



Biomarker Samples Operations Manager, Clinical Translation Job Code 373SC

General Summary

Fate Therapeutics is seeking an experienced clinical translation operations manager to implement and manage the Company's biomarker samples, data integration and analysis plans in support of our clinical translation operations. This role will be responsible for providing sample management support and oversight for all operational aspects of biomarker samples testing related to academic and institutional collaborations across all clinical study stages (start-up, conduct and close-out). The successful candidate will have extensive knowledge and experience in supporting the implementation of biomarker sample operations for several clinical programs in collaboration with clinical operations, biometrics and translational science teams. This is a full-time position located at our corporate headquarters in San Diego, CA initially reporting to the Senior Vice President, Clinical Translation.

Responsibilities

- Implement and maintain efficient, high-quality biomarker sample testing & data delivery and management of data delivery timelines; support relevant team members including clinical data management, biometrics, biostatistics, and clinical operations.
- Liaise with clinical translational scientists to assess sample selection and vendor feasibility for non-clinical exploratory studies.
- Partner with biomarker scientist for biomarker assay development at vendors, leading operations of assay development and ensuring assay readiness in accordance with clinical sample testing timelines.
- Negotiate contracts and vendor selection to support procurement of samples.
- Actively manage full biomarker samples lifecycle for multiple programs including tracking specimen receipt, outsourced testing, organization of high-quality data and final sample disposition.
- Develop and maintain effective working relationships with clinical sites, commercial laboratories and vendors.
- Maintain working knowledge of current GCP, biobanking and sample management policies and best practices.
- Contribute to biomarker portions of key clinical documents including clinical study protocols, informed consents, laboratory reference manuals, and study initiation visit materials.
- Provide study level updates to clinical study teams and biomarker teams including sample collection, assay status and analysis updates.

Qualifications

- PhD with 2 years, MS with 5 years, or BS with 8 years of relevant experience in biotech or pharmaceutical industry.
- Extensive clinical or biological laboratory experience processing and analyzing biological samples.
- Strong project management, planning, organizational and time management skills required; familiar with project management software.
- Strong understanding of clinical trial protocols and regulatory standards for biomarker research; knowledge of ICH GCP preferred.



- Scientific knowledge in cancer biology, biomarkers and drug development, and clinical trial methodology; knowledge of LIMS systems preferred.
- Proven planning and organizational skills and the ability to work effectively and efficiently in a dynamic environment with multiple high priority competing projects and deadlines.
- Prior experience or familiarity with IND preparation and filing preferred.
- Prior experience working with clinical trial sites and related clinical CROs preferred.
- Excellent interpersonal, verbal, written communication, presentation and influence skills.

Working Conditions and Physical Requirements

- 100% on-site work at corporate headquarters in San Diego, CA
- Occasional travel to meetings and conferences as required
- 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 curriculum vitae to: careers@fatetherapeutics.com and reference job 373SC.

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.