Senior Manager, Compliance, Process & Training
Job Code 497IA

Description

Fate Therapeutics is seeking an experienced process and training professional for the role of Senior Manager, Compliance, Process & Training. The successful candidate is responsible for the administration of training and change management activities related to procedural documents and procedural training to ensure employees in Clinical Development are compliant with their training requirements. The Senior Manager will also support procedural document development and activities in Clinical Development. 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

- Partner with the Director of Clinical Compliance to assess gaps and identify training needs within Clinical Development.
- Liaise within Clinical Development to facilitate process development.
- Provide project management and subject matter expertise to develop processes, training materials and solutions, and implementation plans, to align with training and change management strategy/curricula on an ongoing basis.
- Amend or revise training materials as needed to reflect the needs of the Clinical Development organization.
- Conduct training as needed.
- Manage external learning vendors to deliver external training programs as needed. Monitor external training vendor budgets and provide reports on an ongoing basis.
- Manage communication in support of process change and applicable procedural training. Develop and implement change management tactics.
- Coordinate procedural document management, including standard operating procedures (SOPs) and work instructions (WIs) within the electronic document management system (EDMS).
- Coordinate periodic updates per review cycle and training assignments.
- Support ensuring Fate maintains its compliance with ICH GCP as required. Develop and report quality metrics to support GCP activities and review.
- May support Clinical Compliance and documentation compliance activities as required.
- Play a key role in the Quality Management System (QMS) implementation plan and support the QMS roll out.

Qualifications

- BS/BA degree in related discipline and at least 7 years of related experience.
- At least 5 years of experience in Training or Educational Development in a corporate, scientific and/or technical environment.
- Broad knowledge of applied GxP experience in Pharmaceutical and/or Biotech industry especially in clinical drug development space.
- Experience within pharmaceutical/biotech industry.
- Prior experience with Clinical Operations processes preferred.
- Experience with implementation of QMS and/or Learning Management System (LMS) a plus.
- Ability to quickly learn and understand complex technical and scientific information as it relates to training and compliance responsibilities.
- Demonstrated ability to develop and implement key learning objectives and adult learning strategies and tactics.

- 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.
- Thrives 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
- Evening and weekend work as necessary

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 497IA.

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). The Company's pipeline also includes 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 in patients with hematologic malignancies undergoing allogeneic stem cell transplant. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.