Job Description

Draft

Job Title:	Safety Scientist
Reporting To:	Case Processing 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 their clients in compliance with the European Good Practice quality guidelines and documents (GxP) and other relevant international legislation relating to pharmacovigilance.

To be an active member of the Case Processing team, completing delegated and appropriate case processing tasks including:

- the input of Individual Case Safety Reports (ICSRs) into the Safety Database (Argus)
- the evaluation and triage of ICSRs for data entry and submission to the regulatory authorities
- review and assessment of literature articles
- transmission and reconciliation of pharmacovigilance data
- support to the junior members of the team

Key Tasks

Technical

- Daily and weekly checks of client EVWEB accounts
- Download and triage of regulatory AE reports
- Download and triage of AE reports from the EMA MLM service
- Triage of literature articles
- Complete initial case entry onto the pharmacovigilance database
- Data entry and retrieval using validated pharmacovigilance database
- Quality review (QC) of ICSRs completed by the team
- Literature searching to ensure regulatory compliance
- Literature review and write-ups
- Review and update of case processing SOPs following instruction from the subject matter expert (SME)
- Preparation of training material for Case Processing team
- Any other task, following sufficient training, as instructed by line manager or senior management
- 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

General

- Maintenance of personnel training records
- Maintenance of relevant tracking systems pertinent to assigned tasks
- Support junior members of the team with queries and provide advice if required
- Mentor new staff
- Filing and archiving of pharmacovigilance data
- Work as part of the Pharmacovigilance team and maintain flexibility to meet the priorities of the department
- Share ideas to improve systems