



Scientist / Associate Scientist, Bioanalytical Development
Job Code 388AMB

Description:

Fate Therapeutics is seeking a highly-motivated individual with assay development expertise to join the analytical development team. The successful candidate will be responsible for developing analytical methods in support of the development of 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:

- Evaluate and develop fit-for-use analytical methods for the measurement of quality attributes of cell therapy products and in-process intermediates.
- 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 write-ups 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.
- Maintain knowledge of and critically evaluate scientific literature and industry trends in order to contribute maximally to Fate's analytical development efforts.

Requirements:

- Ph.D. in Biological Sciences or other related field and 3+ years of experience or M.S. / B.S. and 7+ years of experience in a biopharmaceutical organization.
- Well-versed in various immunology and molecular biology analytical techniques with expertise in flow cytometry and cell-based functional assays as well as one or more of the following techniques: cellular imaging, immunoassay such as MSD, ELISA, HTRF, qPCR, or ddPCR.
- Proven successful development of fit-for-use analytical methods, preferably for cell therapy products.
- 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.
- 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 388AMB.

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 immunology 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.