Senior Research Associate, Process Development
Job Code 177JM

Description

Fate Therapeutics is seeking an experienced and highly motivated cell therapy process development professional to lead optimization and transfer to manufacturing activities for new cellular immunotherapeutic candidates. This is a full-time position reporting to the Director of Process Development, and is located at our corporate headquarters in San Diego, CA. The successful candidate will work in a multidisciplinary research and process development team to develop scalable, cGMP-compliant processes and documentation for the manufacturing of novel cellular therapeutic products. 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.

Responsibilities

- Support the development and delivery of cellular immunotherapy processes and products to patients according to Fate Therapeutics' clinical and commercial strategic objectives
- Apply process engineering/development knowledge to scale-up and scale-out of bioprocesses to enable multi-site clinical assessment and commercialization of novel cell-based therapeutics
- Develop and qualify bioassays for functional testing of pluripotent and differentiated cell types
- Support transfer of R&D processes to process development and manufacturing
- Assist in the implementation of Quality by Design principles and practices
- Utilize robust statistical tools for experimental design and analysis
- Collaborate with Quality Assurance and R&D to translate research protocols and processes into formal cGMP procedures and batch records; 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
- Maintain detailed laboratory notebook documentation of results and ability to follow laboratory procedures with attention to detail
- Support the selection process, negotiation, establishment and maintenance of contract manufacturing agreement(s) as necessary to support the delivery of programmed cellular therapeutic products
- Support engineering and qualification studies at internal and external GMP facilities
- Author and review relevant sections of pre-IND and IND regulatory submissions

Qualifications

- BS/MS/PhD in Biology, Biochemistry, Chemical Engineering, Biochemical Engineering or Bioengineering with minimum 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, cell washing 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
- Previous experience with developing cellular characterization assays including techniques such as, multiple parameter flow cytometry, ELISA's, and molecular biology experience is preferred
- Prior experience with gene editing and/or viral expression systems is a plus
- Experience writing and executing equipment qualifications preferred
- Knowledge of Quality by Design and Process Analytical Technologies approaches are desirable
- 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

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 177JM.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cell lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.