Associate Director, Drug Safety Science
Job Code 552JK

Description
Fate Therapeutics is currently seeking a motivated individual to support the drug safety science team. This individual will work with the Safety Science Physician Leads to conduct regular systematic review of safety data of clinical product candidates, support authoring and review of clinical and regulatory documents related to safety information and analysis, and coordinate, lead, and present at meetings involving safety data and analyses. This position initially reports to the Director, Drug Safety Operations and is located at our corporate headquarters in San Diego, California or in the San Francisco Bay area.

Responsibilities
- Perform search and review of cumulative safety data, conduct scientific literature search and review scientific literature abstracts for identifying safety signals
- Appropriately elevate signal detection findings impacting assigned products benefit/risk
- Perform data analysis to evaluate safety signals, actively contribute to discussions of product benefit/risk, and write up analysis results
- Contribute to the execution and development of signal detection activities
- Support authoring of Safety Assessment Reports and other safety documents and regulatory responses in collaboration with the Safety Science Physician Lead
- Prepare presentation of the Safety Team's recommendations on safety issues to cross-functional decision-making bodies
- Represent safety science on cross-functional project teams for clinical product candidates
- Present safety information at external meetings
- Perform duties as a Safety Strategy Team leader for smaller or less complex projects under the supervision of the Safety Science Physician
- Review, prepare and present safety data to Safety Assessment Committee (SAC) and has the capacity to take the lead role in data evaluation and discussion of the results with the Safety Science Physician Lead, SAC Core Team members and other key stakeholders
- Support the Safety Science Physician for the preparation of accurate and fit-for-purpose documents related to safety data in response to internal or regulatory authority requests
- Provide safety input to regulatory submissions for new products, formulations or indications
- Collaborate with Safety Science Physician and Clinical Development, Clinical Scientists, and Medical Monitor/Medical Lead representatives in clinical trial safety monitoring
- Support authoring IB Reference Safety Information (RSI) for assigned development products; coordinates meetings and tracks timelines to ensure completion
- Proactively evaluates the clinical implications of safety data from pre-clinical studies, clinical studies, scientific literature and other information sources to establish the safety profile of drugs and manage the risk to patients
- Actively participates in development of assigned product safety profile including core data sheets (CDS) and product labels
- Support Safety Physician in planning, preparation, writing and review of safety portions of periodic regulatory documents/ aggregate reports (DSURs, Annual Reports, PBRERs, PSURs, RMP), works with Safety Science Physician Lead for final safety sections content and conclusions.

- Contribute to the safety science component of contracts/agreements with third parties to ensure quality and integrity of agreement
- Assist in the development of risk management strategy and developing content for Signal Development Plan / Risk Management Plan; prepare responses to regulatory inquiries under the guidance of Safety Science Physician
- Support activities related to new drug applications and other regulatory filings, including assisting the Safety Science Physician in developing a strategy and/or providing safety content for safety-related regulatory activities
- Trains junior team members on signal detection processes and safety processes as needed; acts as a mentor to junior team members on activities related to the Safety Scientist role, especially those activities with related to answering questions from internal cross-functional and/or external groups, knowledge sharing, and problem solving
- Support and provide safety review and input to relevant sections for study protocols, including ICFs; statistical analysis plans; safety-related data collection forms; and design of tables, figures, and listings for safety data from clinical studies
- Represents the Drug Safety in study team meetings, as appropriate
- Collaborate within and across company functions to identify and ensure management of internal and external safety-related documentation and support when required, e.g., safety content support for audits or inspections
- Leads initiatives and task force groups for continuous improvement projects

Qualifications

- BS/RN/PharmD or equivalent with relevant scientific experience and/or training discipline; PhD/MD preferred
- Minimum of 5 years industry experience in safety and pharmacovigilance,
- Experience in oncology required; experience in cellular therapy preferred
- Demonstrated ability to mentor and coach others
- Strong understanding of medical concepts, drug development, pharmacovigilance, risk management and global regulatory safety and risk management health authority requirements
- Strong understanding of project planning methods; demonstrated ability to manage timelines and to prioritize; ability to align operational milestones and activities with operational representatives in other functional areas. Appropriately escalates issues that could impact activity timelines or quality.
- Ability to effectively lead and work well within cross-functional teams, using strong organizational, facilitation, and interpersonal communication skills.
- Strong understanding and communication of scientific subject matter, including authoring scientific documents
- Attention to detail along with excellent scientific, analytical and conceptual skills
- Demonstrated ability to understand, research, independently investigate, interpret, and reach reasoned conclusions regarding complex medical-scientific data from a broad range of disciplines, e.g., clinical trial laboratory data, nonclinical data, scientific literature, and regulatory documents

Working Conditions and Physical Requirements

- Full-time work at company's headquarters in San Diego or from San Francisco Bay area
- Travel between office locations as required
- Occasional evening and weekend work as required

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 curriculum vitae to: careers@fatetherapeutics.com and reference job 552JK.

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). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.