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06/01/1999

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OBJECTIVE

My goal is to become associated with a company where I can utilize my skills and gain further experience while enhancing the company's productivity and reputation.

SKILLS

Good Communication skills, Computer Proficiency
MS-CIT course
MS Power Point
MS Word
 Knowledge about Pharmacovigilance Process
 Knowledge of Clinical Trials
 Effective time Management and organizational skills
 Interpersonalskills
 Data drafting and Representation Skills
 Flexibility and adaptability

TEJASWINI NEWASE

Nira Tal.Purandar Dist.Pune Pin Code 412102

EXPERIENCE

Labcorp Drug Development (Formerly Covance) Pune **17-JAN-2021 - 18-JAN-2022**

safety Science Analyst

I was working as Safety Science Analyst, post Marketing safety (J&J), Covance Scientific Services & Solutions Pvt. Ltd., Pune, January 2021 to till date January 2022.

Job responsibilities:
Case Intake:
Triage and classify individual case safety reports (ICSRs) for report type, seriousness; prioritize ICSR according to regulatory requirements
Conduct duplicate searches to determine correct action for the ICSR (i.e. initial or follow-up).
Completion of remaining case data entry, including validity assessment, product coding, adverse event selection and seriousness assessment
Remove/Reject ICSRs as per client's SOPs
Perform reconciliation of ICSRs as per defined procedures
Clarification of unclear or illegible information from the ICSR sender (i.e. local safety officer [LSO] or Call Center)
Discussion of source documents, product coding and ad-hoc queries with appropriate stakeholders.
Request translation, as required.
Update Follow up intake forms, as applicable.
Redact source documents as per the regional requirement.
Comply with local intake regulations and adhere to the controlled documents to perform the day to day tasks, as applicable.
Manual acknowledgement of receipt as required.

Due Diligence (DD) Schedule in Global Safety Database (as applicable):
Perform the DD activity as outlined in the project specific controlled documents by means of Email, Fax, Telephone, Postal letters, as applicable.
Release the letters as per project specific controlled documents.
Maintain the record of DD schedules and perform the reconciliation as per controlled documents.
Monitor applicable mailbox.
Forward / notify incoming mails to appropriate stakeholder(s).

TATA Consultancy services Pune **11-Mar-2022**

Drug safety specialist

Drug safety specialist
1.Manage one or more responsibilities as assigned by Lead/ Manager. Perform duplicate check in database.

2.Review adverse event reports (ICSRs) received from both solicited and unsolicited

3. Capture, summarize and share detailed feedback for the error identified in case intake/book in/processing/submission activities through Argus safety database/email/manual tracker etc.

4. Share training feedback with training team to be update the guidance material as applicable.

5. Re-QC of cases as applicable with core quality components (CQC) errors.

6. Handle case intake/book-in/processing/submission related queries.

7.Meet specified productivity and quality targets for case handling. Assessment, data entry and quality review of initial and/or follow-up information for cases, including correct identification of cases requiring targeted follow-up should be performed.

8.Co-ordinate and conduct knowledge sharing sessions for different type of case scenarios.

9. Make significant contributions to projects relating to improvements in process.

10. Mentor junior staff in Pharmacovigilance process and in processing different types of cases. For case processing activity, review ICSR checker shared by case processor for every case and suggest corrections

11. for mandatory validation errors, which cannot be ignored.

12. Retrospective QC of submitrand non-submit cases should be done by submission reviewer as detailed in QCP (Quality Control Plan)

13.Perform reconciliation activities for case intake/ book- in/ processing/ submission activity including mailbox reconciliation,End of study unblinding

14. Responsible to take follow ups for pending follow up queries

Experienced in Inform,
Medidata, Argus,
ArisG and Veeva
CDMS data base

EDUCATION

SVPM'S College of Pharmacy Malegaon Bk Baramati **Passing Year - 2022**

Master of Pharmacy

Grades : **75 %**

SVPM's College of Pharmacy Malegaon (Bk) Baramati **Passing Year - 2020**

Bachelor of Pharmacy

Grades : **8.4 CGPA**

Kilachand Junior College Nira Tal.Purandar Dist Pune **Passing Year - 2016**

Higher secondary school Education

Grades : **72%**

Sou.Lilavati Rikhavlal Shah Kanya Vidyamandir Nira Tal.Purandar Dist.Pune **Passing Year - 2014**

Secondary school Education

Grades : **89.80%**

Elite Institute of Pharma Skills Pune **Passing Year - 2021**

Advance Diploma in Pharmacovigilance and Clinical Research

Grades : **First class**

PROJECTS

DEVELOPMENT AND VALIDATION OF RP-UHPLC METHOD FOR SIMULTENEOUS ESTIMATION OF ALBENDAZOLE AND IVERMECTIN IN BULK AND PHARMACEUTICAL DOSAGE FORM

GRADUATE PHARMACY APTITUDE TEST EXAM QUALIFIED IN 2018

TCS GEMS: ON THE SPOT AWARD AWARDED FOR DELIVERING QUALITY RESULTS IN A TIMELY MANNER TWICE IN 2023 AND IN 2024