



Job Description

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Job Title:	Head of Auditing & Quality Assurance Services
Reporting To:	Directors
Employee Name:	
Signature:	
Managers Name:	
Signature:	
Date:	

Job Purpose

To provide a Quality Assurance Service for Panacea client Marketing Authorisation Holders (MAH). This will include provision of the following services:

- Due diligence and vendor management services
- Risk Assessments
- Gap analysis reviews
- Auditing
- Management of client audit strategies and schedules
- CAPA management for clients
- Procedural documentation writing
- Training

To manage and co-ordinate a team of auditors made up of internal employees and contractors.

To provide support as required by the Operations Manager-QMS and Head of Pharmacovigilance and to ensure ongoing Business Continuity.

To line manage the Audit and QA team.

Key Tasks

Technical

- Manage and co-ordinate client Quality Service business including support to the Business Development (BD) team for ad hoc audit requests



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- Assess and advise on appropriate due diligence for new clients
- Manage Panacea audit strategy and schedule
- Manage client MAH audit strategies and schedules when assigned
- Provide an independent auditing team for performance of client and ad hoc audits through use of internal employees and contracted preferred vendors
- Manage external non-compliances (deviations)
- Provide a CAPA management service for clients
- Provide due diligence and vendor management services on behalf of clients including risk assessments, gap analysis services and audits as appropriate
- Write and review procedures for clients
- Training – internal and external
- Ongoing vendor management and auditing of European local responsible personnel (LRPs/LQPPVs) contracted by Panacea on behalf of client MAHs
- Manage appropriate Panacea procedures for provision of the above services
- Participate in inspections by regulatory authorities and internal or external audits.

Team

- Line management of the Panacea Auditing and QA team, including managing team performance, setting performance objectives for team members, conducting regular performance review meetings, and effectively managing holidays and absences
- Provide adequate training and support to all team members
- Provide training and support to the wider Panacea team as required
- Provide input as required to the update and management of the client MAH PSMF(s), particularly Annex G and Section 7
- Liaise with client support team and client managers to ensure shared knowledge and adequate support



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Skills Required

Technical Skills:

- Audit and Inspection experience
- Excellent knowledge and understanding of pharmacovigilance legislation, directives and guidelines
- Process writing experience
- Training experience

Other Skills:

- Data management skills
- Project management skills
- Planning and organising skills
- Communication skills
- Line management skills