Director, Regulatory Affairs
Job Code 179SP

Description

Fate Therapeutics is seeking a motivated and talented individual to join the Regulatory Affairs team. This position is a key member of project development teams, and is responsible for the evaluation of product development concepts from the regulatory perspective. The ideal candidate should have experience in the area of biologic cellular therapy and product development including complex submissions to FDA and ex-US health authorities. Knowledge and awareness of the pertinent regulations and how they apply to this rapidly evolving field are important. The ideal candidate will have a track record of relevant experience gained in an equivalent industry position. Candidates must thrive in a fast-paced team environment. Excellent communication, organizational abilities, and independent problem-solving skills are a must. This is a full-time position reporting to the Head of Regulatory Affairs, and is located at our Company's headquarters in San Diego, California.

Responsibilities:

- Develop and implement global regulatory strategies in support of business objectives on assigned development projects
- Serve as the Company's representative with regulatory health authorities on assigned development projects
- Serve as the Regulatory Affairs representative on project teams and assure the progress of projects by providing regulatory solutions and feedback on the ongoing project development; work closely with development team to troubleshoot technical issues related to regulatory submissions
- Lead the coordination, gathering of information, and review of reports, protocols, documents for regulatory submissions; ensure consistent and appropriate regulatory guidance and communication within the development organization
- Establish and meet timelines for regulatory submission activities to ensure commitments are met; review documents for submission to regulatory agencies to assure accuracy, quality, content and format, and compliance with applicable regulations
- Provide the regulatory plan for assigned project(s) and review the overall product development plan to ensure alignment of development activities in support of regulatory registration plan; maintain awareness and communicate with development team members regarding changing regulatory requirements; provide updates on revised/new regulations and guidance documents and to assess impact on the product development plan

- Develop a plan and oversee the establishment of required regulatory affairs operational infrastructure to support ongoing and planned regulatory activities, includes SOP development and implementation of electronic submission/filing solutions while working closely with the Senior Manager, Regulatory Affairs
- Ensure regulatory compliance with pre- and post-approval filing and reporting requirements
- Create and implement strategies for FDA Type A/C, EOP2, EMEA Scientific Advice and HTA meetings, as well as develop plans for PIP, PSP, INDs, amendments, BLAs and supplements; manage regulatory expedited safety reporting for development projects
- Plan and support IND/BLA filings or other major regulatory interactions, including coordination of FDA or ex-US meeting materials (meeting requests, briefing documents, presentation materials)
- Serve as primary author for key regulatory documents or sections of regulatory documents (briefing documents, meeting requests, and submission documents)
- Train, coach, and supervise staff and provide oversight for regulatory consultants and contractors
- Interact with outside consulting groups and manage activities, as necessary for completing key regulatory initiatives
- Maintain awareness of global regulatory legislation and assess its impact to overall business and product development programs
- Provide guidance to internal groups and business partners based on technical and regulatory knowledge towards development of strategic and tactical plans

Qualifications

- Scientific degree (chemistry, biology, pharmacy or related, pharmaceutical, or engineering sciences)
- Minimum 8 years of increasingly responsible regulatory affairs experience in a clinical stage pharmaceutical or biotechnology company, including supervisory experience, guiding and motivating regulatory and development teams; direct experience with regulatory submissions and product development.
- Deep and broad knowledge of worldwide approvals; experience in the interpretation of US, ICH, and international regulations, guidance documents, etc.
- Experience with EMA submissions is strongly preferred
- Oncology, biologics, and cellular therapy experience is strongly preferred
- Self-motivation, good judgment, strong follow up, organizational, analytical, and problem-solving skills; capable of identifying risks; creative and innovative thinker

- Ability to work effectively with limited direction and guidance and minimal supervision, to set priorities and multi-task to meet timelines in fast-paced and demanding environment, to coordinate with others, and to manage submissions
- Strong team orientation, with excellent writing and 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 some travel for scientific and regulatory 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 179SP.

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.