Manager, Quality Assurance Operations
Job Code 621XC

Description

Fate Therapeutics is seeking a motivated and talented Quality Assurance Manager to provide direct support to and quality oversight of Fate's Utilities, Facilities and Equipment for GMP manufacturing operations and ensure adherence to standard operating procedures (SOPs), internal requirements, industry standards/guidance and cGMP regulations. The successful candidate will also provide support to and oversight of warehouse and materials management operations. The ideal candidate must thrive in a fast-paced environment and must have excellent attention to detail, communication, organizational, and independent problem-solving skills. Candidates must have prior experience working in a cGMP environment and providing QA oversight and support for facility & equipment related activities. 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:

- Provide QA support and oversight for manufacturing and laboratory equipment/instrument enrollment, maintenance, qualification, validation, and changes.
- Support qualification, implementation, and maintenance of facilities, utilities and management systems (e.g. Maximo, EMS, BMS).
- Conduct Quality review and approval of GMP documents, including facility and maintenance work orders, equipment related documentation and logbooks, EM and pest control reports, batch records, qualification and periodic review protocols and reports, SOPS, change control documents, deviation investigations, etc.
- Collaborate with Facility and functional areas to support ongoing site qualification/ validation activities for cGMP manufacturing.
- Work in collaboration with other departments to resolve quality and operational issues
- Provide timely guidance and recommendation using risk-based approaches to ensure phase-appropriate decisions are made.
- Perform QA disposition and release for raw materials, intermediates, and final products.
- Provide timely QA support and review for deviations and CAPAs related to facility, equipment, and material management.
- Proactively identify quality and compliance issues and risks, investigate, and propose solutions, and lead closure of deviations and completion of corrective and/or preventative actions.
- Participate in inspection/audit readiness activities and site walkthrough programs.
- Develop and trend appropriate quality and performance metrics in support of continuous improvement and quality reviews.
- Support QA Management with various projects as needed.

Qualifications

- Bachelor's degree in life sciences, engineering, or a related scientific field with a minimum of five (5) years of relevant Quality Assurance experience in the Pharmaceutical/Biotechnology industry, preferably supporting cGMP manufacturing operations
- Strong experience in providing QA oversight and support for facility and equipment within a GMP environment. Experience supporting GMP facility qualification/validation is a plus.

- Comprehensive knowledge of QA principles, cGMP regulations and industry standards.
- Demonstrated knowledge and experience in quality systems and processes, including deviations, CAPA and change control.
- Good organizational, project management skills, and ability to perform varied tasks in a functionally independent and consistent manner.
- Strong track record of 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
- 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 621XC.

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.