Senior Manager / Manager, Regulatory Affairs (Clinical)

Job Code 480VM

Description

Fate Therapeutics is seeking an experienced and highly motivated regulatory professional to support its expanding cellular therapy programs. The Senior Manager / Manager, Regulatory Affairs (RA) will provide support to the Associate Director, RA in the development and implementation of global clinical regulatory strategies for development products. This individual will support regulatory activities, including strategy development for programs and dossier lifecycle management, and will work closely with cross-functional subject matter experts to ensure an effective partnership and execution of regulatory strategy, regulatory requirements, and the timely submission and approval of regulatory filings. This is a full-time position reporting to the Associate Director, Regulatory Affairs and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Effectively work with internal and external stakeholders to independently manage clinical regulatory activities under the direction of the RA Clinical Lead
- Manage, author, coordinate, and review regulatory submission documents and development activities to support regulatory filings and dossier lifecycle
- Work with the clinical team to provide regulatory review of clinical study protocols, ICFs, SAPs, and CSRs
- Independently research and interpret regulations, and provide regulatory guidance to cross-functional stakeholders; monitor clinical industry and regulatory trends and be able to apply learnings and provide guidance related to such trends
- Establish functional processes, guidelines, and SOP's
- Support the strategy and preparation of health authority meeting materials and responses to requests for information under the direction of the RA Clinical Lead
- Support management with development and implementation of departmental strategies and policies, and contribute to the development and implementation of regulatory strategies to mitigate risks
- Assure compliance with all applicable (domestic and international) regulations
- May mentor or provide oversight of assigned department staff
- Other duties as assigned

Requirements

- A minimum of a Bachelors' degree in a life science with at least 5 years of experience in RA in the biotechnology or pharmaceutical industries
- Demonstrated direct experience with Health Authority submissions and strong knowledge of FDA/EMA regulations and agency submission and approval processes
- Proven experience in applying regulatory knowledge to various clinical activities; strong knowledge of clinical study design, Good Clinical Practice principles, and navigation of clinical development pathways

- Experience leading and managing the preparation of annual reports, DSURs, and Investigator's Brochures
- Strong ability to quickly absorb new technical and strategic information and have the flexibility to adapt accordingly
- Excellent operational skills including planning, organizing, and the ability to deal effectively with a variety of personnel both internally and outside the company to drive projects to timely completion
- Excellent writing, communication, and interpretive skills
- High attention to detail, ability to work on multiple projects with tight deadlines and able to work independently
- Previous cell therapy product experience and regulatory knowledge is highly preferred
- Prior direct interactions with Health Authorities is desirable
- Prior participation in a GCP inspection is desirable
- Experience with CTA filing preferred

Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- Full-time onsite work at Company's headquarters in San Diego
- May require occasional travel for training programs and meetings

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 480VM.

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.