Senior Program Manager / Program Manager, Regulatory Affairs
Job Code 261JB

Description

Fate Therapeutics is seeking an experienced and highly motivated regulatory professional to support its expanding cellular therapy programs. The Senior Program Manager / Manager, Regulatory Affairs (RA) will provide support to the Executive Director, RA in the development and implementation of 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 located at our corporate headquarters in San Diego, CA.

Responsibilities

- Effectively work with internal and external stakeholders to independently manage regulatory activities
- Manage, author, coordinate, and review regulatory submission documents and development activities to support regulatory filings and dossier lifecycle
- Independently research and interpret regulations, and provide regulatory guidance and strategy to cross-functional stakeholders; monitor clinical, non-clinical, and CMC industry and regulatory trends and be able to apply learnings and provide guidance or strategy related to such trends
- Lead and manage the strategy and preparation of health authority meeting materials and responses to requests for information
- 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 lead other department staff
- Other duties as assigned

Requirements

- 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 situations across clinical, nonclinical and CMC disciplines
- 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

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 261JB.