ROBERT SMITH

Drug Safety Specialist

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About 5 years' experience in Pharmacovigilance, Regulatory Affairs and Clinical Data Management (CDM). Collecting source documents, and processed adverse event (AE) reports from clinical trials and post-marketing sources adhering to Standard Operating Procedures. Ensuring compliance with global and local procedural documents and local implementation of Clinical Drug Safety objectives, policies, processes and procedures and timely submission of safety reports.

EXPERIENCE

Drug Safety Specialist
ABC Corporation - JULY 2013 – 2021

- Triaged, assessed, and performed data entry of adverse event (AE) and serious adverse event (SAE) information and Coding adverse events accurately using MedDRA.
- Retrieved necessary data from Outcome Survey databases and/or Interact with the clinical team, medical monitors, investigative site personnel and sponsor representative for all initial and follow-up event information and query resolution.
- Adversed event case processing and reporting requirements to ensure compliance with internal procedures, regulatory reporting requirements and contractual requirements with business partners.
- Responsible for writing case narratives for Safety Database and for post marketing surveillance reports.
- Performed case deactivations (JIRA) and maintaining Non-shire global safety database (Non-SGSS).
- Provided case listing/line listing for PV-Scientists during preparation of PSURs and PBRER for the respective products.
- Identified and requested appropriate follow up information on cases in consultation with the Medical Monitor and/or Drug Safety Physician, to ensure consistency of case entry and high data quality standards.

Drug Safety Specialist
Delta Corporation - 2012 – 2013

- Actively involved in accurately verifying medications and processing adverse events reports.
- Efficiently identified Adverse Events (AEs) and Product Quality Complaints (PQCs) reported as indicated in a Medical Information Request by triaging .
- Also performed medical information extraction and timely entry of these reports into their Drug Safety Database, prepared case narratives and .
- Performed frequent Quality Assurance and final Quality Control processes to maintain high quality standards for the company.

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- Responsible for overseeing specific aspects of adverse event processing and reporting for assigned investigational and marketed products, close .
- Prepared FDA reports on drug safety events for a chemotherapeutic agent.
- Perform as Pharmacovigilance lead in providing Sponsor safety oversight to PV vendor Prepare RFPs and budget for PV vendor Provide Sponsor safety.

EDUCATION

- Master Of Science

SKILLS

Case Processing, MedDra Coding, Reconciliation, Overviewing Vendor, Narrative Writing, PBER Assistance.