Regulatory Affairs Operations Manager
Job Code 254JB

Description

Fate Therapeutics, Inc. is seeking an experienced and highly motivated regulatory professional to support Regulatory Affairs Operations. This is a full-time position reporting to the Executive Director, Regulatory Affairs. The Regulatory Affairs Operations Manager will be responsible for operational aspects of all regulatory submissions, ensuring that the submissions are of the highest quality and submitted on-time. The position will also support the compilation, archiving, and tracking of regulatory submissions and health authority correspondence in partnership with Regulatory Program Management, cross-functional Teams, and external partners. Emphasis will be on strategic planning, management, and execution of all aspects of Regulatory Affairs Operations.

Major Responsibilities Include:

- Collaborate with Regulatory Program Managers, cross-functional Teams, and external partners to plan, create, and submit regulatory health authority dossiers and amendments, including original INDs, CTAs, IMPDs, and marketing applications in electronic or paper formats, as required (i.e., formatting, publishing, submitting, life-cycling, and archiving sequences)
- Oversee in-house technical aspects for health authority submissions; e.g., eCTD document granularity, utilization of content templates, document formatting, eCTD application location and lifecycle assignment, publishing, QC, validation, and transmission to regulatory health authorities (e.g., FDA ESG, EMA IRIS)
- Serve as system owner for in-house regulatory information tools and systems (e.g., eCTD publishing tools, electronic document management system (EDMS), library system, and electronic templates)
- In collaboration with the Clinical Department, ensure regulatory documents are properly mapped and filed in the TMF
- Maintain expert knowledge of electronic submission and computerized system validation standards
- In collaboration with IT, ensure that in-house regulatory information tools and systems are implemented, validated, and maintained in accordance with company SOPs and applicable regulations
- Identify potential risks to submission plans and propose/execute risk mitigation strategies
- Ensure tracking and archiving of regulatory communications and submissions
- Support budgeting and forecasting for function and Regulatory Affairs department
- Provide recommendations on resource needs for regulatory operations and records management activities, including the need for outsourcing (e.g., eCTD or SPL vendor)
- Represent Regulatory Operations in project teams to support submission planning and ensure coordination of system development activities

Requirements:

- Bachelor's degree with 3-5 years' experience working in a biotechnology or pharmaceutical Regulatory Affairs Operations environment with demonstrated ability to present and articulate requirements; Bachelor's degree in IT or life science discipline is preferred
- Detailed knowledge of and strong experience managing eCTD publishing systems, EDMS technology, and publishing and validation software; experience with Lorenz eCTD publishing systems and DXC Toolbox is a plus

- Expert knowledge of global regulatory health authority formatting, publishing, and transmittal requirements for eCTD submissions
- Familiarity with dossier content requirements for global regulatory health authority submissions; strong knowledge of US and EU content requirements is preferred
- Knowledge of CDISC requirements and alignment with FDA's Study Data Technical Conformance Guide (i.e., SDTM, ADaM, and SEND requirements); experience in preparing a Study Data Standardization Plan
- Advanced proficiency using MS Word, MS SharePoint, Adobe Acrobat Professional, and eCTD content templates (e.g., Starting Point and Authorbridge), as well as experience with MS Excel, MS PowerPoint, and MS Project or Smartsheets
- Self-starter, with strong track record of working both independently and in collaboration with program stakeholders
- High attention to detail and ability to work on multiple projects with tight deadlines
- Strong experience administering and maintaining regulatory document authoring templates
- Strong oral, written, and interpersonal communication skills
- Strong project management and organizational skills, with demonstrated ability to absorb new technical/strategic information and be flexible to adapt accordingly

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 254JB.

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 is pioneering the development of off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline is comprised of FATE-NK100, a donor-derived natural killer (NK) cell cancer immunotherapy that is currently being evaluated in three Phase 1 clinical trials, as well as iPSC-derived NK cell and T-cell immunotherapies, with a focus on developing next-generation cell products intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-associated antigens. The Company's immuno-regulatory pipeline 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, 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.