Quality Assurance Associate I
Job Code 597CK

Description

Fate Therapeutics is seeking a motivated and talented 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 in a research or academic setting with a working knowledge of GxP regulations. Experience in a regulated environment and GxP Quality Systems is a plus. This is a full-time position reporting to the Senior Manager, Quality Assurance, and is located at our corporate headquarters in San Diego, California.

Responsibilities:

- Review analytical data and documentation including raw data, test methods, protocols, and reports for accuracy, completeness, and compliance in a timely manner
- Check supporting documentation including laboratory notebooks and associated documents to ensure traceability to raw data and verify all reagents, standards and equipment used are within the acceptance range
- Ensure analysts follow all applicable SOPs and cGMP regulations and work with analysts for document corrections and provide guidance accordingly
- Issue and review batch production documents to support release of drug products and materials
- Assist in the investigation of OOS events and deviations
- Maintain databases and systems used for tracking various activities
- Write, revise, and review Standard Operating Procedures (SOPs)
- Perform document and change control activities according to established procedures
- Provide the required support during regulatory and internal audits
- Perform other Quality-related duties as assigned

Qualifications

- Bachelor's degree in a relevant scientific discipline and a minimum of 1 year of Quality Assurance or Quality Control experience in the Pharmaceutical/Biotechnology industry; Experience with cell culture or cell therapy products is preferred
- Good organizational skills with a professional demeanor and the ability to work well in a team environment with cross-functional team members
- Strong background in analytical methods and testing, and related instrumentation, flow cytometry and PCR experience is a plus
- Working knowledge of cGMP regulations and guidelines
- Strong attention to detail, team orientation with excellent written and oral 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
- Must be comfortable working in a lab setting

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 597CK.

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.