Position: Manager, Pharmacovigilance

Reports to: EVP Clinical Development and Medical Affairs

Location: Waltham, MA

Position Summary:

The Manager of Pharmacovigilance is a key member of our clinical development team and is responsible for the planning, management and execution of clinical pharmacovigilance and risk management for early and late stage clinical development programs in compliance with appropriate regulatory guidelines. The successful candidate will interface with cross functional teams and external resources, collaborating with clinical, regulatory, contract research organizations and key consultants to ensure that all clinical safety pharmacovigilance is performed adequately across the clinical development portfolio.

Key Responsibilities Include:

- Establish and maintain pharmacovigilance policies, procedures, training programs and data that support Clinical Drug Safety objectives
- Coordinate monitoring and assessment of safety profiles through signal detection, data management, and critical review of safety data
- Support clinical development teams in all aspects of clinical safety and pharmacovigilance, including trial design, clinical development protocols, endpoint assessment, Clinical Study Reports, data management, and analysis of safety data
- Manage the review and response to adverse events reported to ensure accuracy, integrity, and completeness of safety information.
- Liaise with Medical Affairs, Clinical Operations, Regulatory Affairs and Quality to ensure appropriate and timely communication and dissemination of safety information to internal and external stakeholders
- Provide PV subject matter expertise both internally to teams and key stakeholders, as well as to regulatory agencies and other external bodies.
- Facilitate cross-functional collaboration within the organization to ensure proper safety standards are met and communicated
- Collaborate with clinical development team to write and review all relevant safety documents (e.g. Development Risk Management Plans, DRUS, Safety Analysis Plans, PSUR, RMPs, and DHCP letters, regulatory submissions, and responses)
- Other duties as assigned.

Education, Registration & Certification:

- Advanced degree in a health science, with relevant clinical development experience

Experience:

- 3-5 years total experience in pharmacovigilance/drug safety, or equivalent relevant clinical development experience in the Biotechnology industry
- Clinical safety experience, preferably in Phase I-III, with experience supporting regulatory submissions
- Strong understanding of clinical research methodologies, clinical biostatistics, pharmacovigilance tools/processes, and relevant regulatory frameworks
- Thorough understanding of the regulatory environment for safety and pharmacovigilance, with working knowledge of FDA and ICH guidelines
- Previous project management experience preferred

Skills, Knowledge & Abilities:

- Comfortable working independently with minimal supervision
- Highly organized, results driven, problem solver with ability to synthesize, organize, manage and communicate safety data from various sources
- Superior written and oral communication skills and the ability to work collaboratively and build relationships with colleagues from different levels of the organization
- Highly motivated with the ability to be flexible in a fast-paced environment

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- A clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

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