



## Job Description

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| <b>Job Title:</b>     | Audit and Quality Assurance Services Manager |
| <b>Reporting To:</b>  | Head of Audit and Quality Assurance Services |
| <b>Employee Name:</b> |  |
| <b>Signature:</b>     |  |
| <b>Managers Name:</b> |  |
| <b>Signature:</b>     |  |
| <b>Date:</b>          |  |

### Job Purpose

To line manage the Audit and Compliance Team.

To manage GVP audits, reports, audit findings and resulting CAPA management on behalf of Panacea Client MAH companies.

To act as lead auditor on assigned GVP audits. To produce quality and timely audit reports and CAPA plans that are sufficient for inspection purposes. To offer mentorship and support to trainee and contract auditors.

To provide Inspection readiness training internally and externally and attend inspections as a Panacea representative as required.

To provide procedural GAP analysis to Panacea clients and updates to client procedures.

To offer vendor management and due diligence support to clients as required. To offer deviation management to clients.

To provide Panacea clients with Quality Assurance and Auditing expertise.



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### Key Tasks

#### Team:

- Line management of Audit and Compliance team, including managing team performance, setting performance objectives for team members, conducting regular performance review meetings, and effectively managing holidays and absences.
- Recruitment of Audit and Compliance team staff, as required.
- In-house training and organisation of external training courses.
- Supporting the Head of Auditing and Quality Assurance Services in her duties and being ready to deputise as needed.

#### Procedures

- Completing SOP 'GAP analysis' on behalf of Panacea as required by Panacea clients
- Offering support to Panacea clients on the creation and maintenance of procedures in line with GVP requirements
- Maintenance of client specific QA procedures as assigned
- Responsible for maintenance and update of the core QA procedures (as assigned).

#### Training

- The creation of Inspection readiness training and other training material for Panacea and associated clients
- The creation of training material
- The delivery of training to Panacea clients
- The delivery of training to Panacea employee's

#### Risk Assessments and Due Diligence

- To assist with the preparation of vendor risk assessment forms for Panacea and for clients
- To assist with the interpretation of completed risk assessment forms to determine audit requirements
- To assist with the preparation and maintenance of documentation relating to due diligence for vendors
- To assist Panacea staff with expert knowledge on country specific GVP requirements



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### Regulatory Intelligence

- To keep abreast of global regulatory intelligence required for audit conduct and QA client needs

### Vendor Management

- To assist the contract management team, as required, with PV agreement creation and maintenance for both Panacea and associated clients
- To conduct vendor selection and management activities as outlined in individual client procedures on behalf of QA clients

### Inspections and Audits

- The planning, preparation, write-up and performance of independent audits against company standards, SOPs, Good Pharmacovigilance Practice (GVP), quality regulations, local laws and guidelines (Travel required)
- Maintenance of client audit schedules
- Drafting of client audit strategies and maintenance of documents
- Maintenance of client PSMF's with client and third party CAPA's
- Liaising with Panacea clients to ensure all audit requirements and other Quality led requirements are fulfilled to high standards, following Panacea or the clients procedures and templates as required for completion
- To assist in the co-ordination of Regulatory Authority inspections including document preparation and coordination of responses to inspection findings to the Regulatory Authorities
- To assist in co-ordinating and hosting internal and external audits and/or inspections including preparation of audit schedules
- To assist with the tracking and management of inspection and audit findings
- The review of Audit or Inspection findings and review of evidence provided
- To train other auditors and provide auditing support

### Deviations and CAPAs

- The tracking and maintenance of client deviations within the Panacea QMS
- The monitoring and maintenance of all client CAPA's within the Panacea QMS as assigned
- Impact analysis of client CAPA's
- Trend analysis of client CAPA's

### Miscellaneous

- The promotion of Panacea Quality services
- Business development activities in relation to Panacea Auditing and QA Services
- Project work related to Quality Systems activities on behalf of clients
- Lead and/or participate in GVP quality improvement projects as directed.



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- Archiving of pharmacovigilance data

### Skills Required

#### Technical Skills

- University Education in life sciences or healthcare
- Previous Global PV Auditing experience (5yr +) essential
- Extensive experience in Pharmacovigilance
- Preferably some experience in GCP regulations and related guidelines
- Regulatory knowledge including EU Regulations and Guidelines
- Working knowledge of Quality Systems requirements and processes related to pharmacovigilance
- Basic understanding of the interface between Regulatory and PhV
- Excellent communication skills (both written and verbal)
- Sound knowledge of IT-based systems, having worked with other Quality management systems previously
- Sound knowledge of the role of risk assessment and CAPA

#### Other Skills

- Quality-orientated
- Fastidious attention to detail
- Excellent interpersonal skills and communication skills, including good presentation and report writing skills
- Self-motivation, determination and confidence in own abilities
- Ability to work to deadlines, under pressure
- Ability to work on your own initiative and as part of a team
- Fluent knowledge of English; additional languages would be desirable
- Project management skills
- Excellent client focus skills
- Excellent computer skills and advanced knowledge of Microsoft Office including Word and Excel.
- A natural tendency towards continuous improvement