Associate Director / Senior Manager, Analytical Operations
Job Code 476BR

Description

Fate Therapeutics is seeking a highly-motivated and conscientious individual with extensive analytical expertise to lead analytical operations in support of Fate's iPSC-derived NK and T cell cancer immunotherapies. The successful candidate will be responsible for establishing and streamlining processes to manage testing conducted by the analytical team to enable regulatory filings and characterize the manufacturing processes and products, as well as support process development, product development, and MSAT initiatives. Operating in a cross-functional and dynamic environment, the individual will partner with various teams to understand priorities and objectives and facilitate the analytical development team to produce high-quality data and reports. The ideal candidates should have a proven track record of managing analytical operations and a strong understanding of a wide array of analytical technologies and techniques. This is a full-time position reporting to the Senior Director, Assay Development and is located at our corporate headquarters in San Diego.

Responsibilities:

- Develop and implement efficient processes to manage the analytical development team study protocols, testing, data review, study report authoring, and cross-functional approvals
- Partner closely with manufacturing and QC teams to manage non-GMP testing (including sampling, data review, reporting, data trending, and troubleshooting) of in-process samples and final product extended characterization tests executed on clinical material
- Critically review raw data, analyzed data, and executed forms/notebooks and actively manage analytical development team to ensure exceptional data quality prior to sharing or reporting test results
- Serve as the primary liaison to enable process development, product development, and MSAT initiatives requiring analytical development support
- Serve as analytical development team representative in operational planning meetings (e.g. requirements for AD equipment, space, materials, storage, etc)
- Manage equipment installation, maintenance, calibration, and routine use schedules for analytical development team
- Develop and implement systems to manage and maintain analytical team data trending (control and test article trending including definition of limits, out-of-trend notifications, etc)
- Responsible for conducting 100% data and content QC for analytical sections in regulatory submissions
- Facilitate adaptation or redevelopment of assays to accommodate new requirements (for example, increase sample throughput)
- Provide support for technology transfer, validation, and testing of developed methods within the QC team and CTLs, as applicable

Requirements:

- M.S. in Biological Sciences or other related field and a minimum of 5 years of relevant analytical operations experience in the biotech and/or pharmaceutical industry; PhD. In Biological Sciences preferred
- Extensive experience with data trending and analysis tools is required
- Proven leadership of analytical operations, preferably for cell therapy products
- Well-versed in a wide array of analytical techniques such as flow cytometry, ELISA, cell culture, qPCR, ddPCR, sequencing, spectroscopy, cell counting, and other applicable methods
- Very strong attention-to-detail is a must
- Excellent interpersonal, verbal and written communication skills
- Experience with project management tools such as Smartsheet or MS Project is preferred
- Knowledge of cGMPs, ICH, and relevant regulatory guidelines and experience in writing relevant regulatory submissions
- Comfortable in a fast-paced small company environment and able to adjust workload based upon changing priorities
- Expertise in immunology, cancer biology, and/or stem cell biology is preferred

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 476BR.

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.