Senior Process Development Engineer
Job Code 270RA

Description

Fate Therapeutics is seeking an experienced and highly motivated cell therapy process development professional to lead scale-up and cGMP-compliant process development for new cellular immunotherapeutic candidates. This is a full-time position reporting to the Senior Director of Manufacturing Science and Technology, and is located at our corporate headquarters in San Diego, CA. This position requires prior experience with mammalian cell culture, process development for cellular therapies, Quality Systems for biologics development, knowledge of statistical and analytical tools for process development, and excellent technical, organizational and interpersonal skills. Candidates with a background in bioengineering and specific expertise in the scale-up and technical transfer of medium- and large-scale bioreactor processes to a cGMP facility are preferred.

Responsibilities:

- Support the development and delivery of cellular immunotherapy processes and products to patients according to Fate Therapeutics' clinical and commercial strategic objectives.
- Establish large-scale closed culture system for iPSC expansion and differentiation and develop automated production platforms utilizing bioreactors. Develop cGMP compliant process, improve process yield, consistency and robustness.
- Author and execute protocols and reports for process development, technology transfer, equipment qualification and facilities qualification.
- Utilize robust statistical tools for experimental design, data analysis, process trending, process capability analysis and root cause investigations.
- Lead statistical analysis and reduction of data resulting from process development studies to assist management with decisions on process design and implementation.
- Support engineering and qualification studies at internal and external GMP facilities.
- Assist in establishing batch records, pilot clean room manufacturing facilities and the overall infrastructure for process development and cGMP manufacturing.
- Train and support junior process development and cGMP operators to implement new processes and production techniques.
- Author and review relevant sections of pre-IND and IND regulatory submissions.
- Assist in the implementation of LEAN, PAT and Quality by Design principles and practices.

Qualifications

- BS/MS/PhD in Biology, Biochemistry, Chemical Engineering, Biochemical Engineering or Bioengineering with minimum BS 8+, MS 6+ or PhD 4+ years industry experience.
- 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 small- and large-scale mammalian cell culture.
- Expertise in scaled aseptic bioprocess operations.

- Expertise with closed culture systems and cell processing equipment and techniques, including cell culture, harvesting and cryopreservation processes.
- Experience with computational Design of Experiments, root cause analysis and statistical tools for process tracking and trending.
- 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.
- Demonstrated ability to assess, mediate, and resolve complex issues.
- Experience in cell therapy manufacturing desired, preferably with NK, T cell and/or pluripotent cell therapies.
- Experience writing and executing equipment qualifications preferred.
- Knowledge of Quality by Design and Process Analytical Technologies approaches are desirable.

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

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 270RA.

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's immuno-oncology pipeline is comprised of universal, off-the-shelf NK cell and T-cell product candidates that are mass produced using its industry-leading induced pluripotent stem cell (iPSC) product platform. In 2019, Fate Therapeutics initiated the first-ever clinical trial in the United States of an iPSC-derived cell product, and is developing this NK cell cancer immunotherapy, FT500, for the treatment of patients with advanced solid tumors and lymphomas that are resistant to checkpoint inhibitor therapy. The Company is also developing FT516, an engineered iPSC-derived NK cell product candidate incorporating a novel high-affinity, non-cleavable 158V CD16 Fc receptor for enhanced binding to monoclonal antibodies, and is advancing a highly-differentiated pipeline of iPSC-derived chimeric antigen receptor (CAR) NK cell and T-cell product candidates designed to simultaneously engage multiple tumor-associated antigens for the treatment of hematologic malignancies and solid tumors. The Company's immuno-regulatory pipeline includes ProTmune™, a pharmacologically-modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of acute graft-versus-host disease (GvHD), and an iPSC-derived myeloid-derived suppressor cell (MDSC) 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.