**Vice President, Process Development**
**Job Code 485BV**

**General Summary**

Fate Therapeutics is seeking the Vice President (VP), Process Development (PD), to lead the development of cellular drug substance and product including the development of induced pluripotent stem cell (iPSC) and iPSC-derived cell manufacturing from research stage to commercialization. The VP will provide leadership to an organization responsible for the PD of off-the-shelf cell therapy, including iPSC Cell Line Development and Banking, Upstream Process Development, Downstream Process Development and Formulation/Drug Product Process Development. As the leader of the process development functions for cell therapy, this position represents a key point of CMC responsibility for advancing Fate's cell therapy pipeline in immuno-oncology and future disease indications. As a leader, the VP, PD is expected to collaborate with all parts of the organization including Research and Development (R&D), Quality Control (QC), Quality Assurance (QA), Analytical Development (AD), Manufacturing, and Regulatory teams and external partners. In addition, the VP will be a member of the R&D leadership team, which is responsible for innovation, preclinical development, new product sciences and product and pipeline development. The ideal candidate will have experience in the area of cell/gene therapy and be aware of the pertinent regulations and how they apply to these fields. This is a full-time position reporting to the Chief Research and Development Officer and is located at our corporate headquarters in San Diego, CA.

**Responsibilities**

- Develop strong functional partnerships and phase appropriate strategies with other corporate functions and execute on aligned strategies to support pre-clinical, clinical development and commercialization plans.
- Accountable for the success of PD operations to deliver on the aligned priorities of the organization.
- Lead the design and execution of phase-appropriate process development, product characterization, technology transfer and validation studies associated with the implementation of cGMP-compliant manufacturing processes and systems for iPSC derived NK and T cell products from the development stage to commercialization.
- Lead the design for process development projects to support CMC IND-related activities, cGMP compliance, streamlined process workflows, and technology transfer protocols for both internal and external cGMP manufacturing facilities.
- Drive continuous improvement through technological innovation to support ongoing product development effort.
- Translate non-clinical and clinical study demand of a new candidate cellular therapeutics to development timelines and manufacturing strategy for IND and BLA.
- Provide technical support to internal and external cGMP operations.
- Support global regulatory filings.
- Support product-related inspections for US and foreign regulatory agencies as needed.

**Qualifications**

- Doctoral (Ph.D.) degree in relevant Science with 10+ years of industrial PD and manufacturing experience, or MS, BS with equivalent experience.
- Experience with process development of cell/gene therapy in various stages of development (preclinical to commercialization).
- Extensive process development, troubleshooting, and validation experience.
- Accomplished expert in process development and engineering, with experience designing and scaling processes.
- Strong knowledge of GLP and cGMP, worldwide regulatory requirements, current industry practices and cell/gene therapy CMC activities. Solid understanding of current industry trends and regulatory expectations associated with process development and manufacturing.
- Understanding of technology transfer including transitioning of research assays into cGMP analytical methods and tech transfer existing or new testing methods to internal and external manufacturing facilities.
- Experience preparing and updating regulatory filings (IND, BLA, MAA).
- Demonstrated experience building and leading exceptional teams. Leadership qualities of the successful candidate include the following: developing high performing teams, cross functional engagement and influence, collaboration, and strategic vision.
- Self-motivated, excellent time management, organizational, and proven problem-solving skills.
- Ability to manage multiple projects, prioritize objectives, and manage resources to achieve established deadlines.
- Outstanding written and verbal communication skills. Ability to effectively communicate scientific and technical concepts, program objectives, data analysis within a matrix environment.
- Knowledge of the principles and practices of budgeting and financial management.
- Knowledge of Quality by Design, Process Analytical Technologies and Six Sigma systems and approaches is desirable.

**Working Conditions and Physical Requirements**

- 80% on-site work at corporate headquarters in San Diego, CA and potentially 20% travel
- Evening and weekend work as 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 485BV.

**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.