JOB TITLE: QUALITY CONTROL MANAGER - BIOTECH

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.

This position is a key role within the Quality and Compliance Department. This position is responsible for oversight and resource management to support the development and validation of assays, QC testing of products, routine EM and raw material sampling/testing to support biologic products made from bacteria. The QC Manager develops staff, manages resources, and ensures that team activities meet company commitments and departmental objectives. In addition, this position is responsible for collaboration and influencing related, cross-functional groups to meet these objectives.
This position is responsible for the development and implementation of strategic plans to position List Labs as a premier CDMO specializing in Live Biotherapeutic Products.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Provide reasoned and timely input to Management and others in developing a structure and vision for Analytical Development/Quality Control at List Labs
- Provide input to the development of project quotes and timelines based on project objectives
- Oversee, qualify, and perform as needed, analytical assays to support the in-process, release and stability testing of clinical development stage of products and List commercial reagent products.
- Develop and manage the testing schedules to meet requirements as developed per cross functional teams and client commitments.
- Ensure that assays are qualified, and if needed, validated
- Build and maintain a staff that is both technically qualified and well trained in cGMP, while providing a motivating environment and opportunities for their professional advancement in a safety conscious environment
- Ensure consistent product quality through appropriate testing programs
- Develop, implement, and update Analytical Development/Quality Control SOPs, testing records, and other documentation needed for cGMP compliance
- Evaluate employee efficiency and productivity
- Interpret data and adhere to strict guidelines on documentation when recording data
- Ensure cGMP documentation generated by analysts in the laboratory meets expectations
- Contributes to building a culture that encourages continuous learning, improvement, and innovation, and encourages team members to expand their technical skill base

QUALIFICATION AND EXPERIENCE

- B.S. or M.S. in biological sciences, preferably in biochemistry, microbiology or or related field
- A minimum of 10 + years of relevant experience in Biotechnology or Pharmaceutical industry

KNOWLEDGE, SKILLS AND ABILITIES

- Expertise in analytics and QC testing for biologic products.
- Experience managing analytical development, routine CDMO based QC testing /stability and EM of a GMP manufacturing area
- Works on complex problems in which analysis of data requires evaluation of identifiable factors
- Exercises judgment within broadly defined practices and policies in selecting methods and techniques for obtaining solutions.
- Is familiar with regulatory guidelines pertaining to assay development, qualification, and validation
- Ability to generate new experimental proposal built on existing methods or techniques
- Highly capable, self-motivated and able to lead a diverse skill set, responsibilities team
- Strong ability to trouble-shoot technical problems
- Excellent organizational skills with ability to meet deadlines and prioritize work on multiple projects
- Excellent oral and written communication skills
- Dedicated, hard-working and dependable