RAKESH NANDHALA
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Email id: **rakeshnandhala41130@gmail.com**

OBJECTIVE:

Pharmacy Professional Completed Pharmacovigilance Internship aspiring for a challenging and growth oriented career in the Clinical Research and Pharmacovigilance domain, in an organization where knowledge if fully utilized to enrich my professional skills and also promote growth of the organization.

Pharmacovigilance Internship:

Completed Pharmacovigilance Internship at Gratisol Labs – October 2022 –March 2023

Summary of Experience:

- Practical hands–on experience on **Oracle Argus Safety Database** – Data Entry, Case Processing, MedDRA coding, WHO Drug Coding, SAE narrative writing.
- Experience in coding of adverse events with **MedDRA** and coding of drugs with **WHO** dictionaries.
- Well versed with Pharmacovigilance concepts and Reporting guidelines including **MedDRA coding and WHO–Drug Dictionary coding**.
- Assessment of case reports for seriousness, causality and expectedness.
- Knowledge of Case Triage, Narrative writing, performing Labelling/ Listedness and Causality determination (Spontaneous & Literature cases).
- Understanding of Drug Development Process including Drug safety and different Phases of Clinical Trials.

EDUCATION QUALIFICATION:

- **B. Pharmacy** from Trinity College of pharmaceutical sciences(Satavahana university with 75%),Peddapalli [2018–2022]
- **Higher Secondary Education** from Sadhana Junior College, Dharmaram, Peddapalli
- **SSC** from ZP High School,Peddapalli.

DOMAIN SKILLS

Clinical Research

- Knowledge on drug development (Phase I –IV) of clinical trial.
- Clinical trial Monitoring (CRA) and Responsibilities of Monitor, CRA, CRC, Investigator, Sponsor.
- ICH–GCP –13 Core PRINCIPLES
- Difference between ICH–GCP and Indian GCP
- Informed consent Process, Reporting (AE, SAE)
- Schedule Y
- Knowledge of GCP and ICH guidelines including basic understanding of regulatory requirements for clinical research and Pharmacovigilance.

Pharmacovigilance

- ADR, Serious Adverse Reaction, SUSAR, SAE, MedDRA, Risk Management, ADR Monitoring, Narrative Reports.
- ICSR, SAE Reporting timelines, ICH– E2a, E2b, E2c guidelines
- PSUR, DSUR, Volume 9A, CIOMS
- Causality Assessment, Signal, Frequency of ADR, De–challenge, Re–challenge
- Hand on experience on **Oracle Argus Safety Database** – Data Entry, Case Processing MedDRA coding, SAE narrative writing.

SKILLS:

- Database : **Oracle Argus Safety Database**
- Office Tools : MS Word, Excel, Power Point
- Operating System : Windows–xp,windows7
- Dictionary : **MedDRA & WHO Drug**.

Trainings & Certifications:

Completed **Advanced Certified Course in Clinical Research & Pharmacovigilance** from Gratisol Labs.

PERSONAL DETAILS

Name	Rakesh
Date of Birth	28August 2001
Marital Status	Un married
Languages	English, Telugu
Nationality	Indian

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.

RAKESH