Associate Director, Clinical Systems Operations
Job Code 397SN

Description
Fate Therapeutics is seeking an experienced Associate Director, Clinical Systems Operations responsible for implementation and ongoing administration of clinical systems supporting Clinical Development. An effective Associate Director, Clinical Systems Operations has a high degree of knowledge in business development, business systems administration, customer relationship management, Software Development Lifecycle (SDLC), and system strategy. This is a full-time position located in the San Francisco Bay Area or at our corporate headquarters in San Diego, CA reporting to the Senior Director, Clinical Development Operations.

Responsibilities
- Collaborates with the Senior Director, Clinical Development Operations to drive strategic vision for Clinical Systems Operations.
- Acts as a subject matter expert for Clinical Development supported systems and serves as a system owner for all relevant systems.
- Accountable for partnering internally and externally to implement and maintain high quality, efficiently designed, clinical systems (CTMS, eTMF, IxRS, ePRO, etc).
- Manages the end-to-end timeline and specifications for the build of outsourced clinical systems including requirements review, testing, deployment, maintenance, and enhancements.
- Partners with Clinical Compliance to ensure Part 11 compliance for all relevant supported systems.
- Serves as a technical liaison to internal and external stakeholders for escalated system issues.
- Participates in systems vendor selection and performs ongoing service provider management and oversight of clinical system vendors.
- Monitors key performance indicators (KPIs) and conducts analysis to identify root causes for issues and recommends process improvements.
- Partners cross-functionally to develop and implement relevant Clinical Systems Operations trainings, processes and procedures.
- Evaluates emerging trends, technologies, and best practices and provide recommendations and direction on strategic roadmaps.

Knowledge/Skills/Abilities
- Ability to see the interrelationship of systems and procedures within a project and understand their interdependencies to the larger organization and drive strategic changes needed by the business.
- Knowledgeable with the processes and principles of program and customer relationship management.
- Up-to-date knowledge of clinical operations processes and Information Systems.
- Analytical problem-solving skills to enable ability to define problem statement clearly and accurately and apply structured and disciplined methodology to identify root-causes.
- Expertise managing third party vendors in delivering service as expected.
- Broad knowledge of applied GxP experience in pharmaceutical or Biotech industry with clinical drug development experience.

- Strong interpersonal, communication and presentation skills to be able to engage with all levels both internally and externally.
- Self-motivated and adaptable to a dynamic environment with the ability to support successful change.
- Comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based upon changing priorities.
- Applies good judgement and professional expertise in new situations.
- Able to develop and mentor staff.

Qualifications

- BS/BA degree in related discipline and at least 7 years of related experience.
- Advanced degree preferred.
- Previous experience in clinical trial planning and execution strongly preferred.
- Experience within pharmaceutical/biotech industry preferred.
- Excellent people management skills with the ability to influence across the organization.
- Lead and thrive in an interactive, team-oriented culture.

Working Conditions and Physical Requirements

- Travel between office locations as required
- 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 397SN.

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.