Senior Regulatory Affairs Associate
Job Code 285VM

Description
Fate Therapeutics is seeking an experienced and highly motivated regulatory professional to support the regulatory affairs team. The successful candidate must thrive in a fast-paced team environment and have excellent communication, planning, and organizational skills, with the ability to prioritize and have good time management skills under tight deadlines. The ideal candidate must be proficient in regulatory agency submission requirements, interpret guidance documents to support the development of strategy, drive life-cycle submissions, and be familiar with the use of electronic document management systems and quality management systems. This is a full-time position reporting to the Senior Program Manager, Regulatory Affairs, and is located at our corporate headquarters in San Diego, CA.

Major Responsibilities Include:
- Coordinate the preparation, submission, and maintenance of domestic and international regulatory submissions including INDs, CTAs, DMFs, amendments, safety reports, DSURs, annual reports, information requests, and background materials for regulatory authority meetings
- Review documents required as part of the Regulatory Greenlight for the shipment of drug product to the clinical sites
- Review regulatory submissions to ensure quality
- Research and evaluate regulations, guidances, and draft guidances to help support the development of regulatory strategy
- Support RA filing goals through collaboration with Researchers, Development personnel and Clinical Development personnel to ensure accuracy of regulatory submission content
- Create and maintain Regulatory Affairs schedules for domestic and international regulatory filings to ensure alignment with agreed strategies
- Collaborate with other quality system stakeholders to develop SOPs and other quality system documents to achieve compliance goals
- Support development of department policies, procedures and best practices commensurate with the requirements of rapidly growing company
- Work in close partnership with Regulatory Operations to ensure accuracy and timeliness of regulatory submissions
- Maintain knowledge of current regulatory environment and interpret and communicate relevant issues
- Perform other duties as required

Requirements

- Bachelor's degree plus a minimum of 3 years' experience in RA, preferably in a clinical stage pharmaceutical or biotechnology company
- Experience performing electronic review of published submissions
- Knowledge of global regulatory health authority requirements for submissions
- Experience driving life-cycle submissions
- Understanding of regulatory and quality compliance requirements
- Strong organizational, analytical, and problem-solving skills
- Proficiency using Microsoft Word, Excel, Project, Adobe Acrobat Professional
- Experience using an EDMS system, particularly Veeva Regulatory Information Management (RIM) Suite
- Strong team orientation, with excellent written and oral communication skills

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 285VM.

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's immunooncology pipeline is comprised of universal, off-the-shelf NK cell and T-cell product candidates that are mass produced using its industry-leading induced pluripotent stem cell (iPSC) product platform. In 2019, Fate Therapeutics initiated the first-ever clinical trial in the United States of an iPSC-derived cell product, and is developing this NK cell cancer immunotherapy, FT500, for the treatment of patients with advanced solid tumors and lymphomas that are resistant to checkpoint inhibitor therapy. The Company is also developing FT516, an engineered iPSC-derived NK cell product candidate incorporating a novel high-affinity, non-cleavable 158V CD16 Fc receptor for enhanced binding to monoclonal antibodies, and is advancing a highly-differentiated pipeline of iPSC-derived chimeric antigen receptor (CAR) NK cell and T-cell product candidates designed to simultaneously engage multiple tumor-associated antigens for the treatment of hematologic malignancies and solid tumors. The Company's immuno-regulatory pipeline includes ProTmune™, a pharmacologicallymodulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of acute graft-versus-host disease (GvHD), and an iPSC-derived myeloid-derived suppressor cell (MDSC) 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.