Senior Manager, Stability and Reference Materials, Quality Control
Job Code 489DF

General Summary

Fate Therapeutics, Inc. is seeking a highly motivated Senior Manager to lead the stability and reference material programs 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 stability and reference standard programs for each project are phase appropriate and meeting the needs of clinical development. This position will be responsible for revising and maintaining cross programs 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, preparing protocols and evaluated data in the context of each protocol. The successful candidate will have demonstrated experience managing stability and reference standard program activities performed internally and 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 Executive Director, Quality Control and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Develop, implement, maintain, and continually assess the Company's stability and reference standard 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 the stability knowledge to allow for leveraging of data to optimize the product storage and shipping cycle.
- Manage method transfer and outsourced testing activities with CMOs.
- Write/review/approve, methods, protocols, and timepoint reports.
- 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 489DF.

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). The Company's pipeline also includes ProTmune™, a pharmacologically modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease in patients with hematologic malignancies undergoing allogeneic stem cell transplant. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.