Senior Regulatory Affairs Associate
Job Code 180SP

Description

Fate Therapeutics is seeking an experienced and highly motivated regulatory professional to support regulatory affairs operations. 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 submissions requirements, the use of electronic document management and regulatory publishing and submission tools, and quality management systems. This is a full-time position reporting to the Senior Manager, Regulatory Affairs, and is located at our corporate headquarters in San Diego, CA.

Major Responsibilities Include:

- Produce regulatory documents INDs, DMFs, amendments, safety reports, DSUR, annual reports and background materials for regulatory authority meetings
- Prepare, submit, track, index and archive electronic submissions
- Perform reviews of regulatory submissions to ensure quality
- Maintain electronic quality management system and eCTD publishing capability
- Support RA filing goals through collaboration with Researchers, Development personnel and Clinical Operations 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
- Provide continuous evaluation of regulatory operations processes to identify and address strengths and weaknesses to maintain efficient and effective operational procedures
- Support development of department policies, procedures and best practices commensurate with the requirements of rapidly growing company
- 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
- Training and experience leading to expert user of programs used in regulatory document preparation and publishing

- Knowledge of global regulatory health authority requirements for submissions, especially those relating to submission requirements including formatting and processing of electronic Common Technical Documents
- Understanding of regulatory and quality compliance requirements
- Strong organizational, analytical, and problem-solving skills
- Proficiency using Microsoft Word, Excel, Adobe Acrobat Professional, CSC Toolbox, eCTD publishing systems and electronic document management systems
- 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 180SP.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cell lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.