Senior Director, Quality Control
Job Code 395JCB

General Summary

Fate Therapeutics, Inc. is seeking a highly motivated Senior Director of Quality Control (QC). This role will provide managerial, technical, operational, and strategic leadership in the development and implementation of all QC-related activities, inclusive of team leadership, business process build-out, establishment of technical operations, methods transfer, feasibility assessment, qualification/validation and execution of multiple methods. The Senior Director will oversee specification setting, support phase-appropriate critical quality attribute determination for all of the Company's cell therapy assets, and lead stability programs both in-house and at external contract laboratories. This role will require strong cross-functional collaboration with Quality Assurance (QA), Regulatory Affairs (RA), Analytical Development, Pharmaceutical Development, Manufacturing Operations, Program Management, and Clinical Development teams. The ideal candidate will foster a quality and continuous improvement company culture to ensure that all QC deliverables are cGMP-compliant in a phase-appropriate fashion to support early and late phase global clinical programs. This is a full-time position reporting to the Head of Quality and located at our corporate headquarters in San Diego, CA.

Responsibilities

- Leadership and management of high-performing QC functions, including bioassays, molecular biology, virology, microbiological, technical, and operational teams.
- Management of methods validations, transfer, testing, and investigations for multiple cell therapy assets. This includes assessment and evaluation for QC fitness of newly transferred methods from Analytical Development team as well as contract/partner research organizations.
- Close engagement with Analytical Development and Quality Assurance to build a sustainable cGMP QC platform to support growing portfolio of clinical development programs. This includes ensuring harmonized approach to method development that supports the transition and implementation of methods fit for commercial QC support.
- Oversight, selection, and management of contract QC laboratories for multiple analytical assets. This includes technical due diligence, routine performance management, and audits to ensure sustained quality analytical deliverables.
- Support internal and external cGMP manufacture and supply of high quality cell therapy products for clinical trials, including oversight of cGMP sample handling, testing, QC release and stability data analyses and method data trending, out of specification investigations, and Certificates of Analysis creation.
- Develop phase-appropriate QC capabilities, business processes, and procedures to ensure robust product supply, including establishment of appropriate processes for specifications setting and holistic control strategy.
- Ensure that QC is aligned with all CMC stake holders, and in continuous collaborative state with QA, RA, Analytical Development, Pharmaceutical Development, Manufacturing Operations, Program Management, and Clinical Development teams, as well as with external vendors (CROs and CMOs), and Qualified Persons.
- Team management and leadership, including team members and development plans. The Senior Director will establish continuous learning and improvement programs for the QC team, thereby ensuring all team members are engaged and passionate about their work.

- Promote a company-wide culture of safety, quality, and responsible mindset. This includes having appropriate metrics and community ownership of these key cultural traits.
- Maintain current knowledge base of regulations, corporate policies, and industry best practices, trends, and standards to ensure that the QC function and the Quality Management System remain in compliance with applicable company requirements and global regulations.
- Other duties as may be required.

Qualifications

- BS, MS, or PhD in a Biochemistry, Analytical Chemistry, Molecular Biology, Pharmaceutical Sciences or other relevant scientific field of study with at least 12 years of relevant experience working in QC and/or Analytical Development with cGMP experience in the pharmaceutical/biotechnology industry; advanced degree is preferred.
- In-depth technical and regulatory understanding of biologics, gene, or cell therapy QC and understanding of holistic control strategy for these therapeutic entities, as well as applicable international regulations and standards in all phases of clinical development.
- Proven leadership experience and people management skills.
- Excellent written and verbal communication skills.
- Early to late clinical stage and commercial cGMP and CMC experience.
- Established experience working with and management of third party contractors and vendors.
- Experience with regulatory submissions, ideally for products which were ultimately approved for commercial distribution, and regulatory inspections.
- Strong collaboration, team-building, and organizational skills are required; 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.
- 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

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 395JCB.

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.