Manager, Manufacturing
Job code 217AM

Description

Fate Therapeutics is seeking an experienced and highly motivated manufacturing professional responsible for oversite and operation of the cGMP clean room suite. The successful candidate is expected to plan and prepare for production, schedule tasks, and assign duties to operators to meet the production schedule, assess production records and meet release timelines. This person will set the example for safety and compliance and demonstrate expertise and knowledge in executing processes across a variety of production activities related to Fate's cell therapy clinical trials. This person will ensure adherence to written procedures (SOPs) related to housekeeping, monitoring of equipment and facilities, and manufacturing of cell therapies internally at Fate. The successful candidate demonstrates expertise and technical leadership in cGMP compliance and an in depth understanding of process flow with the ability to make decisions based on that experience. The individual will manage and coordinate activities across multiple departments to troubleshoot complex and non-routine equipment events, communicate effectively, initiate, assess and close low minor deviations, review batch records, and logbooks. This is a full-time position reporting to the Director, Manufacturing & QC, and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Interviews, hires, coaches, motivates, and develops staff as needed. Sets performance objectives and development plans. Monitors performance progress, conducts annual performance reviews for all direct reports, and recommends advancements for operators when appropriate.
- Ensures the safety of the work environment and the safety of the patients by compliance with company procedures and policies, and cGMP requirements.
- Ensures the schedules of the people, facility, equipment, materials, and documents are established and maintained to support the capacity/throughput of the facility.
- Identifies and mitigates risks in manufacturing operations that could negatively impact delivery of safe and effective therapies to patients.
- Designs and operates manufacturing systems that are technically sound, promoting effective and efficient operations, and complying with cGMP requirements.
- Provides leadership support during trouble shooting of equipment, operation and processes.
- Leads/ supports deviation initiation, investigations and closure. Participates in cross functional project teams, supports technical transfers with relevant teams/ individuals.
- Ensures deviations, CAPA, change controls, process transfers, and other business drivers are supported.
- Reviews and approves documents, including standard operating procedures, batch records, material specifications, and validation protocols and reports.
- Optimizes use of raw materials, equipment and personnel in producing quality products; Point person for technical and compliance issues and liaison with internal groups (QA, QC, Regulatory etc.) to facilitate issue resolution.
- Possesses excellent equipment understanding, including understanding equipment function and application. Understands biotechnology processing, the purpose of unit

operations, clean design and behavior, and microbial control concepts, including aseptic technique.

Qualifications

- Bachelors / Masters in relevant science or engineering discipline, or equivalent in work experience.
- 8+ years of experience in cGMP biologics manufacturing, experience in biotech or cell therapy manufacturing preferred.
- 2+ years supervising staff in a management role.
- Knowledge of cGMP regulations and FDA guidance applicable to biologics and cell therapy manufacturing.
- Demonstrated experience building and leading exceptional teams.

Working Conditions and Physical Requirements

- Will require working with cells and cell lines
- Will require working with hazardous materials
- 100% on-site work at corporate headquarters in San Diego, CA
- 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 resume to: careers@fatetherapeutics.com and reference job code 217AM.

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 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.