Associate Manager, Quality Assurance Operations
Job Code 566HH

Description

Fate Therapeutics is seeking a motivated and talented Associate Manager, Quality Assurance Operations, to support Fate's internal and external cGMP manufacturing operations and ensure adherence to standard operating procedures (SOPs), internal specifications/requirements, cGMP regulations and guidelines, and applicable regulatory requirements. 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 Senior Manager, Quality Assurance, 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 QA disposition and release for raw materials, intermediates and final products
- Provide Quality Assurance oversight in support of product development and in-process, release and stability testing of raw materials, drug substance, and drug product
- Proactively identify quality and compliance issues, investigate and propose solutions, and lead closure of deviations and completion of corrective and/or preventative actions
- Provide QA support during cGMP manufacturing operations, including frontline/floor QA support in cleanrooms
- Deliver QA review of SOPs, batch records, change controls and 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
- Provide administrative support and assist with timeline tracking and QA metrics
- Support QA Management with various projects as needed

Qualifications

- Bachelor's degree in life sciences and a minimum of five years of relevant Quality Assurance experience in the Pharmaceutical/Biotechnology industry, preferably supporting cGMP manufacturing operations
- Comprehensive knowledge of QA principles, cGMP regulations and industry standards
- Demonstrated knowledge and experience in quality systems, including deviations, CAPA and change control
- Excellent understanding 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 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 566HH.

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.