manufacturing FDA regulated products.
- Experience in validation, qualification, and calibration.
- Knowledge of Fill Finish and Biologics production environments required.
- Ability to write standard operating procedures, specifications, and technical reports.
- Strong interpersonal, communication, analytical and organizational skills.
- Proficient in Microsoft Office applications (Word, Excel, Access).