Senior Manager, Quality Control
Job Code 202AM

Description

Fate Therapeutics is currently seeking a motivated professional with Quality Control experience to support Fate's clinical and manufacturing programs. The successful candidate will oversee the team's execution and analysis results using flow cytometry and other cell-based assays to assess the potency of hematopoietic stem cell-based therapeutics under clinical development as well as testing for release of products. Candidates should have experience working with human derived specimens, including sample preparation, assay development, and analysis of data. This is a full-time position reporting to the Director of Manufacturing and Quality Control and is located at our corporate headquarters in San Diego.

Primary Responsibilities

- Oversee team's activities in performing flow cytometry and other cell-based assays to support Fate's clinical programs including testing of human specimens from ongoing clinical trials and samples from manufacturing processes
- Perform and oversee QC testing including but not limited to endotoxin, process residuals, potency assays using flow based, ELISA and other techniques
- Serve as the technical expert for review of all results for development, manufacturing as well as clinical research
- Oversite and management of QC staff
- Design, execute, and analyze data from complex, polychromatic flow cytometry experiments using an 8-color, 10-parameter flow cytometer
- Oversee tech transfer of assays to QC from development
- Compile raw data, perform data trending, and write detailed comprehensive summary reports of assay development and quality control activities
- Perform validation and qualification of assays for potential use as release assays for Fate clinical stage products
- Oversee QC document review, data entry, data analysis and results reporting
- Write and review SOPs and associated forms related to QC assays and reporting

Requirements

- B.S. degree in Biological Sciences or other related field with a minimum 7+ years of laboratory experience in clinical or biopharmaceutical setting, cell therapy preferred
- Minimum of 5 years in a Quality Control Lab setting, preferably biotech
- Multicolor flow cytometry experience is a must; familiarity with the BD FACSCanto flow cytometer, BD FACSDiva software and FlowJo is a plus
- Experience with assay and equipment validation
- Experience working with human blood and blood products using sterile technique, cell culture or other related experience

- Highly organized, detail oriented with excellent record keeping abilities, and strong analytical and problem solving skills
- Must work well in a collaborative environment and have excellent communication skills (written and verbal)
- Qualified applicants should have familiarity with hematopoietic cell populations
- Familiarity with a GLP, GMP, or CLIA laboratory environment is preferred

Working Conditions and Physical Requirements

- Will require working with cells and cell lines of human and/or animal origin
- Full-time onsite work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work will be required

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 202AM.

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 products using its proprietary induced pluripotent stem cell (iPSC) product platform. 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.