



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.
- Collection, evaluation and submission of Individual Case Safety Reports.
- Preparation and submission of Periodic Safety Update Reports.
- Development and execution of risk management plans, risk assessment and risk communications.
- Signal management activities, maintenance of Safety Data Exchange.
- Ensuring pharmacovigilance compliance with relevant legislation.
- Ensuring that all pharmacovigilance processes and procedures are consistent and appropriate.

SECONDARY RESPONSIBILITIES:

- To manage end to end Individual Case Safety Report (ICSR) processing.
- 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 maintain Pharmacovigilance system master file.
- To Compile PSURs and ASRs as required. This may include acting as the project coordinator, 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.
- To 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.