Head of Drug Safety
Job Code: 553WC

Description

Fate Therapeutics is seeking an experienced Head of Drug Safety to lead the clinical safety strategy and drug safety activities in the support of clinical studies for assigned drug projects and products; provide drug safety and risk management expertise and guidance to support the Clinical Development organization, Safety Oversight Committees (SOCs) and cross-functional program teams; overseeing safety science and drug safety operations to establish and maintain robust processes and systems to fulfill regulatory safety reporting requirements; and formulate and implement risk management strategies (e.g., REMS) in accordance with global regulatory requirements. This position will involve the continuous and efficient monitoring of safety data to perform signal evaluation and characterize the safety profile of compounds in clinical development, ensuring accurate and timely submissions of regulatory safety reports and summary documents, and where applicable, participating in the strategic collaboration with external partners. Additionally, the Head of Drug Safety is responsible for leading the drug safety/safety science team's strategy and growth in the company as well as serving as an individual contributor or delegating responsibilities for review of ICSR and aggregate data. This position reports to the SVP, Clinical Development, and is based at the Company's corporate headquarters in San Diego, California or in the San Francisco Bay area.

Responsibilities

- Develops and implements safety strategies that contribute to the creation of new, differentiated medicines and support the generation benefit/risk profile in alignment with stakeholders both internally and externally.
- Provides leadership for the drug safety organization and ensures that Health Authority requirements and expectations related to drug safety and pharmacovigilance are met.
- 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
- Oversees drug safety operations, and is accountable for:
    - Review of individual case report assessment and determining regulatory reporting responsibilities as required
    - Provides medical review of case narratives for medical content, accuracy, and signal detection
    - Maintenance of the drug safety system and processes in compliance with GVP and industry-standard practices
- Interprets aggregate safety data for periodic reports and evaluating for potential new signals
- Leads the safety science team in signal detection, signal evaluation, data analysis, and benefit-risk evaluation for assigned compounds
- Leads the safety team in risk management and mitigation activities, including medical and safety leadership for Risk Management Plans
- Accountable for active contribution/authorship of individual case assessments and evaluation of aggregate safety data for periodic reports
- Provides medical input and utilizes appropriate sources of information and database searches to retrieve relevant data for evaluation of safety signals
- Contributes medical judgment on complex safety issues
- Presents safety data to DSMBs for assigned products and internal Safety Assessment Committees

- Responsible for the Safety Data Exchange Agreements and other documents shared with external partners; provides vendor oversight for assigned products
- Accountable for drug safety representation in cross functional project teams, may lead cross-functional project teams
- Participates in SOP updates, audits, and inspection readiness
- Responsible for overseeing authoring/updates core safety information for assigned projects
- Authors/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 as applicable 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 regarding Drug Safety activities
- 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.
- Oversees presentation of safety material at 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 drug safety processes
- Managerial responsibilities include oversight and growth/development of drug safety operations, safety science teams, and medical physician teams; training/development/evaluation of drug safety personnel, department metrics/KPIs, training and compliance, and CAPAs within the department; participation in budget and resourcing planning; provide strategy to support efficiency, consistency and scalability of all drug safety team activities.

Qualifications

- Medical degree (e.g., MD, MBBS, DO)
- A minimum of 10 years experience as a Medical Safety Physician or similar pharmacovigilance leadership role in the pharmaceutical or biotechnology industries; experience in oncology preferred
- A minimum of 5 years in direct managerial experience and responsibility overseeing a clinical safety team, such that the applicant will have a broad knowledge of drug development and will have an understanding of
    - Project management at a senior level
    - Preclinical discovery, preclinical product development and associated regulatory issues
    - Drug approvals process in the US and EU, experience of direct interactions with US and EU regulatory authorities
- 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
- Experience with drug safety responsibilities for Phase I-IV studies, PASS, and post-marketing adverse event reporting

- Experience in drug safety activities supporting IND and NDA filings
- Experience in building drug safety department from start up through postmarketing phases
- Experience identifying and resolving gaps in tools, resources, and processes for a robust drug safety department
- Expert knowledge of the regulations governing pharmacovigilance
- Working knowledge of industry standard pharmacovigilance databases
- Strong leadership and management 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

- Travel between office locations as required
- 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 curriculum vitae to: careers@fatetherapeutics.com and reference job 553WC.

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.