Senior Manager / Manager, Quality Assurance
Job Code 243LR

Description

Fate Therapeutics is seeking an experienced and motivated Manager of Quality Assurance to support Fate's internal and external cGMP manufacturing operations. The successful candidate must thrive in a fast-paced team environment, have excellent communication, planning and organizational skills, and manage quality assurance activities to meet Fate's priorities and timelines. The candidate must have experience and a proven track record of establishing and maintaining a quality management system to support GXP-compliant manufacturing operations and will be expected to effectively follow Fate's SOPs and policies. 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 review of internal and external production documentation, including batch records, analytical records and any supporting documentation to ensure compliance with cGMP and Fate policies and procedures.
- Perform Quality audits of contract organizations including manufacturers, laboratories, and suppliers.
- Provide Quality Assurance oversight in support of product development and in-process, release and stability testing of raw materials, drug substance, and drug product.
- Lead QA support of tech transfer to CMOs and qualification of manufacturing activities.
- Proactively identify compliance issues, investigate and propose solutions, and lead closure of deviations and completion of corrective and/or preventative actions.
- Perform day-to-day activities of Document Control including creation and/or revision, processing, routing, and releasing controlled documents.
- Provide QA support during manufacturing operations.
- 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 independently, prioritize, and complete activities in a timely manner.
- Strong verbal and written communication skills and ability to work with others in a positive and collaborative manner.
- Strong understanding and knowledge of GXP, ISO, and ICH concepts and guidelines and implementation of GXP in a Phase appropriate manner.
- 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 243LR.

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-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.