Director, Pharmacovigilance (PVG) Operations
Job Code 291WC

Position Description

We are seeking a hands-on pharmacovigilance professional to lead and direct PVG safety risk management operations for Fate Therapeutics sponsored clinical trials of engineered immune cell therapy for the treatment of cancer. This position oversees adverse event report collection and processing at participating clinical trial sites, manages PVG training and compliance, and leads the collection and reporting of individual case safety reports (ICSR) and other defined safety data across all clinical development programs. The position provides strategic leadership and guidance to PVG staff and establishes and maintains relationships with CROs and vendors supporting PVG operations deliverables. This position collaborates cross-functionally with clinical development, clinical operations, regulatory affairs, and quality assurance teams. This position will initially report to the VP, Clinical Development, and is based at the Company's corporate headquarters in San Diego, California.

Major Responsibilities

- Provide PVG Operations leadership for Fate Therapeutics clinical programs, which are being assessed in multiple oncology disease settings, including hematologic malignancies and solid tumors, with the potential for registration intent globally.
- Direct and manage ICSR collection processing and reporting activities
- Provide oversight of drug safety database maintenance
- Have hands-on involvement in all aspects of safety reporting and study conduct in collaboration with Fate development and contracted personnel with a commitment to ensure that all clinical activities including data review, analysis, and reporting of results operate to the highest ethical, safety and quality standards and are in compliance with Fate, GCP and regulatory requirements.
- Achieve defined performance metrics for PVG operations processes; partner with clinical stakeholders to set clear data standards for provision of information to facilitate high quality compliant ICSR processing.
- Lead continuous improvement activities in PVG; identify when changes to policy, process, or organization are needed to improve compliance, quality, and efficiency; drive implementation of agreed upon changes.
- Manage CROs and vendors to support ICSR process including leading preparation of safety-related plans; develop operational strategies to optimize cost, capacity, quality and performance between internal and external resources.
- Play a key role in the interaction with regulatory authorities; provide audit/inspection response subject matter expertise for safety case related findings.
- Attend and participate at investigator meetings and engage in preparation of subject narratives, review of study reports and other documents (Investigator Brochures, protocols and informed consent forms), and preparation and / or review of periodic and interim safety reports (DSURs, Annual Reports).
- Work closely with functional groups to ensure that protocol development and implementation follow the safety monitoring plan.

- Provide leadership and line management to the PVG operations staff, including proactively managing, coaching, training and developing staff.
- Identify future resource needs and identify, recruit, train and develop appropriate talent.

Requirements

- B.S. / M.S. in Biomedical Science or related field; MD, PharmD or PhD a strong plus.
- Proven leadership experience in pharmaceutical safety including a thorough understanding of safety operations and regulatory requirements, with a broad understanding of downstream activities such as signal detection, evaluation and risk management processes.
- Experience interacting with regulators during inspections.
- Knowledge of FDA, EMEA and other international PVG regulations.
- A hands-on, independent and driven individual who can take charge of the work and is willing to contribute at different levels, e.g. engage with investigators, KOLs, etc. in one-on-one interactions.
- Vendor management experience.
- Experience with U.S. and European regulatory authorities and submissions is desirable.
- Experience or exposure to the development of cell therapies is desirable.
- Self-motivation, good judgment, strong follow up, organizational, analytical, and problem-solving skills; capable of identifying risks; creative and innovative thinker.
- Ability to work, lead and motivate a cross-functional matrix team.
- Excellent written and oral communication skills. Ability to communicate effectively through formal presentation and through informal scientific discussion with credibility, accuracy, and confidence with internal and external stakeholders and experts.
- Ability to travel as required.

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 291WC.

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.