Senior Director, Manufacturing Science and Technology (MSAT)
Job Code 251WW

General Summary

Fate Therapeutics is seeking a highly motivated Senior Director, Manufacturing Science and Technology (MSAT), to provide technical and organizational leadership to develop solutions in support of clinical and commercial manufacturing for internal and external manufacturing operations. The position will provide program leadership for IND projects, liaison with Manufacturing, Process Science and Assay Development, Quality Assurance, Quality Control, Regulatory, Clinical and various project stakeholders to promote Product Development aims. The successful candidate will act as a Fate representative during interactions with US and international regulatory bodies and participate in CMC leadership team to set annual objectives. Fate's development programs involve novel cell therapies which present with unique product manufacturing, quality and regulatory challenges. The ideal candidate should have experience in the area of cell therapy and/or biologics and be aware of the pertinent regulations and how they apply to these fields. This is a full-time position reporting to the SVP, Technical Operations and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- The primary responsibility of MSAT is to establish, characterize and maintain GMP manufacturing processes in a state of control.
- Defining and operationalizing, in collaboration with Process Science and Assay Development, a strategy to ensure commercially viable and robust product manufacturing.
- Evaluation of bioreactor process, new scale up technology and process automation for introduction into GMP manufacturing.
- Defining and developing the next generation of production capabilities.
- Manage internal and external collaborations to attract key technologies. Educate and train team members and stakeholders on new technologies.
- Establish and lead teams to source, vet, qualify, and implement cell manufacturing equipment, supplies, reagents, infrastructure.
- Set and delivers on challenging KPIs to drive more effective performance.
- Understanding external business & regulatory environments, proactively identifies performance risks, and develops effective mitigation strategies by leveraging a network mindset.
- Manufacturability assessment and Due Diligence.
- Technology transfer, technical support & training on the production floor.
- Process monitoring & control, Data science, MES.
- Ensure site has the capability to support the product life cycle through material changes, scale-up/down, optimization and cost reduction/value improvement initiatives.
- Support investigation, identify root cause for critical deviations during process validation and determine CAPA for manufacturing.
- Write and review technical documentation Operational technical leadership to ensure product reliability, support portfolio growth.
- Drive innovation. Develop and implement tools, systems, and processes to identify and implement innovative cell manufacturing processes.
- Effectively & efficiently communicate results internally and externally. Prepare data reports for internal use, regulatory filings, and scientific conferences.
- Responsible for the selection process, negotiation, establishment and maintenance of contract manufacturing agreement(s) to support the delivery of programmed cellular therapeutic products.

- Deliver the required Chemistry, Manufacturing and Controls information in support of investigational product filings, annual reports, and inspections.
- Provide scientific and technical expertise in the design, qualification, and validation of manufacturing operations in order to meet global standards of quality and regulatory compliance.
- Act as a Fate representative during interactions with US and international regulatory bodies in matters pertaining to compliance with relevant standards, cell therapy manufacturing processes, product composition and distribution.
- Assist in the preparation of annual operational and capital budgets including staffing, equipment, reagents and supplies and costs associated with process development and contract manufacturing.
- Assist in the development of scientific, risk-based product development visions for the company.
- Assist in the implementation of Quality by Design principles and practices.
- Help cultivate highly productive and results-driven teams through leading by example and displaying a can do attitude.

Qualifications

- PhD in relevant Science or Engineering discipline with minimum 10 years' experience.
- Strong knowledge of global compliance and manufacturing operations.
- Background in Cell Therapy Manufacturing required.
- Skilled in cell culture and aseptic processing; experienced with closed culture systems and cell processing equipment and techniques; knowledgeable of critical process parameters associated with cell culturing, harvesting and cryopreservation processes.
- Understanding of technology transfer including transitioning of research techniques into cGMP production methods and start-up of existing or new processes at internal and external manufacturing facilities.
- Demonstrated experience building and leading exceptional teams.
- Work collaboratively with Program Leaders from all functional areas (i.e. Quality, Regulatory Affairs, Clinical, Research and Operations).
- Self-motivated, excellent time management, organizational, analytical and problem-solving skills.
- Ability to manage multiple projects, prioritize objectives, and manage resources.
    - Ability to assess, mediate, and resolve complex issues.
    - Ability to build and maintain relationships in a matrix organization using collaborative approaches to achieve mutual goals.
- Ability to effectively lead teams and manage staff.
- Ability to effectively communicate scientific and technical concepts, program objectives, data analysis within a matrix environment.
- Knowledge of the principles and practices of quality assurance and quality improvement.
- Knowledge of Good Manufacturing Practices (GMP).
- 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 251WW.

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 products using its proprietary induced pluripotent stem cell (iPSC) product platform. 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 next-generation cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-associated antigens. 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 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.