Principal Scientist / Senior Scientist, Potency and Functional Characterization
Job Code 560RJ

Description

Fate Therapeutics is seeking an experienced and highly-motivated Principal/Senior Scientist with extensive cell-based 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 works with the Analytical Sciences team and will be responsible for establishing techniques to identify and evaluate functional attributes of Fate's NK and T cell products and implement the established methods for product release and characterization. Individual will operate in a matrixed environment that spans across multiple functions including 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 innovation, demonstrated skill set and knowledge 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 Director, Potency Assays in the Analytical Sciences department and is located at our corporate headquarters and research facilities in San Diego, California.

Responsibilities:

- Develop and optimize phase-appropriate cell-based potency (expression and MOA) and other functional bioassays that are used for in-process and final product lot release and stability testing as well as characterization studies for NK and T cell therapy programs
- Design and execute method development studies via design of experiment (DoE) and qualification protocols in collaboration with more junior scientists to generate high quality data by following best practices of assay and instrument operations
- Perform data analysis and communicate scientific data and concepts effectively through presentations, protocols, test methods and reports
- Perform risk assessments, gap assessment for analytical methods and aim to enhance compliance and robustness
- Author analytical test methods (SOPs), method development and qualification reports and regulatory documents
- Support implementation of new platform technologies to increase analytical capabilities, plays a key role in improving processes and procedures
- Work with process development and manufacturing teams in support of product testing and investigations and collaborate closely with the Quality Control group to provide support for technology transfer, validation, and testing of developed methods within the QC team and CTLs, as applicable
- Provide mentorship and support training of junior scientists and other teams developing analytical methods, as a technical expert in potency assays

Requirements:

- Ph.D. in relevant scientific discipline e.g. immunology, cell biology, biochemistry or molecular biology with 5+ years of experience in analytical development, QC and method lifecycle management in biotech or pharmaceutical industry
- Extensive experience with developing and troubleshooting cell-based assays for immune cell functional profiling (killing assays, cytokine production, proliferation, and migration), 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 Flow cytometry, ELISA, qPCR, ddPCR, NGS, spectroscopy, cell counting, and other applicable methods
- Experience with development and qualification of cell-based assays for QC release testing and product characterization is required
- Expertise in immunology and/or cancer biology is required
- Experience with statistical programming or software (e.g. R, JMP) a plus
- Comfortable in a fast-paced small company environment and able to adjust workload based upon changing priorities

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 and research facilities 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 560RJ.

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). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.