



Job Description

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Job Title:	Safety Scientist
Reporting To:	Data Evaluation Manager
Employee Name:	
Signature:	
Managers Name:	
Signature:	
Date:	

Job Purpose

To carry out essential pharmacovigilance related tasks on behalf of Panacea Pharma Projects Limited and its clients in compliance with the European Good Practice quality guidelines and documents (GxP) and other relevant International legislation relating to Pharmacovigilance.

To provide support to the Data Evaluation team in performing weekly literature searches, the preparation and submission of Periodic Safety Update Reports (PSURs), preparation and review of signal detection and transmission and reconciliation of pharmacovigilance data.

Key Tasks

Technical

- Prepare signal detection documents ready for review and review signal detection reports
- Data retrieval using validated pharmacovigilance database
- Weekly review of the literature for identification of safety information for signal management and aggregate report writing



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- Preparation, review and submission of PSURs for clients. Provision of PSURs to third parties, in line with PVAs, when required
- Participation in inspections from regulatory authorities and internal or external audits
- Regulatory Intelligence checks as per current procedures
- Project work on behalf of clients, as required
- Review and update of Panacea procedures relating to Data Evaluation activities

Administration

- Maintenance of personnel training record
- Maintenance of relevant tracking systems pertinent to assigned tasks
- Archiving of pharmacovigilance data

Compliance with European and national legislation, and co-operation with clients are essential parts of the role.

General

- Filing and archiving of pharmacovigilance data
- Working in accordance with Panacea procedures and policies
- Work as part of the Pharmacovigilance team and maintain flexibility to meet the priorities of the department
- Share ideas to improve systems

Skills Required

Technical Skills

- Knowledge and understanding of pharmacovigilance legislation, directives and guidelines
- Working knowledge of data elements for transmission to regulatory authorities for PSURs
- Proficient use of the pharmacovigilance database



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Other Skills

- Communication and negotiation skills
- Data management skills
- Project management skills