Sai Abhinash Mavilla

Senior Process Associate

Contact

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Skills

Training and Development

Problem-Solving

Flexible and Adaptable

Argus Database Proficiency

Dependable and Responsible

Critical Thinking

Interpersonal Communication

Written Communication

MS Office

Attention to Detail

Teambuilding

Narrative writing, Adverse event coding, Suspect Drug and concomitant coding, Seriousness assessment,

To seek and maintain full-time position that offers professional challenges utilizing interpersonal skills, excellent time management and problem-solving skills.

Work History

2023-01 - Current

Senior Process Associate

Tata Consultancy Services, Pune

- Responsible for analyzing and processing all adverse experience information received for investigational and marketed products according to the standard procedures for reporting to worldwide regulatory agencies by Global safety data base
- Handling of MEDICAL DEVICE COMBINATION PRODUCTS, only DEVICE PRODUCTS reports. Processing the reports having True event, Pregnancy terms, PQC, Medication error and Off-label terms
- Responsible for coding all medical history, events, drugs/procedures/indications and laboratory tests according to the appropriate dictionary (For e.g., MedDRA, Company Product Dictionary, WHO-DD). Writing medically relevant safety narrative of cases and checking the completeness and accuracy of the data entered in the various fields
- Met month-end reporting objectives and deadlines.
- Performed reconciliations to drive accuracy and validity of financial information.
- Supervised processes to eliminate weak points or bottlenecks in business operations.
- Identified modifications to processes and procedures that would promote better efficiency.
- SME activity for Pregnancy reports and Legal reports

SECONDARY RESPONSIBILITIES

- As a part of the training team, taking sessions on the updated SOPs, Product/ Protocol guidelines.
- **Legal Pre-scanning and Literature Assessment Activity**
- **SME for Pregnancy and Legal ICSR reports**

Causality assessment, Awareness on different Regulatory Authorities, Awareness of MedDRA dictionary

Languages

English

Telugu

Hindi

2021-11 - 2022-11

Drug Safety Associate

Qinecsa Solutions (formerly Bioclinica), Mysore

As Quality Check Reviewer

- ·Review data entered in safety database for completeness and accuracy
- ·Provide quality feedback to team resources.
- ·Track and maintain quality metrics

As Case Processor

- ·Responsible for data entry of Individual case safety reports into the safety database.
- ·Review and evaluate AE case information to determine required action based onand following internal policies and procedures.
- ·Process all incoming cases to meet timelines.
- ·Full data entry including medical coding and safety narrative.
- ·Responsible for coding all medical history, events, drugs/procedures/indications and laboratory tests according to the appropriate dictionary (For e.g., MedDRA, Company Product Dictionary, WHO-DD).
- ·Responsible for writing medically relevant safety narrative of cases and checking the completeness and accuracy of the data entered in the various fields.

2021-03 - 2021-11

Drug Safety Associate Trainee

IQVIA RDS India Pvt. Ltd, Through 3rd Party APEXON (formerly Technosoft Global Sol.pvt Ltd)., Bangalore

Education

2016-06 - 2020-05

B.Pharmacy

Narayana Pharmacy College - Nellore

PARTICPATIONS

- Passed out with 8.21 (CGPA).
- Attended to a "PHARMORIA MINI" conducted in Ratnam Institute of Pharmacy
- Attended a second international conference on "Health Technology Assessment ", organized by ISPOR Narayana Pharmacy College

2013-06 - 2015-05

Bi.P.C

Sri Gayathri Junior College - Nellore

Certifications

2021-03 Registered Pharmacist-145598/A1