Director, Clinical Compliance
Job Code 392SN

Description

Fate Therapeutics is seeking an experienced Director, Clinical Compliance responsible for developing, implementing, and executing quality management system processes to maintain Good Clinical Practice (GCP) compliance and to promote continual process improvement. The Director, Clinical Compliance is responsible ensuring the ethical and compliant conduct of Fate's clinical trials by overseeing GCP audits, ensuring inspection readiness, and ensuring clinical trial and eTMF compliance. 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 study teams to ensure GCP compliance through all states of clinical trial conduct.
- Interprets clinical trial regulations and guidelines to provide guidance and subject matter expertise.
- Partner with functional areas to develop or refine methodologies for selection, oversight, and risk mitigation of external parties (e.g. vendors, clinical sites) to ensure compliance with GCP ICHE6.
- Lead inspection preparation activities, facilitate inspections, advise on inspection responses.
- Implement CAPA-management process, partner in Root Cause Analyses, advise on content of CAPAs.
- Review and provide guidance on clinical trial documents (e.g., manuals, study plans, etc.) for compliance with regulations, regulatory guidelines and standard operating procedures (SOPs).
- Identify and partner cross-functionally for the remediation of any GCP compliance issues for clinical studies and functional areas.
- Partner with Quality Assurance to develop and implement internal/external audit program.
- Partner with Quality Assurance on Clinical Development vendor qualification activities.
- Partner within the organization to implement processes for generating and controlling quality documents (e.g. policies, SOPs), and advise other functional areas in implementing their document control strategies.
- Provide support for functions implementing quality agreements with key external parties.
- Provide support for business units validating and/or maintaining Part 11-compliant computer systems.
- Develop and review SOPs related to the quality management system and eTMF and provide input on SOPs for other functional areas.
- Oversee the development and conduct training sessions on best practices, trends, regulatory requirements guidance, and GCP topics to facilitate continuous improvement in study execution and on-going adherence to standards and regulations.
- Oversee eTMF document control to ensure the eTMF is audit ready and compliant.

Knowledge/Skills/Abilities

- Advanced knowledge of ICH-GCP guidelines and applicable drug development regulations.

- Has supported GCP inspection readiness activities and participated in regulatory authority inspections.
- 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 10 years of related experience, at least 5 years of which must be in a quality function.
- Certifications (e.g. Certified Quality Auditor) preferred.
- Experience within pharmaceutical/biotech industry preferred.
- Experience within cell-therapy or cancer immunotherapy a plus.
- 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 392SN.

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.