Description

The QC analyst role is responsible for product testing and general lab operations. The role reports to the head of QC Microbiology (QCM) at a new laboratory currently under construction at Capsida's manufacturing site in Thousand Oaks, CA. This is an opportunity to join a growing and dynamic organization. A successful candidate will have scope and exposure to develop within the gene therapy therapeutic sector.

Responsibilities

- Performs microbiological sample testing related to environmental, gowning, and manufacturing operations. Support includes data entry (LIMS) and data analysis.
- Performs microbiological testing related to bioburden (membrane filtration, endotoxin, and growth promotion testing.
- Performs support for in-house microbial identification (MALDI-TOF) and external sterility and mycoplasma testing including coordination of sample shipments and receipt of final results from test labs.
- Performs product release testing in support of Capsida manufacturing operations according to Standard Operating Procedures and Test Methods in compliance with cGMP.
- Support new and existing equipment and test method development/validation which may include creation and/or review of IQ, OQ, PQ protocols and reports as well as standard operating procedures.
- Maintain complete and accurate records of all work performed.
- Ensure maintenance and calibration of equipment including controlled temperature environments, analytical equipment, pipettes, etc.
- Ensure laboratory supplies and required inventory are maintained.
- Document, technically evaluate, interpret data, and trend results.
- Review data for quality, consistency, and accuracy
- Write technical protocols and reports.
- Perform method transfers, method qualifications, etc. per approved protocols.
- Conduct laboratory investigations as required.
- Participate in continuous improvement projects and activities.

Requirements

- Bachelor's Degree in Microbiology or other relevant disciplines in life sciences OR
- Bachelor's Degree in Microbiology, Biology, or other relevant disciplines in life sciences with 1-3 years of experience in QC laboratory environment OR

- Bachelor's Degree in Microbiology, Biology, or other relevant disciplines in life sciences with 3-5 years of experience in QC laboratory environment including assay development.
- Strong knowledge of QC principles and procedures in microbiology such as environmental and bioburden monitoring as well as microbial identification.
- Experience with cGMP environments and associated documentation requirements.
- Knowledge of equipment and method validation/qualification requirements
- Good laboratory documentation skills and protocol writing and revision experience.
- Strong interpersonal and communication skills, both written and oral
- Strong planning, organization, and time management skills.
- Team player with positive energy and commitment to meet project timelines.
- Knowledge of analytical instrumentation with the experience and ability to troubleshoot and monitor trends.

Preferred Qualifications

- Understanding of applicable regulatory requirements (21 CFR, USP, EP, ICH)
- Experience with analytical lab start-up operations
- Understanding of how to host and provide materials for audits and inspections.

Compensation and Benefits

The well-being of our employees and their families is of the highest importance. As such, we offer a competitive salary and exceptional benefits, including generous stock options, medical, dental, vision, disability, life insurance, and significant PTO.

Additionally, we offer:

- Relocation compensation
- Fully stocked kitchen
- Social lunches, happy hours, and other events on a regular basis

We are an equal opportunity employer. All applicants will be considered for employment without regard to age, race, color, religion, sexual orientation, gender identity, national origin, veteran or disability status, or any classification protected by federal, state, or local laws.

Resume's can be directed to careers@capsida.com