



Sr. Technical Field Specialist, Product Development
Job Code 38PM

Company Overview

Fate Therapeutics is an innovative biotechnology company developing novel stem cell modulators (SCMs), biologic or small molecule compounds that guide cell fate, to treat patients with very few therapeutic options. Fate Therapeutics' lead clinical candidate, ProHema, consists of pharmacologically-enhanced hematopoietic stem cells (HSCs) designed to improve HSC support during the normal course of a stem cell transplant for the treatment of patients with hematologic malignancies. The Company is also advancing a robust pipeline of human recombinant proteins, each with novel mechanisms of action, for skeletal muscle, beta-islet cell, and post-ischemic tissue regeneration. Fate Therapeutics also applies its award-winning, proprietary, induced pluripotent stem cell (iPSC) technology to offer a highly efficient platform to recapitulate human physiology for commercial scale drug discovery and therapeutic use. With support from the U.S. Army, Fate Therapeutics is also investigating therapeutic intervention strategies to regenerate cells within the inner ear that are responsible for hearing. Fate Therapeutics is headquartered in San Diego, CA, with a subsidiary in Ottawa, Canada.

Description

Fate Therapeutics' development group is seeking a motivated and talented individual to lead the development of novel cellular therapies, comprising Fate's clinical stage *ex vivo* cell therapy program. The successful candidate will demonstrate technical expertise and leadership in development and manufacturing of cell therapy products, producing tangible and timely results as products progress from early development towards registration and subsequent commercialization.

The ideal candidate will have extensive expertise in development and clinical manufacturing of cell therapy products in a GTP/GMP environment, as well as relevant industry experience in the conduct of clinical trials for investigational products. Candidates must thrive in a fast-paced team environment. Excellent communication, organizational abilities, and problem-solving skills are a must.

Responsibilities

The ideal candidate will perform, oversee, or lead a range of activities focused on product development, tech transfer, and implementation of manufacturing for clinical trials. Activities will include:

- Oversee the transfer of manufacturing and assays to clinical sites
- Provide training and technical support to clinical site manufacturing staff through onsite and remote training
- Monitor and troubleshoot site manufacturing performance and data via correspondence and onsite visits
- Develop and optimize manufacturing processes
- Develop and optimize assays for product characterization, in process testing, and release testing, including cell counting and flow cytometry
- Develop and optimize novel functional assays, in collaboration with research team



- Design, conduct, and interpret studies to qualify new materials, devices, methods, assays, and processes used in cGMP manufacturing
- Write, review, and approve SOPs, technical reports, validation reports, and regulatory documents
- Establish and maintain productive working relationships with internal organizations such as Research, Quality, and Regulatory
- Conduct internal activities such as seminars and presentations, budgeting, and project planning
- Establish and maintain productive relationships with external organizations such as academic institutions, contract developers and manufacturers, regulatory authorities, and professional organizations
- Ensure that industry standards and best practices are effectively applied
- Participate in and lead technical meetings for sharing and applying scientific knowledge
- Provide technical, lab quality, and managerial leadership

Candidate Requirements

- B.S. or advanced degree in biology or medical technology
- ASCP or CLS certification preferred
- At least 5 years experience in cell therapy product manufacturing in academic, hospital, or blood center setting
- At least 3 years industry experience in clinical trials of biologics or medical devices
- Expertise in ex vivo cell processing, cryopreservation, and testing (cell counting, flow cytometry, clonogenic assays) for hematopoietic stem cell products
- Experience with aseptic processing and use of automated closed system devices
- Understanding of FDA regulations, including cGTPs and cGMPs
- Experience with qualification and validation activities for equipment, methods, and manufacturing processes
- Experience with data management and analysis
- Strong organizational, analytical, and problem-solving skills
- Strong team orientation, with excellent written and oral communication skills

Working Conditions and Physical Requirements

- May require working with blood and cell lines of human and animal origin
- May require work with hazardous materials
- May require occasional evening and weekend work
- Requires significant travel for clinical programs and scientific/professional meetings

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 38PM.