Senior Manager / Manager, TMF and Document Management
Job Code 541IA

Description

Fate Therapeutics is seeking an experienced clinical operations professional for the role of Senior Manager / Manager, TMF and Document Management. The successful candidate will support the document management of Fate-sponsored clinical trials to ensure adequate quality of procedural documents and electronic trial master files (eTMFs). 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 Director of Clinical Compliance.

Responsibilities

- Coordinate procedural document management, including entry of standard operating procedures (SOPs) and work instructions (WIs) within the electronic document management system (EDMS).
- Coordinate periodic updates to Clinical Development procedural documents per review cycle and training assignments.
- Maintain business processes and tools for evaluating, tracking, and transmitting trial master file essential documents within the electronic system.
- Partner with the Director of Clinical Compliance and Clinical Operations to improve and/or revise eTMF filing structure using industry standard reference model.
- Process clinical study documentation in accordance with SOPs, FDA, and ICH GCP guidelines.
- Perform quality-control review and/or oversight of cross functional documents that are submitted for entry into the TMF.
- Liaise with clinical teams to resolve any issues identified with the documents submitted.
- Assist the clinical team in the close-out and archiving of clinical documentation and reports to ensure completeness and inspection readiness.
- Support ensuring Fate maintains its compliance with ICH GCP as required. May develop and report metrics to support GCP activities and review.
- Support Clinical Compliance and Clinical Development documentation compliance activities as needed.
- May interact with vendors to which TMF /eTMF maintenance is outsourced.

Qualifications

- BS/BA degree in related discipline and at least 5 years of related experience (at least 7 years related experience for Sr Manager).
- At least 5 years of experience in clinical operations related to essential documents collection and procedural document management.
- Experience within pharmaceutical/biotech industry required.
- Advanced experience with electronic document management systems (eg, Veeva Vault or similar).
- Broad knowledge of applied GxP experience in Pharmaceutical and/or Biotech industry especially in clinical drug development space.
- Experienced in essential document collection and procedural document management; support of multiple functions within Clinical Development preferred.
- Knowledge of applicable regulations, such as FDA, ICH GCP, EU CTR.
- 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.

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 541IA.

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.