Medical Director, Safety Science
Job Code 292WC

Position Description

We are seeking a hands-on, experienced Medical Director, Safety Science to lead the clinical safety strategy for assigned drug projects and products, provide drug safety expertise and guidance to Clinical Development, Safety Oversight Committee (SOC) and cross-functional Clinical Project Teams, and drive proactive implementation of risk management initiatives in accordance with global regulatory requirements. This position will involve continuous, efficient monitoring of safety data to perform signal evaluation and predict and manage the safety profile of compounds in clinical development, consistent communication of safety topics across all regulatory safety documents, and strategic collaboration with external partners. This position reports to the VP, Clinical Development, and is based at the Company's corporate headquarters in San Diego, California.

Major responsibilities

- Proactively evaluates the clinical implications of safety data from pre-clinical studies, clinical studies, literature, and other information sources in order to predict/establish the safety profile of compounds in clinical development
- Performs individual case report assessment and determines regulatory reporting responsibilities as required
- Provides medical review of case narratives for medical content, accuracy, and signal detection
- Interprets aggregate safety data for periodic reports and evaluating for potential new signals
- Leads signal detection, signal evaluation, data analysis, and benefit-risk evaluation for assigned compounds
- Leads risk management and mitigation activities, including medical and safety leadership for Risk Management Plans
- Writes individual case assessments and evaluates aggregate safety data for periodic reports
- Provides medical input into identification and utilization of appropriate sources of information and database searches to retrieve relevant data for evaluation of signals
- Offers medical judgment on complex safety issues
- Presents safety data to DSMBs for assigned products and internal Safety Assessment Committees
- Contributes to/reviews the Safety Data Exchange Agreements and other documents shared with partners; provides vendor oversight for assigned products
- Participates in cross-functional project teams; communicates across organizational levels and functions
- Contributes to the maintenance of the pharmacovigilance system and processes
- Participates in SOP updates, audits, and inspection readiness
- Writes/updates core safety information for assigned projects

- Writes/reviews and provides technical input for the safety sections of regulatory documents for assigned projects (i.e. protocols, IBs, ICFs, CSRs, IND submissions, annual reports, etc.)
- Prepares and/or reviews safety documents and provides strategic input into responses to regulatory inquiries
- Participates in external meetings with Health Authorities
- Participates in non-regulatory meetings, including those with consultants and other companies, such as licensing partners
- Guides and/or trains external personnel/parties involved in Company's clinical studies
- Collaborates effectively in cross-functional and cross-cultural project teams and environments, and work with external providers
- Maintain clinical and technical expertise in the therapeutic areas i.e. through review of scientific journals, attendance at scientific and key technical meetings, etc.
- May participate/present safety material to Investigator's meetings and other medical meetings
- Participates in selection and bidding activities for vendors and contractors
- Ensures that safety science practices comply with GVP as well as internal safety processes
- Managerial responsibilities as necessary

Requirements

- Medical degree (e.g. MD, MBBS, DO)
- At least 5 years minimum experience as a Medical Safety Physician or similar pharmacovigilance leadership role in the pharmaceutical or biotechnology industries
- A thorough knowledge of clinical research and global regulatory requirements, and practices governing expedited and periodic safety reporting, signal generation, safety evaluation, and risk management activities
- Strong skills in the management of safety information originating from both clinical development and post-marketing sources
- Expert knowledge of the regulations governing pharmacovigilance
- Working knowledge of industry standard pharmacovigilance databases
- Strong leadership skills and ability to communicate with individuals at all levels
- Excellent oral and written communication skills
- Excellent analytical skills and ability to work independently
- Ability to exercise creativity and judgment

Working Conditions and Physical Requirements

- May require occasional evening and weekend work
- Full-time onsite work at Company's headquarters in San Diego
- Travel as required to clinical sites and clinical/professional 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 code 292WC.

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 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 product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include 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.