Senior Manager, Quality Assurance
Job Code 201LR

Description

Fate Therapeutics is seeking an experienced and motivated Senior Manager of Quality Assurance. This position will be responsible for supporting cGMP operations for Fate's cGMP Manufacturing Operations. The successful candidate must thrive in a fast-paced team environment, have excellent communication, planning and organizational skills, and be able to independently manage review times to meet Fate's priorities and communicated timelines. The candidate must be proficient in the use and maintenance of quality management and document control systems and will be expected to effectively follow Fate's SOPs and policies and cGMP compliance regulations. This is a full-time position reporting to the Quality Assurance Associate Director and is located at our corporate headquarters in San Diego, California.

Responsibilities

- Conduct Quality Systems reviews of production documentation, including production batch records, analytical records and any supporting documentation to ensure compliance with cGMPs and Fate policies and procedures, and prepare disposition documentation.
- Perform routine reviews of all cGMP documentation including laboratory notebooks, equipment logs and facility monitoring reports.
- Create and/or utilize various databases to track compliance issues and their resolution.
- Provide QA support during manufacturing operations.
- Assist with investigation and resolution of cGMP or procedural compliance failures, as well as work with staff from other departments to resolve compliance issues found during the Quality Systems review.
- Perform quality oversight of the GMP facilities.
- Assist with training of personnel to ensure compliance and conformance to Fate's requirements.
- Perform day-to-day activities of Document Control including creation and/or revision, processing, routing, and releasing controlled documents, to include:
    - Issuing and verifying batch record issuance, assigning lot numbers, assigning part numbers, and issuance of various other document numbers.
    - Creating, distributing, and auditing controlled documents.
    - Editing/formatting of various controlled documents.
- Assist with Quality audits of internal departments, as well as potential and/or current vendors and contract organizations.
- Support Contract Manufacturing Operations as QA Person-In-Plant.
- Support QA Management with various projects as needed.

Qualifications

- Minimum 7+ years of Quality Assurance related experience in a cGMP regulated manufacturing environment is required
- Bachelor's degree or higher in a relevant scientific area is strongly preferred
- Demonstrated ability to work accurately, follow instructions/schedules/timelines and handle multiple priorities

- Knowledge and ability to sufficiently train others on regulatory compliance issues
- Strong interpersonal skills and ability to work with others in a positive and collaborative manner
- Strong verbal and written communication skills
- Strong prioritization and organizational skills
- Knowledge of cGMP concepts and guidelines, as well as good documentation practices
- Ability to utilize multiple word-processing and database applications
- Experience with an electronic document system is preferred
- Experience with contract manufacturing operations is a plus

Working Conditions and physical requirements

- Will require 10%-50% travel
- Occasional weekend and/or evening hours required
- Full-time onsite work at corporate headquarters in San Diego, CA

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 201LR.

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.