



Sr. Manager/Manager, Quality Control
Job Code: 619RL

General Summary

Fate Therapeutics, Inc. is seeking a highly motivated Sr. Manager/Manager to join the Quality Control (QC) department to support both Contract Manufacturing organization (CMO) and internal reprogramming biology and molecular engineering team. The successful candidate will play a key role in QC activities related to CMO vendor qualification and monitoring, QC test method selection and trending, testing results review and troubleshooting effort to release Fate clinical manufacture products. Experience with cell bank bacterial and viral testing is required. The candidate must thrive in a fast-paced team environment, have excellent communication, planning, and organizational skills, and manage assigned activities to meet Fate's priorities and timelines. This role requires extensive interaction with CMOs, Research & Development, Quality Assurance, Program Management, Regulatory Affairs, and within Technical Operations. This is a fulltime position reporting to the Associate Director, Quality Control and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Key QC representative for a cross-functional team in support of CMO manufacturing.
- Collaborate in reviewing and maintaining all the QC test methods at CMO and ensure timely communication to leadership with QC related tasks, deadlines, and issues.
- Lead the investigation of abnormal test results, deviation, CAPA, and out-of-specification reports for QC test method in support of CMO manufacturing and product release.
- Develop technically justified recommendations and resolutions to investigation conclusions and ensure timely communication and alignment within cross-functional team, and timely completion of reports, corrective actions, and associated activities.
- Actively participate in CMO vendor qualification and audit processes.
- Contribute to the development and continuous improvement of the QC method to support FATE internal reprogramming biology and molecular engineering team and support the method development, qualification, and troubleshooting efforts.
- Manage new method evaluation and outsourced testing activities with CMOs.
- Write, review, and/or approve QC methods protocols, and reports to support CMOs functions.
- Attend quality control meetings and present CMO related information to department leaders.
- Maintain current knowledge base of regulations, corporate policies, and industry best practices, trends, and standards to ensure that the function remains in compliance with applicable company requirements and global regulations.
- Assist in the implementation of new assay methodologies and the associated instrumentation.
- Responsible for exhibiting professional behavior with both internal and external business associates that reflects positively on the company and is consistent with the company's policies and practices.

Qualifications

- Degree in Virology, Microbiology, Biology, Biochemistry, or related discipline, with a minimum of 5 years in biotechnology, clinical, or pharmaceutical QC laboratory experience is required; other qualifications with additional experience will also be considered.
- Experience with cell line and cell bank bacterial testing, viral testing, and other safety testing is required.



- Demonstrated successes working with multiple contract manufacture organizations and contract testing organizations.
- Experience working in a regulated environment (e.g., GMP, GLP, or CLIA) is required, with strong knowledge of FDA, ISO, EMA, GMP and ICH requirements, particularly as they apply to environmental monitoring and microbiology related to biologics and cell therapies.
- Good organizational skill and interpersonal communication skills. Proven ability to effectively develop, communicate, and gain support for execution of plans and strategies with a wide range of stakeholders.
- Strong scientific, analytical, and problem solving skills as well as sound judgment.
- Demonstrated ability to work effectively both independently and with others.
- Highly organized, detail-oriented with excellent record keeping abilities, and computer proficiency.
- Ability to work in a fast paced environment that will require management of several competing priorities while driving all projects forward and meeting program/project deliverables.
- Flexible, collaborative, and proactive leader who can positively and productively impact initiatives.

Working Conditions and Physical Requirements

- Will require working with cells and cell lines of human and/or animal origin.
- Occasional evening and weekend work will be required.
- 100% on-site work at corporate headquarters in San Diego, CA

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and curriculum vitae to: careers@fatetherapeutics.com and reference job 619RL.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.