Associate Director, Regulatory Affairs
Job Code 357JB

Description

Fate Therapeutics is seeking an experienced and highly motivated regulatory professional to support its expanding cellular therapy programs. The Associate Director, Regulatory Affairs (RA) will provide support to the Vice President, RA in the development and implementation of regulatory strategies for development products. The Associate Director, RA is responsible for developing global Chemistry, Manufacturing and Control (CMC) regulatory strategies and content plans. The primary responsibility is to lead the CMC regulatory activities related to cellular therapies in clinical development. The Associate Director will support CMC Teams and provide direction on the interpretation and application of global CMC regulations and guidance related to cell therapies. This is a full-time position located at our corporate headquarters in San Diego, CA, reporting to the VP, Regulatory Affairs.

Responsibilities

- Serve as the RA CMC Lead on project teams and provide regulatory expertise and input on cross-functional team recommendations to facilitate successful product development globally.
- Lead CMC teams to develop global submission plans that comply with local regulatory requirements and commitments.
- Author and/or lead the preparation of regulatory dossiers for submission to global Health Authorities throughout the product lifecycle.
- Effectively and thoughtfully communicate with Health Authorities while maintaining good rapport and credibility. When appropriate lead meetings with Health Authorities under supervision of a senior member of the RA Department. Develop and reach consensus on regulatory CMC strategy for Health Authority information request responses, as needed.
- Provide accurate regulatory assessments of CMC changes to project teams and refine regulatory strategies as needed based on emerging data, therapeutic area, and evolving regulatory landscape.
- Drive a corporate culture of continuous improvement to ensure compliance with Health Authority laws and recommendations, as well as industry best practices.
- Develop and update contingency plans for issues that may affect product registration, regulatory compliance, and the continued lifecycle management of development products.
- Escalate issues to Regulatory Management that may affect registration, regulatory compliance and continued lifecycle management of the product.
- May lead selected initiatives within the Regulatory Department and/or provide oversight of assigned staff.

Requirements

- A minimum of a Bachelor of Science in biological, pharmaceutical, chemical, or engineering sciences with generally a minimum of 7+ years of experience inclusive of post graduate

education and/or pharmaceutical or health care industry experience or equivalent is required. An MS, PhD, or PharmD. degree preferred.

- Experience in biologics is preferred.
- Strong knowledge of global Health Authority laws, regulations, guidance and regulation submission routes available for assigned products is required.
- Strong experience directly writing submission documents that support clinical trials, marketing, and lifecycle management is required.
- Experience in regulations or product development in gene therapy (i.e., CAR-Ts, AAVs, CRISPR technology etc.) is preferred.
- Experience developing regulatory strategies and an understanding of product development, seen as an expert on product development and how it is applied in global regulatory strategy is required.
- Strong attention to detail with high-level verbal and written communication skills is required; effectively communicates cross-functionally. Ability to present and defend regulatory strategies and opinions to project teams.
- Strong ability to quickly absorb new technical and strategic information and have the flexibility to adapt accordingly.
- High attention to detail, ability to work on multiple projects with tight deadlines, and able to work independently.
- Demonstrates clear understanding of priorities and leads others by example to drive for results.
- Good understanding of competitors in the area and what they are doing in early/late development is 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 357JB.

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.