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OBJECTIVE:

Seeking a challenging position in **Clinical Research & Pharmacovigilance (Drug Safety Surveillance (DSS) domain)** to develop and deliver scientific medical content with acceptable quality standards and meeting timelines as well.

Summary of Experience:

- Professional experience on case processing, Safety narrative writing, assessment of seriousness, expectedness/listedness of **Adverse Events.**
- Working experience on **Argus** database which has used for reporting of **Adverse Event Reports**.
- Expert in processing of **Spontaneous Cases**
- Experience in coding of adverse events with **MedDra**, coding of drugs with **WHO DD** dictionary and **Company Drug Dictionary.**
- Good Experience in **Safety Narrative Writing** for serious and non serious cases.

PROFESSIONAL EXPERIENCE:

Advance Drug Safety and Pharmacovigilance Trainee
Gratisol Labs, Hyderabad, India
Roles & Responsibilities:

- Demonstrate understanding of ICH-GCP guidelines, 21 CFR Part 11, standard operating procedures (SOPs) and medical terminologies.
- Ensuring Compliance with reporting timelines and quality standards.
- In-depth knowledge of coding adverse events using MedDRA and medications using WHO-Drug Dictionary and Company Drug Dictionary, principles, submission criteria, regulatory timeline requirements and guidelines.
- Awareness on Oracle Argus Safety Database (Triage, Book-in, Data entry, Case Processing, event coding, narrative writing)

PREVIOUS WORK EXPERIENCE

- Worked as Hospital Pharmacist in Kamala Hospital, Hyderabad (March. 2018 – Dec 2020)
- Worked as Hospital Pharmacist in Nizam institute of medical sciences Hospital, Hyderabad (Mar. 2014 – Dec 2016)

Roles & Responsibilities:

- Auditing all the in-patient order for drug name strength, dosage and duration of therapy, therapeutic duplication and to check for possible drug interaction.
- Checking the physician's drug orders for appropriateness in the patient care areas and rectification of any medication error observed with appropriate documentation as per hospital protocol
- Prepare and quality-check sterile medications, for example intravenous medications
- Query handling as raised by different healthcare professionals.

- Check prescriptions and dispensing medicines to the patients.

SKILLS:

Database	:	**Oracle Argus Safety Database**
Office Tools	:	MS Word, Excel, Power Point
Operating System	:	Windows 98, XP, windows 7
Dictionary	:	**MedDRA & WHO Drug**

TECHNICAL DOMAIN SKILLS

Clinical Research

- **Schedule Y.**
- ICH-GCP -13 Core PRINCIPLES.
- Difference between ICH-GCP and Indian GCP.
- Knowledge on drug development (Phase I -IV) of clinical trial.
- Informed consent Process, Reporting (AE, SAE).

Pharmacovigilance

- ADR, Serious Adverse Reaction, SUSAR, SAE, MedDRA, ADR Monitoring, Narrative Reports.
- Concomitant Drugs.
- Seriousness Criteria.
- PSUR, DSUR, CIOMS.
- ICSR, SAE Reporting timelines.
- Causality Assessment, De-challenge, Re-challenge.

EDUCATION QUALIFICATION:

- M. Pharmacy (Pharmacology), KGR Institute of Medical Sciences, Hyderabad, Telangana with 75 %.
- B. Pharmacy from Brown's College of Pharmacy, Khammam, Telangana with 74.6%.
- Bi.P.C from Manjeera Junior College, mellacheruvu, Telangana 73%.
- S.S.C from Ushodaya Vidyalayam, Chinthalapalem, Telangana 75**%.**

PERSONAL DETAILS

Name	: Vijayalakshmi kandula
Husband Name	: Narsimha Reddy
Address	: 8-3-251/B, Yousufguda, Sri Krishna Nagar, Hyderabad
Sex	: Female
Date of Birth	:18- Aug-1989
Nationality	: Indian
Languages Known	: English, Hindi and Telugu

DECLARATION:

I do hereby declare that the particulars of information and facts stated herein above are true, correct and complete to the best of my knowledge and belief.