Principal / Senior Scientist, Bioassay Development
Job Code 514AB

Description:
Fate Therapeutics is seeking a highly-motivated individual with extensive assay development and flow cytometry expertise to join the analytical development team. The successful candidate will be responsible for developing analytical methods using flow cytometry in support of the development of novel, off-the-shelf, engineered iPSC-derived NK and T cell therapies. Operating in a cross-functional and dynamic environment, the individual will work closely with Quality Control, Process Development, Manufacturing Sciences and Technology, Product Development, Regulatory Affairs, and Manufacturing teams. The ideal candidate should have a proven track record of developing, implementing, and transferring QC-suitable analytical testing methods that are compliant with regulatory requirements. This is a full-time position reporting to the Associate Director, Analytical Development and is located at our corporate headquarters in San Diego, California.

Primary Responsibilities:

- Serve as subject matter expert in selection and development of robust, state-of-the art multicolor flow cytometry methods to quantify and phenotype iNK and iT cell therapy final product, in-process materials, and starting materials for GMP testing.
- Establish supporting protocols to standardize flow cytometry instruments and ensure consistent assay performance.
- Automate and standardize data analysis methods that are compliant with regulations.
- Maintain knowledge of industry trends and critically evaluate, new flow cytometry platforms, single cell analysis technologies and scientific literature in order to contribute maximally to Fate's analytical development efforts.
- Evaluate and develop fit-for-use analytical test methods for the measurement of functional activity and quality of cell therapy products.
- Design, execute, and document method development and qualification activities.
- Perform previously established methods in support of process development, product release and stability, and product characterization needs.
- Perform data analysis and data trending to track assay performance.
- Manage assay transfer to the QC team and external partners.
- Draft and review relevant regulatory submissions for newly-developed methods.
- Coordinate activities within a collaborative work environment across key groups to support method development as well as the characterization of Fate's products.
- Provide mentorship and support to other teams developing analytical methods, as a technical expert.
- Follow good documentation and review practices, and effectively communicate scientific results and strategies in presentations and written reports.
- Draft technical reports, standard operating procedures, and test protocols in support of analytical development.

Requirements:

- Ph.D. in Biological Sciences or other related field and a minimum of 7 years of experience in a biopharmaceutical organization; M.S. candidates may be considered depending on experience.
- Proven successful development of fit-for-use multicolor flow cytometry methods, preferably for cell therapy products
- Expert in flow cytometer operation, maintenance, assay design and troubleshooting.
- Proficiency in one or more of following analysis programs: FlowJo, FACS Diva, OMIQ, FCS express. Experience in automation of data analysis is preferred.
- Requires a strong background in bioanalytical development, as well as a knowledge of cGMPs, ICH, and relevant FDA guidelines and experience in writing relevant regulatory submissions
- Excellent interpersonal, verbal and written communication skills
- Well-versed in various cytometry techniques such as aseptic cell culture, cell sorting, multicolor flow cytometry, image cytometry, and other applicable methods.
- Comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based upon changing priorities
- Expertise in stem cell biology, immunology and/or cancer biology is strongly preferred

Working Conditions and Physical Requirements

- 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 514AB.

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.