Sadiqua Ansari

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Summary

Enthusiastic and dedicated pharmacovigilance expert with more than 6 years of extensive experience in case booking, data entry, quality review, meddra coding, narrative writing and medical assessment of ICSRs. Remarkable working knowledge on monitoring and tracking of serious adverse events, non-serious events and events with special case scenarios (pregnancy cases, medication error or off label use etc.). Basic knowledge of FDA and international regulations. Eager to contribute to team success through hard work and consistent support.

Skills

- Case Processing on ARISg, ARGUS, Sapphire Databases and Veeva Vault
- Meddra/WHO DD Coding
- Safety narrative Writing
- Knowledge on pre and post marketing PV
- Basics of ICH-GCP
- GVP module VII
- Regulatory Submission
- Clinical TMF
- SMP writing

Experience

DRUG SAFETY ASSOCIATE | 06/2022 - Current

Novotech (Australia) PTY LTD. - Melbourne, VIC

- Attending study kick-off meeting to discuss the project scope of work.
- Setting up study information to the safety database.
- Drafting Safety Management Plans (SMP) and reporting forms.
- Providing training to CRAs during the study start up.
- End to end case processing in safety database, including generation of safety narratives, CIOMS, E2B R3 files and MedWatch reports.
- Determine and perform appropriate case follow-up.
- Reconciliation of safety data against the clinical database.
- SUSRs Submission to HAs, Investigators and alliance partners.
- Mailbox reconciliation and monitoring.
- Filing of all study related documents on TMF.

SENIOR PROCESS ASSOCIATE | 01/2021 - 03/2022

Tata Consultancy Services, India. - Mumbai, India

As a Case processor

Hands on experience with validated database Sapphire.

Performed end-to-end processing for E2B imported and spontaneous reports such as case logging, Triage, Data Entry, Quality Review, Query initiation and case Closure.

Case assessment of ICSRs as per SOPs, determining outcome of the events, identifying adverse event of special interest, raising queries with site for missing and discrepant information.

writing the concise summary of relevant clinical and relevant information into case narratives for initial and follow up

reports.

As a Quality Reviewer

Performing quality check of the cases processed by new hires and providing them timely feedback with the comments.
Ensure the case completeness with quality data.

As a Submission Specialist

Complete all on time submissions to all applicable reporting destinations.
Generating CIOMS I as per Marking company requirements and Business rules.
Follow-up with Local Safety Managers to ensure on-time submissions and request details on late submissions.
Performs oversight of the Submissions Mailbox.
Monitoring E2B failures and investigating immediately.
Provide training and support to newer members of the submission team.
Maintain record of day-to-day operations in a shared excel sheet for the reconciliations process.

SENIOR SAFETY SCIENCE SPECIALIST | 09/2018 - 12/2020

Labcorp Drug Development (formerly Covance) - Mumbai, India

Setting priorities for the cases to be process with respect to the Service Level Agreement (SLA), Turn Around Time (TAT), and regulatory timelines.
As a case processor perform duplicate search to prevent duplicate case entries, analysis of case as valid or invalid, appropriate coding of events, determination of suspect product or co-suspect, safety narrative writing and generating follow up reports.
Responsible for processing of various types of ICSRs for therapeutically different molecules from solicited and spontaneous sources such as medical device reports, Drug exposure during pregnancy cases (DEDP) reports,other safety findings, product complaints, cluster cases, social or digital media cases, EV-HUMAN R3, regulatory cases, LP reports and discharge summaries.
Involved in a literature case processing in accordance to the Standard Operating procedures (SOPs), which provides end to end guidance.
Writing Corrective Action and Preventive Action for late cases to Regulatory Authorities.
Providing process specific training to new hire for particular molecule.

JUNIOR DATA ANALYST | 04/2016 - 08/2018

Cognizant Technological Solutions - Mumbai

Day-to-day safety operations such as mail box management, case receipt, local review, data reconciliation, query handling, data entry and quality review of Individual Case Safety Reports (ICSRs) into ARISg.
Responsible for drafting or review of Serious Adverse Event (SAE) case narrative, SUSAR reports (e.g. MedWatch), Clinical Study Report (CSR), IRMS (Information Request Management System), License Partner, NIS (Non-Interventional Studies), courtesy letters patient narratives.
Raise urgent and non-urgent queries for any discrepancy identified in the case and raise follow up letter with questionnaire as appropriate.
Interpretation and analysis of laboratory values and make required assessment of event terms and highlight the medical records.
While handling ICSRs performed expectedness, listedness and causality for events by referring labeling documents.
Delivered feedbacks to management regarding new hires and suggested training needs to ensure compliance with data quality and contract timelines.
Point of contact for internal queries and address to responsible team or provide a resolution.

Education and Training

Shivaji University, Kolhapur - Kolhapur | Bachelor of Pharmacy

Medicine, 05/2015

Certifications

- Introduction to pharmacovigilance offered by UMC.
- Signal detection and Causality Assessment offered by UMC.
- Introduction to FDA Human Drug Review and Approval Basics.
- Six Sigma Yellow Belt.
- Art of Articulation at TCS.