Clinical Manufacturing Specialist
Job Code 190AM

Description

Fate is currently seeking a motivated technologist to join our Process Development and Manufacturing team. The successful candidate will execute process development studies in support of Fate's clinical development programs. The position will be responsible for maintaining lab equipment, performing experiments to qualify process improvements for manufacture of Fate's products in clinical development, and performing analysis of data. The position will involve manufacturing document drafting and review, data entry and analysis for product lots manufactured for clinical trials. The position will conduct manufacturing site visits and provide technical support for Fate manufacturing activities. The successful candidate will have excellent organizational and communication skills, a keen attention to detail and thrive in a team environment. This is a full time position reporting to the Director of Manufacturing and QC and is located at our corporate headquarters in San Diego, California.

Responsibilities:

- Maintain lab equipment, perform calibrations and complete routine laboratory tasks such as restocking and ordering.
- Perform, document and analyze experiments examining the characteristics of ex vivo modulated hematopoietic stem cells as well as other products in development.
- Work with human derived blood products. Prepare samples for use in research, assay development and product development.
- Perform basic immunological-based techniques including cell viability, Hematopoietic Progenitor Cell Assays and flow cytometry assays.
- Execute process development studies for Fate products to support FDA submissions. Assist with performing and documenting experiments, organizing data and analyzing results.
- Maintain laboratory notebooks, computer files/databases and assist in report writing to support IND filings.
- Support supply chain management activities for the development lab at Fate as well as for clinical sites manufacturing for Fate clinical trials.
- Review and write departmental SOPs as necessary.
- Provide technical support to Fate clinical trial sites telephonically and/or on site visits as necessary. This includes but is not limited to, training, tech transfer, and providing oversite of manufacturing activities for Fate clinical trials.
- Review clinical trial batch production records and enter manufacturing data into databases.

Qualifications

- B.S. / M.S. degree in Biological sciences or equivalent scientific discipline.
- Minimum 3 years related experience in a clinical stage biotech or pharmaceutical company. At least one year of cell therapy processing experience strongly preferred.
- Experience working with blood and blood products using sterile technique, cell culture or other related experience.
- Working knowledge of cGMPs, GTPs and GCPs.
- Must be highly organized, detail oriented and have strong analytical and problem solving skills.
- Must work well in a team environment with admirable interpersonal and communication skills (written and verbal).

- Experience writing study protocols, executing experiments, drafting study reports and batch records.
- Experience working with external customers, providing technical support as well as training.

Working Conditions and Physical Requirements

- Perform lab studies with human blood/cells in a BSC.
- Will require work with hazardous materials.
- Requires occasional evening and weekend work.
- Requires 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 190AM.

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.