Example of Pharmacovigilance Scientist Job Description

Our growing company is looking to fill the role of pharmacovigilance scientist. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

Responsibilities for pharmacovigilance scientist

- Assist with writing and maintenance of Safety Monitoring Plans and Safety Data Exchange Agreements
- Oversight of signal evaluation/safety monitoring activities
- Assure oversight for the review of safety events to ensure accuracy, integrity and completeness of safety information, and to ensure consistency of medical coding of safety data
- Provide pharmacovigilance (PV) data analysis and writing expertise as required for preparation of a range of US and global regulatory reports, including PBRER, PSURS,INDSRS and Signal Detection issues
- Responsible for data compilation, validation, evaluation and written conclusions for aggregate safety documents consistent with Company and global regulatory requirements
- Perform signal triage using medical judgment
- Prepares aggregate reports summarizing safety data, making conclusions about safety signals (or lack thereof)
- Direct the planning, preparation, writing and review of portions of aggregate reports
- Support and provide oversight to staff with regards to safety in clinical trials
- Review of Adverse Events or Serious Adverse Events (AEs/SAEs) from clinical trials

Qualifications for pharmacovigilance scientist

- Interacts collaboratively and effectively in a team environment (including Safety, Clinical Development, Medical Affairs, Clinical Operations, and Regulatory), with external colleagues
- A life sciences/pharmacy/nursing degree, and demonstrated Patient Safety and/or Clinical/ Drug Development experience
- Supports GPV team for its compliance goals with regards to data collection, analysis, reporting standards and operational consistency across interventional, non-interventional trials, IITS
- Collaborates with Clinical Operations, Data Management, Clinical CRO and Study Teams in development of the safety related data collection forms, table design, and listings for safety data from interventional/non-interventional trials
- Servers as a primary reviewer on safety/PV related topics for study protocols, statistical analysis plans and other clinical related documents and provides input an collaborate with other departments (e.g., clinical operations, medical information, regulatory affairs, medical affairs, commercial CRO and data management)
- Writes the safety section in collaboration with team members on regulatory responses, IBs/CCDS, study protocols, CRFs, Data Monitoring Committees reports and requests, and other documents, and provide the necessary quality control