



Job Description

Draft

Job Title:	Compliance and Auditing Specialist
Reporting To:	
Employee Name:	
Signature:	
Managers Name:	
Signature:	
Date:	

Job Purpose

To co-ordinate and manage risk assessments and audit programmes on behalf of Clients.

To review and approve audit reports prepared by independent auditors on behalf of Clients.

To review and manage Corrective and Preventative Actions (CAPAs) proposed by audited parties through to completion.

To prepare and manage due diligence of vendors as part of vendor management.

To act as co-auditor/auditor for GvP Audits independently managed by Panacea Pharma Projects Ltd (Panacea).

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 (QMS) at Panacea.



Job Description

Draft

Key Tasks

Inspections and Audits

- To assist in the co-ordination of the preparation for Regulatory Authority inspections of Panacea client MAHs
- To assist in co-ordinating and hosting internal and external audits including preparation
- To assist with the preparation of audit schedules
- To assist with the management of Annex G of the client PSMF(s)
- To assist with any required Internal reviews of Panacea as required
- To communicate with clients and auditors/inspectors with regard to audits and inspections
- To work alongside the Pharmacovigilance team, providing clear communication with regard to requirements for upcoming audits/inspections
- The review of audit reports, preparation of CAPA response documents and communication with teams for technical input until CAPAs are agreed
- To assist with the provision of oversight of upcoming audits to the Technical Executive Board
- GvP auditor on behalf of Panacea

Deviations

- To act as back-up to assist in the creation of deviation reporting forms, agreeing root cause. To assist in the tracking and maintenance of internal deviations, both planned and unplanned.

Panacea CAPAs

- Management of external party CAPAs from audit/inspection only
- To act as back-up to assist with the logging, creation and management of CAPAs including evidence, closure, QPPV communication
- To act as back-up in the creation of relevant impact analysis review form and relevant tracker and forms created
- To act as back-up to provide monthly reminders for open deliverables to owners and escalate overdue CAPAs
- To provide notification of CAPA status update for the maintenance of the PSMF



Job Description

Draft

External non-compliance

- To act as back-up to assist with tracking and management of external non-compliances
- To act as back-up to assist with the management and tracking of all external non-compliance

Procedures

- To assist in the update and maintenance of QMS procedures, documents, guides and templates as required
- To assist in making minor updates to procedures in line with internal CAPAs
- To assist with the maintenance of justification documents as requested
- Back-up for updates to the SOP Access programme
- Quality checks for procedures as assigned
- Assistance with PSMF Annex E as requested
- Client SOP management as requested

Training

- To assist with the creation of training materials as required
- Back-up for assistance with staff training and production of training record sheets as requested
- Tracking and ensuring the compliant receipt of back to work or new starter training records

Risk Assessments and Due Diligence

- Back-up for the maintenance of Vendor list and requests for due diligence
- To assist with the maintenance of the risk assessment schedule and due diligence process
- General management of tracking of due diligence (including out of hour test calls)
- To assist with the general management and tracking of due diligence
- To provide back-up to assist with the transfer of the due diligence risk scoring in the creation and maintenance of Annex G
- Writing and assessing risk assessments – internal and external
- Client specific due diligence as required



Job Description

Draft

Miscellaneous

- Change control processing within Quality
- To offer support/back-up within the Quality team for any quality related task
- Project work related to Quality Systems activities on behalf of clients as required
- To assist with the validation process of any IT system as required, including the running of scripts
- Archiving of pharmacovigilance data
- Helping to ensure that all pharmacovigilance data is backed-up and archived accurately

Skills Required

Technical Skills

- Working knowledge of Quality Systems requirements and processes related to pharmacovigilance
- Working knowledge of the requirements of audit and CAPA management
- GvP Auditing experience

Other Skills

- Communication and negotiation skills
- Data management skills
- Project management skills
- Fastidious attention to detail