JOB TITLE: QUALITY CONTROL SPECIALIST I

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 is primarily responsible for following procedures for the collection and testing of samples from the facility environment, raw materials, and performing media growth promotion. This position performs routine testing of live biotherapeutic products and documents results in the required format. The QC Specialist/Analyst Imay review quality data according to existing procedures. This level is closely managed and works on well-defined tasks or projects of limited complexity.

The successful candidate will have demonstrated the ability to learn quickly, operate independently, and accomplish objectives. They will work closely with the other scientists in the fermentation, QA/QC and production teams.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Perform routine environmental monitoring (EM) in cleanrooms that meet ISO requirements. Testing includes, but is not limited to, viable and non-viable air particles and surface viable count.
- Collect and test water and steam samples for bioburden, endotoxin, and conductivity, aligned with USP requirements.
- Perform growth promotion of culture media.
- Perform basic microbiological traditional methods including, but not limited to, Gram staining, plate counting, streaking and plating of isolates.
- Support sampling, testing, and release of raw materials.
- Generate EM trending reports.
- Participate in laboratory investigations, deviations, and CAPA records.
- Review and update test methods and instrumentation SOPs as needed.
- Perform work according to Standard Operating Procedures (SOPs) and in compliance with Good Manufacturing Practices (cGMP), 21 CFR 211 and 21CFR 610.

QUALIFICATION AND EXPERIENCE

- BS in biological sciences or a related field is required.
- 0-3 years of relevant industry experience in a manufacturing environment.
- A minimum of 1 year of relevant experience working in Biotechnology or Pharmaceutical industry in a QC laboratory.
- cGMP experience or working knowledge preferred.

KNOWLEDGE, SKILLS AND ABILITIES

- Knowledge of cGMP a plus.
- Self-motivated and integrates well within a team.
- Good organizational skills with ability to meet deadlines and prioritize work on multiple projects under supervision.
- Excellent oral and written communication skills.
- Dedicated, hard-working and dependable.
- Must be proficient with computer applications (i.e. Microsoft Office products and Adobe Acrobat)

Pay range: $50,000 - $75,000 annually