Safety Physician

POSITION SUMMARY

Support the Pharmacovigilance team in reviewing, querying, documenting and reporting on all serious adverse event (SAE) cases related to clinical studies and other safety related activities as needed. This position is based in either China or the U.S. This role will report to the Head of Global Safety & Pharmacovigilance.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

Ensure high quality, accurate, timely medical contributions to the safety evaluation of Denovo products. The medical related activities, including but not limited to:

- Perform medical review of individual case safety reports (ICSR) generated from clinical trials.
- Navigate safety database including the advancing of cases within the workflow and understanding and conducting of various medical coding applications.
- Assess cases for seriousness, causality, expectedness and medical accuracy including review of source documentation, content/narratives and event coding; raise queries to gain complete and accurate case information if needed.
- Provide drug safety input for individual product quality complaints.
- Accountable for timelines and quality of case safety reports outsourced to CRO.
- Represent PV team as medical safety expert on cross-functional study and program teams for assigned products and studies, provide expert guidance regarding safety matters and issues.
- High comfort level in working in multidisciplinary teams; provide input and relay information to PV management.
- Participate SAE reconciliation related activities.
- Provide medical content and review of aggregate safety reports such as DSUR.
- Review and provide medical content for key study-related documents, e.g. protocol, IB, ICF, SMP as needed.
- Participate in product development activities including Training Staff, SOP and Work Instructions development.
- Review safety data for the identification of new safety signals, in accordance with signal detection practices.

JOB QUALIFICATIONS

- Required MD degree or equivalent
- A minimum of 3 years Drug Safety/Pharmacovigilance experience in a biopharmaceutical industry or global CRO is preferred.
- Ability to understand and evaluate technical, scientific and medical information and understand the safety/medical implications, exposure to clinical data collection, assessment, and analysis.
- Proficiency with safety database (e.g. Oracle ARGUS, ARISg), MedDRA coding, Microsoft Excel, Word, and PowerPoint.
- Familiarity of GCP, ICH and Global regulations, especially in regions of company product development and/or marketing.
- Proficient in English (read, write, speak).
- Excellent teamwork and collaboration; proficiency in verbal and written communication.

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. 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.