Job Title: Director, Quality Assurance

List Biological Laboratories, Inc. is a privately held company located in Campbell. The company specializes in the production of both native and recombinant bacterial toxins used for research purposes as well as GMP toxins and live biotherapeutic products, for exciting and emerging industry, for use in clinical trials use.

List Labs offers a congenial small company environment, tremendous opportunities for learning a variety of skills and the convenience of working in the South Bay Area.

We are currently seeking a Director of Quality Assurance to fulfill a critical role in the Quality Assurance Department to assure compliance to cGMP and other applicable regulatory requirements, as well as managing the Quality Assurance and Quality Control departments.

The candidate will be responsible for material disposition, audits, documentation control and review, internal and external GMP audits, technical documents, and evaluation and recommendations for improvements to GMP systems.

Key Responsibilities

- 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.
- Interacts with clients and follows up on client inquiries.
- Conducts cGMP audits including audit preparation, execution of the audit, the audit report, and follow up to any findings.
- Assigns duties and monitors the quality of work; assures QA staff conforms to organizational policies and procedures and government regulations.
- Ensure compliance with internal procedures to ensure that established quality and process procedures are being followed by appropriate personnel at all times.
- 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.

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 biotech industry. At least 10 years must have been at the senior management level with direct QA oversight experience over QA/ QC

activities. Management experience in both large and small companies is highly desirable.
- 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 strongly preferred.
- 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).

Apply here