JOB TITLE: QUALITY CONTROL SPECIALIST III

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 highly motivated and solution-driven individual to join the dynamic Quality Control (QC) team. This position actively supports testing of drug substances and drug product samples for release and stability for the company and client products. This position includes leading the development, transfer, and implementation of new analytical methods to support manufacturing and QC operations. As level III, the incumbent will be involved in training junior staff in complex QC tasks, testing methods, and other procedures.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Perform testing and associated QC Laboratory operation tasks without errors per applicable SOPs and test methods.
- Develop expertise in assigned assays/techniques.
- Perform data review of QC testing records to ensure data integrity and adherence to standard operating procedures and cGMP principles.
- Perform investigations to resolve issues related to assay failures, system deficiencies, OOS/OOT results, or product impact assessments.
- Assist in the start-to-finish qualification of analytical methods, from material planning to implementation of qualified methods.
- Assist in equipment and instrument qualification, calibration, and preventive maintenance.
- Perform cross-training to support staff availability within QC department.
- Author technical documents such as SOPs and reports.
- Lead laboratory investigations, deviations, and CAPAs.
- May support business operations with sampling, testing, and releasing of raw materials.
- May support the water and environmental monitoring programs as per USP and ISO requirements, respectively.
- May assist leadership with planning, scheduling, and task assignments.

QUALIFICATION AND EXPERIENCE

- B.S. or M.S. in biological sciences preferably in microbiology or related field
- A minimum of 5 years of relevant experience working in Biotechnology or Pharmaceutical industry in a QC laboratory
- A minimum of 3 years in a cGMP environment

KNOWLEDGE, SKILLS, AND ABILITIES

- Hands on experience with traditional microbiological methods like growth promotion, colony plate counting, and streaking and plating required.
- Hands on experience on compendial testing as per USP <61> and USP <62> required.
- Hands on experience in BSL-3 laboratories is a plus.
- Skills and knowledge of general chemical and immunological test methods such as Karl Fischer, HPLC, Gel electrophoresis, UV spectroscopy, PicoGreen, Western Blot, and ELISA
- Hands on experience on compendial testing as USP <85> and USP <643> is a plus.
- Advanced knowledge of cGMP regulations (21 CFR 211 and 21CFR 610), safety and data integrity as relevant to a QC laboratory.
- Experience in executing phase appropriate method qualifications and validations a plus.
- Highly independent and self-motivated and integrates well within a team.
- Good organizational skills with ability to meet deadlines and prioritize work on multiple projects.
- Excellent oral and written communication skills.
- Must be proficient with computer applications (i.e., Microsoft Office products and Adobe Acrobat).

Pay range: $75,000 - $130,000 annually