



JOB DESCRIPTION

ROLE: Sr. Executive/Executive - Pharmacovigilance

SALARY AND BENEFITS: Negotiable

LOCATION: Vadodara

JOB TIMING: 12:00pm to 09:00pm (India time)

PRIMARY RESPONSIBILITIES:

- To provide proactive safety surveillance and pharmacovigilance activities across the lifecycle of Thame products support.
- Development and execution of risk management plans, risk assessment and risk communications.
- Collection, evaluation and submission of Individual Case Safety Reports, reparation and submission of Periodic Safety Update Reports.
- Risk Management Plans, signal management activities, negotiation, implementation and maintenance of Safety Data Exchange.
- Ensuring pharmacovigilance compliance with relevant legislation appropriate for each client.
- Ensuring that all pharmacovigilance processes and procedures are consistent and appropriate.

SECONDARY RESPONSIBILITIES:

- To perform Individual Case Safety Report (ICSR).
- To close processed ICSRs.
- To report spontaneous ICSRs to Health Authority.
- To report Suspected Unexpected Serious Adverse Reactions to Health Authorities, ECs and investigators.
- To perform electronic reporting to Health Authority via EV Web Trader, including testing of the system and registration with Eudravigilance.
- To translate documents into English, if applicable.
- Write or contribute to PSURs and ASRs as required. This may include acting as the project co-ordinator, collating the needed information, incorporate reviewers' comments and finalizing the document.
- To assist with pharmacovigilance processes, supporting preparation of SOPs, product safety reviews and literature reviews as required.
- To review literature screening search results, identifying ICSRs and other safety-related findings.
- The PV Officer will support the PV manager, as well as the Qualified Persons Responsible for Pharmacovigilance, on a day to day basis as needed.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Master degree in Pharmacy/Science/PhD.
- Experience of 3+ years in pharmaceutical in drug safety/Pharmacovigilance.
- Excellent interpersonal, written and verbal communication skills.
- Willingness to work in a matrix environment and value the importance of teamwork.
- Strong knowledge of product development process and regulations relating to post marketing safety.