



## Job Description

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|------------------------|--------------------|
| <b>Job Title:</b>      | Compliance Officer |
| <b>Reporting To:</b>   |                    |
| <b>Employee Name:</b>  |                    |
| <b>Signature:</b>      |                    |
| <b>Manager's Name:</b> |                    |
| <b>Signature:</b>      |                    |
| <b>Date:</b>           |                    |

### 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 assist the Contracts Manager with the management of safety (SDEA) contracts required by Panacea and their clients. To ensure that contracts are in place as required and all contracts are kept up-to-date using appropriate tracking methods.

To manage the Product Distribution Summaries used by the Case Processing team.

To assist with vendor selection and vendor management responsibilities.

To co-ordinate and manage audits and inspections hosted by Panacea as directed by line manager.

To assist and provide support in the maintenance of the Quality Management System at Panacea.



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### Key Tasks

#### Contract Management

- Provide back-up and support to the Contracts Manager with writing and maintaining pharmacovigilance agreements / safety data exchange agreements (PVAs/SDEAs) on behalf of Panacea and their client Marketing Authorisation Holders (MAH)
- Manage and maintain the Product Distribution Summary documents used by the Case Processing team
- Conduct quarterly and ad hoc reviews of Client Specific documentation relating to vendors
- Maintain Client MAH Tracker for Contracts with PV Content

#### Risk Assessments and Due Diligence

- Assist with the maintenance of the Vendor list and requests for due diligence
- Assist with the maintenance of the risk assessment schedule and due diligence process
- General management of due diligence and vendor management tracking (including out-of-hours test calls)
- Provide back-up to assist with the transfer of the due diligence risk scoring in the creation and maintenance of PSMF Annex G
- Assist with the writing and assessing of risk assessment questionnaires – internal and external
- Client-specific due diligence and ongoing monitoring

#### External non-compliance

- Act as back-up to assist with tracking and management of all external non-compliances

#### Inspections and Audits

- Assist with the co-ordination of preparations for Regulatory Authority inspections of Panacea client MAHs
- Assist with co-ordinating and hosting internal and external audits including preparation
- Assist with the preparation of audit schedules
- Assist with the management of Annex G of the client PSMF(s)
- Assist with any required internal reviews of Panacea as required



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- Communicate with clients and auditors/inspectors in regards to audits and inspections
- Work alongside the Pharmacovigilance team, providing clear communication in regards to requirements for upcoming audits/inspections
- Review of audit reports, preparation of CAPA response documents and communication with teams for technical input until CAPAs are agreed
- Assist with the provision of oversight of upcoming audits to the technical executive board

### General

- Participation in inspections by regulatory authorities and internal or external audits
- Project work on behalf of clients as required
- Provide support and assistance as required for new client contacts and new contracts or work with clients
- Review and update of Panacea procedures
- Review and writing of client procedures
- Provide company training sessions as required
- Maintenance of personnel training record
- Maintenance of relevant tracking systems pertinent to assigned tasks
- Archiving of pharmacovigilance data