Manager, Regulatory Affairs (CMC)
Job Code 481LL

Description

Fate Therapeutics is seeking an experienced and highly motivated regulatory professional to support its expanding cellular therapy programs. The Manager, Regulatory Affairs (RA) will provide support to the Associate Director, RA in the development and implementation of global Chemistry, Manufacturing and Control (CMC) regulatory strategies for clinical development products. The RA Manager will support CMC Teams and provide direction on the interpretation and application of global CMC regulations and guidances related to cGMP and cell therapies. 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

- Support the RA CMC Lead on project teams and provide regulatory expertise and input on cross-functional team recommendations to facilitate successful product development globally.
- Support RA CMC Lead and CMC teams to develop global submission plans that comply with local regulatory requirements and commitments.
- Author and/or manage the preparation of regulatory dossiers for submission to global Health Authorities throughout the product lifecycle.
- When appropriate support 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.
- Support a corporate culture of continuous improvement to ensure compliance with Health Authority laws and recommendations, as well as industry best practices.
- Support development of 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 a minimum of 5 years of relevant experience inclusive of post graduate education and/or pharmaceutical or health care industry experience or equivalent is required.
- 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 understanding of CMC submission documents that support clinical trials, marketing, and lifecycle management is required.

- Strong understanding and knowledge of GXP, ISO, and ICH concepts/guidelines and implementation of GXP in a Phase appropriate manner in conformance to US & EU standards.
- Knowledge of regulations or product development in cell/gene therapy (i.e., CAR-Ts, AAVs, CRISPR technology etc.) is preferred.
- Strong attention to detail with high-level verbal and written communication skills is required; effectively communicates cross-functionally.
- Strong ability to quickly absorb new technical and strategic information and have the flexibility to adapt accordingly.
- Ability to work on multiple projects with tight deadlines, and able to work independently.

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 481LL.

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.