Associate Director, Quality Control
Job Code 386JCB

General Summary

Fate Therapeutics, Inc. is seeking a highly motivated Associate Director of Quality Control (QC) with flow cytometry, qPCR, and/or cell-based assay experience to support its expanding cellular therapy programs. This role will provide oversight and support execution, optimization, transfer, qualification, and validation of analytical methods for product stability programs and materials control, as well as support manufacturing in-process control (IPC) and lot release of product, within a Good Manufacturing Practices (GMP) environment. The successful candidate will have experience executing analytical test methods, working with mammalian cell culture, analyzing emerging data to assess the characteristics of hematopoietic and stem cell-based therapeutics, and GMP method qualification and validation. 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 Head of Quality and located at our corporate headquarters in San Diego, CA.

Responsibilities

- Develop, implement, maintain, and continually assess the Company's QC function and Quality Management System (QMS) for applicable regulated activities to meet internal company standards and external global regulatory requirements.
- Lead and support strategic planning by timely communication of QC deliverables, constraints, risks and options, and collaborating with Research & Development, Quality Assurance, Program Management, Regulatory Affairs, Technical Operations, and CMOs.
- Oversee product stability study design, monitoring, reporting, and data trend-analysis, as well as support product release, within a GMP environment.
- Oversee QC elements of raw materials qualification program.
- Establish robust analytical development strategies, inclusive of method qualification and validation, to ensure product quality and meet regulatory requirements.
- Generate stability specifications for raw materials and products, and support generation of release specifications and Certificates of Analysis.
- Manage method transfer and outsourced testing activities with CMOs.
- Write/review/approve, methods, protocols, and validation reports.
- Write/review/approve deviations, investigations, and CAPAs both within the Company and with CMOs.
- Establish, administer, and maintain policies, standard operating procedures (SOPs), work instructions, and forms relating to the QC function and the QMS.
- Author and review CMC analytical sections for regulatory submissions and annual reports
- Perform periodic internal QC system reviews and audits, as well as participate in preparing for and representing QC in regulatory inspections.
- Implement, perform and oversee internal quality auditing of QC function (including applicable vendors or subcontractors), customer quality audit response, and other QC related quality management system activities.

- Maintain current knowledge base of regulations, corporate policies, and industry best practices, trends, and standards to ensure that the QC function and the QMS remain in compliance with applicable company requirements and global regulations.
- Manage and train QC staff.
- Other duties as may be required.

Qualifications

- Bachelor's Degree in Analytical Chemistry, Life Science, Microbiology, Biochemistry, or related discipline, with a minimum of 7 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 applicable to biologics and cell therapies.
- Proven ability to effectively develop, communicate, and gain support for execution of plans and strategies 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 running multicolor flow cytometry, with working knowledge of BD flow cytometers, BD FACSDiva software, and FlowJo,
- Experience running qPCR, ELISA, and cell-based assays.
- 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 386JCB.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for cancer and immune disorders. 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 product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include 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, and a myeloid-derived suppressor cell immunotherapy for promoting immune tolerance in patients with immune disorders. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.