Example of Pharmacovigilance Scientist Job Description

Our innovative and growing company is searching for experienced candidates for the position of pharmacovigilance scientist. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for pharmacovigilance scientist

- Submit/provide MedWatch/CIOMS I/E2b reports as applicable
- Providing therapeutic area PV support for Moderna's developmental products in close collaboration with senior PV, Clinical and Medical personnel
- Oversight of day to day PV operational activities for Moderna's investigational products
- Oversight of vendor case management and continued process improvement
- Review and provide PV therapeutic area input for development of protocols, IBs, SAPs, CSRs and other relevant project/study documents
- Represent Pharmacovigilance on clinical teams and initiatives both within and across functional areas
- Assist in usual pharmacovigilance activities including ongoing signal monitoring, benefit/risk assessment, regulatory activities and interactions
- Facilitate cross-functional Safety Review Committee meetings, including coordinating aspects of signal evaluation/safety review activities
- Participate in evaluation of potential safety issues in conjunction with senior PV staff, Medical Monitors, and other functional areas as appropriate
- Participate in writing of aggregate safety reports (e.g., DSURs), as required

Qualifications for pharmacovigilance scientist

- Demonstrated proficiency in global regulatory requirements, guidelines and industry best practices for pharmacovigilance with experience in safety

and non-interventional clinical trials, registries, patient programs, market research programs)

- Minimum of three years industry experience with minimum of five years post-marketing PVRM experience
- Minimally a basic working understanding of drug/device safety filing procedures competent knowledge of domestic and international regulatory requirements highly desirable
- Must be experienced with standard word processing, spreadsheet, and safety data base packages (Argus preferred)
- Proven ability to critically think through complex medical/safety reports and effectively summarize key information in a concise narrative presentation
- Flexible, highly organized with the ability to prioritize and detail oriented