



**Senior Manager, Clinical Systems Operations / Manager, Clinical Systems Operations
Job Code 569SY**

Description

Fate Therapeutics is seeking an experienced Senior Manager or Manager, Clinical Systems Operations to support implementation and ongoing administration of clinical systems supporting Clinical Development. The successful candidate will have experience working on different systems (IRT, eTMF, CTMS, Safety) with the ability to work on multiple tasks/projects across different platforms. This is a full-time position based in San Diego, CA or the San Francisco Bay area, reporting to the Associate Director, Clinical Systems Operations.

Responsibilities

- Partner internally and externally to implement and maintain efficiently designed and high-quality IRT system; support implementation and maintenance of other clinical systems (CTMS, eTMF, and Safety).
- Collaborate with system vendors, IT partners, quality assurance and the business owners to coordinate implementation activities.
- Participate in defining project scope and deliverables to support business goals in collaboration with other team members, stakeholders, and leadership.
- Contribute to the authoring and execution of qualification tests and act as a subject matter expert for Clinical Development supported systems.
- Oversight of outsourced clinical systems activities including requirements review, testing, deployment, maintenance, and enhancements.
- Partner with Clinical Compliance to ensure Part 11 compliance for all relevant supported systems.
- Serve as a technical liaison to internal and external stakeholders for escalated system issues.
- Partner cross-functionally to develop and implement relevant Clinical Systems Operations trainings, processes and work instructions.
- Evaluate emerging trends, technologies, and best practices and provide recommendations and direction on strategic roadmaps.
- With support of senior team members and/ or management, analyze user enhancement requests to deliver solutions focused on establishing and improving business processes that improve efficiency, address process gaps, and enable automation and growth of the organization.

Qualifications

- BS/BA degree in related discipline and a minimum of 7 years of experience for a Senior Manager or 5 years of experience for an Manager with implementation and maintenance of clinical systems; advanced degree preferred.
- System implementation experience with IRT systems strongly preferred.
- Experience working on SaaS systems.
- Experience supporting end users in issue resolution.
- Up-to-date knowledge of clinical operations processes and information systems.
- Ability to see the interrelationship of systems and procedures within a project and understand their interdependencies and the changes needed by the business.
- Analytical problem-solving skills to enable ability to define problem statement clearly and accurately and apply structured and disciplined methodology to identify root-causes.
- Broad knowledge of applied GxP experience in pharmaceutical and/or biotech industry especially in clinical drug development space.



- Comfortable in a fast-paced environment with minimal direction and able to adjust workload based upon changing priorities.
- Self-motivated and adaptable to a dynamic environment with the ability to support successful change.
- Excellent written, verbal, and interpersonal communication skills.

Working Conditions and Physical Requirements

- Travel between office locations as required
- Occasional travel to meetings and conferences as required
- Occasional evening and weekend work as needed

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 569SY.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. 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 pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.