Process Development Scientist, Cell Therapy
Job Code 188JM

Description

Fate Therapeutics is seeking an experienced and highly motivated cell therapy process development professional to develop manufacturing processes for new cellular immunotherapeutic candidates. The successful candidate will work in a multidisciplinary research and process development team to define robust manufacturing processes and associated analytical systems, develop scalable, cGMP-compliant processes and documentation for the manufacturing of novel allogeneic cellular therapeutic products. This position requires prior experience with mammalian cell culture, process development for cellular therapies, assay development, and excellent technical, organizational, and interpersonal skills. This is a full-time position reporting to the Director of Process Development, and is located at our corporate headquarters in San Diego, CA.

Responsibilities:

- Support the development and delivery of cellular immunotherapy processes and products to patients according to Fate Therapeutics' clinical and commercial strategic objectives
- Author and execute protocols and reports for process development and technology transfer
- Collaborate with Quality Assurance and R&D to translate research protocols and processes into formal manufacturing procedures and batch records
- Establish process critical to quality attributes during process development
- Design, refine, and develop functional assays for characterization of process intermediates and final product
- Train and support junior process development and cGMP operators to implement new processes and production techniques
- Support engineering and qualification studies at internal and external GMP facilities
- Author and review relevant sections of pre-IND and IND regulatory submissions

Qualifications

- PhD in Immunology, Biology, Biochemistry, Biochemical Engineering or Bioengineering with minimum 1-year industry experience
- Previous experience with developing cellular characterization assays including techniques such as, multiple parameter flow cytometry, ELISA's, and molecular biology experience is required
- Expertise with small and large-scale mammalian cell culture as well as impeccable aseptic bioprocessing techniques
- Demonstrated ability to work collaboratively with Program Leaders from all functional areas (i.e. Quality, Regulatory Affairs, Clinical, Research and Operations) to achieve project objectives on schedule
- Expertise with closed culture systems and cell processing equipment and techniques, including cell culture, harvesting, cell washing and cryopreservation processes is desired
- Experience writing protocols, reports, procedures and batch records
- Experience with Good Manufacturing Practices (cGMP)

- Self-motivated with excellent time management, organizational, analytical, and problem-solving skills
- Experience in cell therapy manufacturing desired, preferably with NK, T-cell and/or pluripotent cell therapies
- Prior experience with gene editing and/or viral expression systems is a plus
- Highly self-motivated and goal-oriented

Working Conditions and Physical Requirements

- 90% on-site work at corporate headquarters in San Diego, CA. 10% travel possible during technology transfer activities
- Evening and weekend work as reasonable and necessary
- Will require working with cells and cell lines of human and/or animal origin
- Will require working with hazardous materials

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 curriculum vitae to: careers@fatetherapeutics.com and reference job 188JM

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 is pioneering the development of off-the-shelf cell therapies using its proprietary induced pluripotent stem cell (iPSC) product platform. This platform uniquely enables the single-cell selection of a precisely engineered iPSC clone and the subsequent creation and maintenance of a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for consistently and repeatedly manufacturing homogeneous cell products in quantities that support the treatment of many thousands of patients in an off-the-shelf manner. The Company's immuno-oncology pipeline is comprised of FATE-NK100, a donor-derived natural killer (NK) cell cancer immunotherapy that is currently being evaluated in three Phase 1 clinical trials, as well as iPSC-derived NK cell and T-cell immunotherapies, with a focus on developing augmented cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-specific antigens. The Company's immuno-regulatory pipeline includes ProTmune™, a next-generation 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.