Quality Assurance Associate III/II, Supplier Quality / Materials
Job Code 568RB

Description
Fate Therapeutics is seeking a motivated and talented individual to support clinical-stage development quality assurance activities. This role will work cross- functionally to improve and execute the material control and Supplier Quality programs and to ensure compliance 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 reportingto the Manager, Quality Assurance, and is located at our company's headquarters in San Diego, California.

Responsibilities:
- Assist with the maintenance of the Supplier Quality program
- Assist with supplier compliance, including audits, Quality Agreements, SCARs, Supplier Questionnaires, Supplier Request for Information, and management of supplier-initiated changes, including:
    - Supplier qualification and material specification development processes using phased appropriate, risk-based tools for qualification, classification, and performance monitoring
    - Quality Agreements to assure key quality expectations are reflected in the supplier's operations and updates for changes are managed
- Assist with supplier audits (Develop plan, prepare reports, communicate findings, audit responses, compliance assessment outcome)
- Maintain approved supplier list
- Monitor and report on meaningful Supplier Quality SQM performance metrics (KPI) as well as Supplier performance metrics
- Collaborate with cross-functional stakeholders on matters pertaining to supplier controls, significant concerns related to Quality system performance, risk-based audit execution, issue escalation, procurement strategy and regulatory compliance
- Participate as a representative of SQM on project teams
- Assure all Supplier Quality SQM-related quality documentation and records are completed thoroughly and timely to maintain compliance
- Support inspection readiness plans and interact with regulatory agencies during inspections on Supplier Quality SQM-related matters, as needed
- Support the development and optimization of the material enrollment program
- Perform material enrollment/assessment activities, including the categorization of materials, development of qualification and risk reduction activities, and establishment of material testing requirements
- Schedule and coordinate Material Review Board meetings, including the identification of Subject Matter Expert participation, material supporting documentation required, etc.
- Support the evaluation of potential new sources of material and selection of appropriate suppliers based onsupplier assessments/questionnaires/audits, quality performance and systems, and risk profile
- Review data and documentation in support of raw material release

- Identify material issues and discrepancies and manage the investigations to resolve the issues
- 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 a minimum of two years of relevant experience in Quality Assurance (level will be dependent upon experience)
- Prior QA experience in the biotechnology or pharmaceutical industry that includes work on early stage products
- Strong writing skills, including the drafting and review of technical documents, reports, and investigations
- Excellent organizational skills with a professional demeanor and the ability to work well in a team environment with cross-functional team members
- Working knowledge of 21 CFR Part 11, 211 and 210, FDA/ICH guidelines, andindustry/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 some travel up to 10-15% travel for supplier audits and visits
- May require occasional evening and weekend work supporting cross-functional QA responsibilities.
- 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 primaryduties may be required from time to time.

For consideration send cover letter and resume to: careers@fatetherapeutics.com and reference Job Code 568RB.

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.