Senior Manager, Raw Materials, Quality Control
Job Code 537JR

General Summary

Fate Therapeutics, Inc. is seeking a highly motivated Senior Manager to lead the raw materials program for our cell therapies programs. The space of responsibility will be across clinical development and looking to the future into the commercial life cycle. This role will be accountable for ensuring that the raw materials and components for each project are phase appropriate and meeting the needs of clinical development. This position will be responsible for revising and maintaining cross programs specifications, standards and operating procedures as required to ensure global regulatory standards are understood and followed. The selected individual will be responsible for reviewing the technical aspects of each program, ensuring testing is completed correctly and evaluating data. The successful candidate will have demonstrated experience with vendor qualification, setting raw material specifications, managing timelines and vendors at external facilities. The successful 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 Research & Development, Quality Assurance, Program Management, Regulatory Affairs, Technical Operations, and Contract Manufacturing Organizations (CMOs). This is a full-time position reporting to the Associate Director, Environmental Monitoring/Microbiology & Raw Materials and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Develop, implement, maintain, and continually assess the Company's raw materials program activities to ensure practices meet internal company standards and external global regulatory requirements.
- Lead and support strategic planning by timely communication of sample pull, testing and data assessment deliverables, constraints, risks and options to collaborating business partners.
- Contribute to the development and continuous improvement of raw material knowledge to allow for leveraging of data to help reduce costs and enable flexibility in the supply chain.
- Manage method transfer and outsourced testing activities with CMOs.
- Write/review/approve, methods, raw material specifications and prepare certificates of analysis
- Write/review/approve deviations, investigations, and CAPAs both within the Company and with CMOs.
- Perform periodic internal system reviews and audits, as well as participate in preparing for and representing QC in regulatory inspections.
- 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.
- Manage and train staff.
- Other duties as may be required.

Qualifications

- Bachelor's Degree in Chemistry, Engineering, Microbiology, Biochemistry, or related discipline, with a minimum of 5 years in biotechnology, clinical, or pharmaceutical QC laboratory experience is required; advanced degree is preferred.
- 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, in particular as they apply to biologics and cell therapies.
- Proven ability to effectively develop, communicate, and gain support for execution of plans and strategies for stability and reference standard programs with a wide range of stakeholders.
- Excellent judgment and creative problem-solving skills, including negotiation and conflict resolution skills, and excellent interpersonal, organizational, and written and oral communication skills.

- Leadership and management skills to grow and manage a high performing Quality organization.
- Experience working with cell culture, human blood, and blood products using sterile technique.
- Demonstrated skills in project management and working with vendors and contractors.
- Experience with regulatory submissions, ideally for products which were ultimately approved for commercial distribution, and regulatory inspections.
- Ability to work in a fast paced and dynamic environment that will require management of several competing priorities while driving all projects forward and meeting program/project deliverables.
- Energetic, flexible, collaborative and proactive; a 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 537JR.

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.