Senior Scientist / Scientist, Quality Control
Job Code 375AL

General Summary

Fate Therapeutics, Inc. is seeking a highly motivated Quality Control (QC) Scientist with flow cytometry, qPCR, and/or cell-based assay experience to support its expanding cellular therapy programs. This role will support execution, optimization, transfer, qualification, and validation of methods for manufacturing in-process control (IPC), lot release, and stability testing of clinical drug product within a Good Manufacturing Practices (GMP) environment. The successful candidate will be adept at 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 is a full-time position located at our corporate headquarters in San Diego, CA reporting to the Associate Director, Quality Control.

Responsibilities

- Perform GMP IPC, lot release, and stability testing using flow cytometry, qPCR, and/or cell-based methods
- Facilitate and perform method optimization, transfer, qualification, and validation for manufacturing in-process control (IPC), lot release, and stability testing of clinical drug product within a GMP environment
- Ensure timely completion of testing and tasks as assigned
- Report results in detailed and organized presentations and reports
- Participate in the evaluation of emerging data and trending analysis
- Participate in cross-functional training, as well as identifying and facilitating continuous method and process improvements
- Revise test methods, SOPs, raw material specification, and/or sample plans as appropriate
- Participate in lab maintenance and updates on equipment calibrations and equipment use logbooks according to cGMP standards
- Assist in the implementation of new assay methodologies and the associated instrumentation
- Onboard new materials and reagents and participate in materials risk assessment
- Identify and support initiation and completion of deviations, CAPAs, and laboratory investigations

Qualifications

- PhD in Analytical Chemistry, Life Science, Microbiology, Biochemistry, or related discipline with a minimum of 2 years in biotechnology, clinical, or pharmaceutical QC laboratory experience is required
- Experience working in a regulated environment (e.g., GMP, GLP, or CLIA) is highly preferred
- Experience running multicolor flow cytometry, with working knowledge of BD flow cytometers, BD FACSDiva software, and FlowJo
- Experience running ddPCR, qPCR, ELISA, and/or cell-based assays
- Experience working with cell culture, human blood, and blood products using sterile technique
- Strong scientific, analytical, problem solving, and communication skills as well as sound judgment, with the ability to work both independently and effectively with others
- Highly organized, detail-oriented with excellent record keeping abilities, and computer proficiency
- Ability to work in a high-paced team environment, meet deadlines, and prioritize work from multiple projects with little supervision

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 375AL.

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.