Manager, Research Quality Assurance
Job Code 613XC

Description

Fate Therapeutics is seeking a motivated and talented Manager of Research Quality Assurance to support Fate's Research, Pre-clinical and Translational Science activities, and ensure compliance with applicable Good Scientific Practice, data integrity and GLP/GCLP requirements. The successful candidate will collaborate with business partners to develop and implement appropriate quality systems, and must thrive in a fast-paced team environment with excellent attention to detail, communication, organizational abilities, and independent problem-solving skills. The ideal candidate must have preclinical or translational research experience in the pharmaceutical / biotechnology industry, and has demonstrated experience working within GLP/GCLP areas. This is a full-time position reporting to the Director, Quality Assurance Operations, and is located at our corporate headquarters in San Diego, California.

Responsibilities:

- Develop and implement appropriate quality systems and controls to support research, preclinical and translational science activities, and ensure compliance with international standards (Good Scientific Practice, Data Integrity) and applicable GLP/GCLP requirements.
- Conduct Quality review of internal and external study documentation, including study protocol, study reports, lab notebook records and any supporting documentation to ensure data integrity and compliance with Fate policies and procedures.
- Provide Quality Assurance support and oversight for Research and Translational Science activities to ensure high quality study, data and documentation are generated.
- Proactively identify quality and compliance risks and collaborate with stakeholders to develop and implement action plans to address gaps.
- Manage the program for the review of research project documentation (e.g. lab notebooks and systems). Generate reports for Fate management on the review results, support issue resolution and closure.
- Provide QA review of SOPs, Deviations and CAPAs, change controls and process document changes through Fate's electronic document management system.
- Develop and provide training to research associates to ensure clear understanding of data integrity and quality requirements.
- Conduct or support quality evaluation/audits of CROs, academic institutions and laboratories to assess capabilities and compliance.
- Support regulatory submissions and review submission documents.
- Escalate issues to QA management and support QA Management with various projects as needed.

Qualifications

- Bachelor's degree in life sciences and a minimum of five years of experience in the pharmaceutical/biotechnology industry. A Master of Science degree is preferred.
- Understanding of cGxP regulations especially in the area of GLP and GCLP. Specific experience working in research or preclinical quality is considered a plus.

- Team orientated with excellent ability to interact across all levels of the organization and work with cross-functional teams.
- Ability to work independently, well organized, detail oriented, able to prioritize and complete activities in a timely manner.
- Ability to influence and collaborate with others in a positive manner, and work effectively together towards a common goal.
- Ability to multi-task and shift priorities quickly while working under time constrains. Strong work ethic and determination to succeed.
- 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 613XC.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. 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 pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.