Executive Director / Senior Director, Quality Assurance
Job Code 193SA

General Summary

Fate Therapeutics is seeking an experienced Quality Assurance and Control professional to lead clinical stage development quality activities. In this key position, the individual will develop, implement, manage, audit, and maintain GxP (cGMP, GCP, and GLP) quality systems and will work across all disciplines (e.g., manufacturing, clinical development, research, and regulatory affairs) to ensure that Fate's ongoing development program maintains regulatory compliance with local, state, federal, and international health authority requirements. Fate's development programs involve novel cell therapies which present with unique product manufacturing, quality, and regulatory challenges. The ideal candidate should have experience in the area of cell therapy and/or biologics and knowledge of the pertinent regulations and how they apply to these fields. This is a full-time position reporting to the Chief Development Officer and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Oversee the strategic development, management, and maintenance of a cGXP compliant quality system
- Direct quality assurance and quality control personnel and projects to assure compliance with corporate and regulatory requirements
- Act as a key liaison between Company and external parties regarding Quality, Regulatory and Validation (including Computer Systems); communicate directly with external parties' senior Quality and/or Regulatory staff
- Support regulatory filing requirements for IND's, CTA's, NDA's and other regulatory compliance communication
- Oversee batch record audits and assure proper batch release
- Assure appropriate reviews and approvals of manufacturing records for execution and product release
- Take lead role in organizing and completing investigations, coordinate with other departments involved, and drive closure in a timely manner
- Oversee audits/inspections, including preparation, execution, reporting, and follow up to any finding and serve as a liaison between the Company and auditors
- Provide trend analyses, and KPI/metrics to peers and senior management
- Oversee resolution of product non-conformances and provide appropriate investigation of product manufacturing issues, including tracking non-conformances, approving dispositions, and initiating corrective action plans, as needed
- Review and approve development study protocols and reports
- Review and approve key ancillary reagent stability protocols and data reports
- Direct QA staff in review and approval of deviations, out of specifications and CAPAs in support of laboratory testing and cell processing facility product manufacturing
- Develop and approve Technical and Quality Agreements with contract manufacturing sites, including clinical cell processing facilities

Qualifications

- Scientific degree (chemistry, biology, pharmacy or related, pharmaceutical or engineering sciences)
- At least 8 years of experience managing the quality aspects of cell therapy and / or biologic products, including manufacturing and technical qualification, analytical testing, and product release in a clinical stage pharmaceutical or biotechnology company
- Excellent working knowledge of cGMP's, FDA regulations (21 CFR Parts 210, 211), ICH Guidelines for Manufacture of API's and practical experience in auditing practices and procedures
- Working knowledge of GLP, GCP, GTP, and relevant ICH guidelines preferred
- Strong supervisory skills with ability to thrive in a matrix environment
- Self-motivation, good judgment, strong follow up, organizational, analytical, and problem-solving skills
- Strong team orientation, with excellent written and oral communication skills
- Other:
    - Identify and support a Qualified Person (QP) in accordance with directive EC/2001/83, when required

Working Conditions and Physical Requirements

- May require up to 25% travel for auditing, training and meetings
- May require occasional evening and weekend work

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 193SA.

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 is pioneering the development of off-the-shelf cell therapies using its proprietary induced pluripotent stem cell (iPSC) product platform. This platform uniquely enables the single-cell selection of a precisely engineered iPSC clone and the subsequent creation and maintenance of a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for consistently and repeatedly manufacturing homogeneous cell products in quantities that support the treatment of many thousands of patients in an off-the-shelf manner. The Company's immuno-oncology pipeline is comprised of FATE-NK100, a donor-derived natural killer (NK) cell cancer immunotherapy that is currently being evaluated in three Phase 1 clinical trials, as well as iPSC-derived NK cell and T-cell immunotherapies, with a focus on developing augmented cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-specific antigens. The Company's immuno-regulatory pipeline includes ProTmune™, a next-generation 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.