Senior Quality Assurance Associate
Job Code 466HH

Description

Fate Therapeutics is seeking a motivated and talented Senior Quality Assurance Associate to assure adherence to standard operating procedures, GXP guidelines, and applicable regulations. The ideal candidate must thrive in a fast-paced team environment and must have excellent attention to detail, communication, organizational abilities, and independent problem-solving skills. Candidates must have experience working in a cGMP environment and have hands-on experience in electronic Quality Systems. This is a full-time position reporting to the Manager, Quality Assurance, and is located at our corporate headquarters in San Diego, California.

Responsibilities:

- Write, review, and revise standard operating procedures relating to Quality Systems
- Process document changes through FATE's electronic document management system
- Issue and review batch records and production documents to support release of drug products and materials
- Maintain Quality tracking systems for controlled documents and data
- Participate in Complaint, OOS, and deviation investigations and lead closure of associated documentation including performing CAPA effectiveness checks
- Assess effectiveness of current QMS procedures, implement improvements, and participate in the implementation of new e-QMS programs
- Review and release raw materials according to FATE's material control program
- Proactively maintain an understanding of regulations and best practices for a robust Quality Management System e.g. FDA, USP, ICH, etc.
- Provide administrative support and assist with timeline tracking and QA metrics
- Perform other Quality related duties as assigned

Qualifications

- Bachelor's degree and minimum of three years of relevant Quality Assurance experience in the Pharmaceutical/Biotechnology industry, or equivalent education and experience
- Comprehensive knowledge of Document Control standards, practices, and principles
- Experience with a hard copy quality management system with planning for integration to an electronic document management system
- Experience in maintaining GXP training records, materials or courses
- Experience in data gathering, metrics development, and report generation
- Experience with databases with expertise in the Microsoft suite (e.g. PowerPoint, Word, and Excel)
- Good organizational, project management skills and ability to perform varied tasks in a functionally independent and consistent manner
- Ability to analyze, interpret technical procedures and regulations; experience in writing procedures
- Ability to influence and collaborate with others; detail- and results oriented
- Strong organizational, analytical, and problem-solving skills
- Strong team orientation, with excellent written and oral communication skills

Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- May require occasional travel

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 466HH.

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 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 product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include 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.