Director / Associate Director, Potency Assays
Job Code 475BR

Description

Fate Therapeutics is seeking a highly-motivated individual with extensive assay development expertise to lead the development of potency and functional characterization assays for Fate's iPSC-derived NK and T cell cancer immunotherapies. The successful candidate will be responsible for establishing strategies and techniques to identify and evaluate functional attributes of Fate's NK and T cell products and implement the established methods for product control and characterization. Operating in a cross-functional and dynamic environment, the individual will partner with Quality Control, Research, Process Development, Manufacturing Sciences and Technology, Translational, Quality Assurance, Regulatory Affairs, and Manufacturing teams. The ideal candidates should have a proven track record of providing leadership to enable and accelerate cell therapy product development and experience developing and implementing potency assays that are compliant with regulatory requirements. This is a full-time position reporting to the Senior Director, Assay Development and is located at our corporate headquarters in San Diego.

Responsibilities:

- Facilitate a collaborative work environment with key groups to create and implement a strategy for identification of critical functional attributes for Fate's products
- Lead potency assay development and qualification with consideration for phase-appropriate requirements and company objectives
- Lead development of extended characterization methods with an emphasis on functional attributes but may also include assessments of phenotype and process impurities
- Evaluate suitability and performance of state-of-the-art and emerging technologies and platforms to enable development of novel test methods
- Author and/or provide technical feedback on analytical development, qualification, and validation reports
- Provide support for technology transfer, validation, and testing of developed methods within the QC team and CTLs, as applicable
- Provide mentorship and support to other teams developing analytical methods, as a technical expert
- Draft and review relevant regulatory submissions

Requirements:

- M.S. in Biological Sciences or other related field and a minimum of 8 years of relevant potency assay development with demonstrated leadership and management experience in the biotech and/or pharmaceutical industry; Ph.D. in Biological Sciences preferred
- Extensive experience with developing and troubleshooting cell-based assays for immune cell functional profiling (killing assays, cytokine production, proliferation, and migration)
- Proven leadership and development of analytical development teams, preferably for cell therapy products
- Excellent interpersonal, verbal and written communication skills

- Strong background in analytical development, as well as a knowledge of cGMPs, ICH, and relevant regulatory guidelines and experience in writing relevant regulatory submissions
- Well-versed in a wide array of analytical techniques such as ELISA, qPCR, ddPCR, NGS, spectroscopy, cell counting, and other applicable methods
- Comfortable in a fast-paced small company environment and able to adjust workload based upon changing priorities
- Expertise in immunology and/or cancer biology
- Strong people management skills and ability to build, influence and lead a team

Working conditions and Physical Requirements

- Will require working with cell lines of human origin
- May require working with rodent models
- 100% on-site work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work will be required

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 resume to: careers@fatetherapeutics.com and reference job code 475BR.

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.