Pharmacovigilance Operations Lead

POSITION SUMMARY:

The Pharmacovigilance Operations Lead provides leadership in the areas of PV regulations /policies and PV operations. Responsible for the oversight of PV CROs with day-to-day PV operational activities including but not limited to ICSR activities and aggregate reports in accordance with global and regional Regulatory regulations. Contributes to PV inspection and audits, and continuous process improvement.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES:
The responsibilities will include, but are not limited to the following:

- Leads global PV operations, develops, maintains, and implements PV safety policies and procedures to ensure compliance with global regulations and requirements.
- Provides oversight of safety reporting by the PV CROs, including the review and monitoring of compliance through monitoring reports and other oversight activities and ensures the implementation of effective corrective and preventative action plans.
- Interfaces and collaborates with Clinical Operations, Clinical Development, Biostatistics/Data Management, Quality Assurance, and Regulatory Affairs and others as needed, provides safety supports for all Denovo programs.
- Assists in developing or updating of drug safety & PV quality and compliance-related SOPs, Working Instructions, and job aids.
- Responsible for the development and implementation of the global PV training strategy (e.g., training matrix development, process, contribute to the collection, organization, and presentation of all required global PV compliance metrics including vendor and partner oversight metrics).
- Responsible for the implementing and updates of appropriate safety management plans (SMP), joint operating guidelines (JOG), vendor oversight plan, etc.
- Assists in preparation and submission of PV aggregate safety reports (eg, DSUR, PSURs) in accordance with regulatory requirements and standard operating procedures.
- Assists in managing safety surveillance procedures including signal detection and evaluation related activities in accordance with SOPs and guidelines.
- Provides safety content review of study protocols, IBs, ICFs, CSRs, and other safety related documents as needed.
- Supports clinical trial SAE reconciliations.
- Develops and maintains Pharmacovigilance System Master File (PSMF), serves as Subject Matter Expertise (SME) for audits and inspections as well as ensures all safety-related documentation in an audit-ready state.
- Supports PV project management activities (eg, organize safety team meetings, maintains safety project timelines, takes meeting minutes, archives safety-related documents, etc.).
- Manages PV vendor contracts, agreements and management of invoices and budget related activities.

JOB QUALIFICATIONS:

Education, Certifications, Experience:

- Education: life sciences or healthcare professional required (e.g., PhD, PharmD, PA, MS, RN)
- Around 10 years of experience in the pharmaceuticals, biotech or CRO is preferred, with 4-5 years' experience in PV operations.
- Proven record in leading/managing PV Operations team and/or PV CROs.
- Excellent team / project leadership skills
- Good knowledge and experience using a global drug safety database, e.g. Argus

Knowledge, Skills and Abilities:

- Strong and dynamic leadership skills, with excellent negotiation, conflict resolution, decision making, problem solving, communication (written and verbal) and presentation skills.
- Demonstrated ability to multi-tasks in a fast-paced environment and rapidly growing company.
- In-depth knowledge of medical terminology/MedDRA, GCP, ICH guidelines, and current FDA and international regulations.
- Expert knowledge in global pre-marketing drug safety and PV compliance activities.
- Experience in the preparation of individual and aggregate safety reports.
- Good knowledge of regulatory authority inspection process with a focus on PV.
- Good networking and team skills for successful cooperation with internal and external customers.
- Self-motivated, detail oriented with prioritization, and time management proficiencies.

SPECIAL WORKING CONDITIONS:

- Physical Activities: On a continuous basis, sit at desk for a long period of time; intermittently answer telephone and write or use a keyboard to communicate through written means. Some walking and lifting up to 25 lbs. may be required. The noise level in the work environment is usually low to moderate. The physical demands described above are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- Occasional travel may be required.

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.