B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Dy. Manager/Manager - Pharmacovigilance
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 and 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 Agreements, Pharmacovigilance System.
- Master Files and transmission and reconciliation of pharmacovigilance data.
- Ensuring pharmacovigilance compliance with relevant legislation appropriate for each client.
- Ensuring that all pharmacovigilance processes and procedures are consistent and appropriate.

SECONDARY RESPONSIBILITIES:

- Overall management of pharmacovigilance activities.
- Ensuring compliance EMA reporting requirements.
- Perform periodic aggregate safety data review according to a signal detection strategy and escalate possible safety issues and Clinical Monitor as needed for assigned Thame product(s).
- Generate periodic aggregate safety reports for Thame product(s) and Monitor medical and scientific literature for published articles relevant to the safety profile for Thame product(s).
- Define search criteria, run validated database searches, and analyze data for safety signal detection in consultation with Clinical Monitor Plan and perform analysis in support of response to regulatory, and Investigators Inquiries regarding safety issues.
- Support development and execution of risk management plans, risk assessment, and risk
- communications Conduct safety data analysis in support of developing and updating safety sections of regulatory documents, informed consent, annual reports, company core data sheets, product labels, etc.
- Provide support of developing and updating Investigator Brochures and study protocols Provide safety data analysis in support of Safety Review Committee (SRC).
- Manage the relevant day-to-day aspects of safety agreement with licensing and/or collaboration partners (CRO's).
- Lead efforts to improve processes and increase work efficiency applicable to the Safety Surveillance.
- Execute triage for appropriate causality assessment on Individual Case Safety Report (ICSRs) for regulatory reporting.
- Create follow-up queries, and case follow-up measures for case processing.
- Manage and ensure compliant safety reporting in accordance with local and international reporting regulations.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Master degree in Pharmacy/Science/PhD.
- Experience of 8+ years in pharmaceutical in drug safety/Pharmacovigilance.
- Experience in adverse event reporting systems, FDA and EU drug safety requirements.
- Experience in ARISg, ARGUS, MedDRA, and WHO dictionary.
- Strong knowledge of product development process and regulations relating to post marketing safety.