



Example of Pharmacovigilance Scientist Job Description

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Our growing company is searching for experienced candidates for the position 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

- Act as core member for assigned products
- Ensure timely, quality reports/safety analyses related to core deliverables with oversight as appropriate
- Provide complete PVRM product life-cycle support for assigned product(s)
- Serve as Pharmacovigilance resource to clinical and post-marketing cross functional teams
- Collaborate with clinical and post-marketing teams to foster communication of potential safety concerns
- Participate in the development of protocols, annual updates to the compound-specific safety reference documents (Investigator's Brochure, core safety information, etc), contribute and review Informed Consent Forms (ICF), ensure safety oversight in cooperation/leadership of the clinical trial medical team, represent PVRM in SAE reconciliation, final CSR narrative writing/review and contribute to the review of the final clinical safety report (CSR)
- Perform study-start activities, as necessary
- PVRM Liaison with Merrimack medical information team, Merrimack quality, and Merrimack Medical Affairs, and commercial team
- Acts as primary author/reviewer for assigned product aggregate periodic reports such as the DSUR, PADER, PBRRER and others
- Perform on-going individual case quality review of representing company review in accordance with study Safety Management Plans, Safety exchange

Qualifications for pharmacovigilance scientist

- Knowledge and experience in infectious diseases and/or vaccines is preferred
- Ability to effectively present to cross-functional teams is required. Drug & Product Safety Science
- Ability to effectively present to cross-functional teams is required
- Provide clinical, regulatory and technical pharmacovigilance expertise to DS&E medical function & DS&E leadership
- Lead the preparation of aggregate safety reports for newly launched Novartis products to meet regulatory requirements
- Alert the Medical Safety Physicians to potential safety issues recognized through single case medical review or aggregated data sets