



Job Description

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Job Title:	Regulatory Affairs Specialist
Reporting To:	
Employee Name:	
Signature:	
Managers Name:	
Signature:	
Date:	

Job Purpose

To assist the Regulatory Affairs team in carrying out the activities relating to Regulatory Affairs services that Panacea Pharma Projects Ltd (Panacea) undertakes on behalf of clients.

To coordinate with clients and any external third parties to ensure that all Regulatory Affairs activities are carried out efficiently and to the client's satisfaction.

To assist the Pharmacovigilance team with maintenance of Product Information (CCSI/CCDS, SmPCs, PILs) on behalf of pharmacovigilance clients, Regulatory Intelligence checks, XEVMPD requirements, and maintenance of Panacea's product management system.

Some involvement in other regular Pharmacovigilance activities may be required as instructed by the Operations Director.

Key Tasks

Technical

- To carry out Regulatory Affairs tasks and services on behalf of clients
- To liaise with third parties, as required, to coordinate Regulatory Affairs work
- To maintain XEVMPD on behalf of client MAHs
- To carry out updates to client Core Safety Data (CCSI/CCDS)
- To carry out Regulatory Intelligence checks relevant to Regulatory Affairs
- To review and update Product Labelling



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Team

- To participate in specified project groups to help develop and grow the regulatory team
- To provide advice to the Pharmacovigilance team when required in respect to Regulatory Affairs matters

Administration

- To ensure that all documents related to Regulatory Affairs are stored correctly

Skills Required

Technical Skills

- Good knowledge and understanding of Medicines legislation, directives and guidelines related to Regulatory Affairs
- Working knowledge of the guidelines and requirements for Regulatory Affairs.
- Knowledge of eCTD and other IT systems related to Regulatory Affairs e.g. EMA portal

Other Skills

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