Quality Assurance Associate
Job Code 295MW

Description

Fate's Quality Assurance (QA) group is seeking a motivated and talented individual to support development and implementation of the materials management program. The successful candidate will assure adherence to standard operating procedures, GXP guidelines, and applicable regulations. The ideal candidate will have experience working in a cGMP environment, and have hands-on experience in material enrollment, receipt, and disposition. Candidates must thrive in a fast-paced team environment and must have excellent attention to detail, communication, organizational abilities, and independent problem-solving skills. This is a full-time position reporting to the Senior Manager, Quality Assurance, and is located at our company's headquarters in San Diego, California.

Responsibilities:

- Day to day management of the material management program, including, but not limited to:
  - Performing routine inspection/assessment/disposition on all incoming materials
  - Rejecting material that fail to meet quality expectations and specifications and follow nonconforming material reporting (NCMR)
  - Work with Subject Matter Experts to establish appropriate material specifications and enroll new material
  - Resolve quality-related issues for material
- Write, revise, and review documents relating to materials management
- Proactively maintain an understanding of regulations and best practices for a robust Quality Management System e.g. FDA, USP, ICH, etc.
- Interact and follow-up with vendors, contract laboratories and Contract Manufacturing Organizations in support of Fate's development, manufacturing, and clinical activities relating to materials
- Inspection and release of raw materials
- Schedule and co-chair material review boards for high-risk materials as needed and assist with QA recommendations/action needed for enrollment
- Provide administrative support and assist with timeline tracking and QA metrics
- Perform other Quality related duties as assigned

Qualifications

- Bachelor's degree in a relevant scientific discipline
- Minimum 1 year of prior hands on experience with material disposition 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
- Experience preparing and reviewing cGMP documentation in support of manufacturing operations

- Working knowledge of 21 CFR Part 211 and 210, FDA/ICH guidelines, and industry/technology standard practices including GMP, GCP, and GTP
- Excellent writing skills and proficiency with MS Office applications, particularly Word and Excel
- Strong attention to detail 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 295MW.

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.