Manager / Specialist, Quality Assurance
Job Code 382MW

Description

Fate's Quality Assurance (QA) group is seeking a motivated and talented individual to support clinical-stage development quality assurance activities. This role will work cross-functionally to execute and improve the material control and supplier quality management program and ensure compliance and assess risk and quality of materials used in the development of clinical stage cell therapy products. The successful candidate will assure adherence to standard operating procedures, GXP guidelines, and applicable regulations. Experience working in a cGMP environment is a must and candidates must thrive in a fast-paced team environment and have excellent attention to detail, communication, organizational, and independent problem-solving skills. This is a full-time position reporting to the Associate Director, Quality Assurance, and is located at our company's headquarters in San Diego, California.

Responsibilities:

- Assess risk and implement risk mitigation procedures and testing of raw materials
- Lead enrollment of new materials under established programs
- Execute phase-appropriate supplier qualification using risk-based tools for qualification, classification, and monitoring
- Evaluate potential new sources of supply and select appropriate suppliers based on supplier assessment / audits, quality performance and systems, and risk profile
- Review, define, and monitor requirements for supplier quality management processes and supplier performance measurement
- Identify supplier issues and discrepancies and manage the investigations to resolve issues
- Perform supplier qualification activities including audits and executing Quality Agreements
- Review data and documentation in support of the use and release of raw materials
- Develop reports on supplier quality performance and maintain databases and systems used for tracking various activities
- Generate, revise, and review Standard Operating Procedures (SOPs)
- Perform document and change control activities according to established procedures
- Provide the required support during the regulatory and internal audits
- Perform other Quality-related duties as assigned

Qualifications

- Bachelor's or associate degree and 5+ years of relevant experience in Quality Assurance, Quality Auditing, and Supplier Management
- Prior QA experience in the biotechnology or pharmaceutical industry that includes work on early stage products
- Excellent organizational skills with a professional demeanor and the ability to work well in a team environment with cross-functional team members

- Strong working knowledge of 21 CFR Part 11, 211 and 210, FDA/ICH guidelines, and industry/technology standard practices including GMP, GCP, and GTP
- Strong attention to detail, creative problem-solving, and communication skills
- Able to work independently and prioritize tasks in a fast paced and dynamic environment

Working Conditions and Physical Requirements

- May require occasional evening and weekend work.
- Full-time onsite work at company's headquarters in San Diego.
- Frequently required to work on a computer up to 8 hours a day.
- Occasionally required to stoop, kneel, and lift up to 50 pounds.

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 curriculum vitae to: careers@fatetherapeutics.com and reference Job Code 382MW.

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.