

Shaik.shaheena aslam
Mobile: 8106704147
Email: Shaik.Shaheenaslaml9@gmail.com

OBJECTIVE:

To secure a challenging position in the organization and to excel as a Successful Employee in the organization and to strive for the growth of it by becoming the part of the team with hard work and commintent.

EDUCATION QUALIFICATION:

- **B.Pharmacy** from M.AM college of parmacy, Narsaroapet.
- **Higher Secondary Education** from vivekananda Intensive junior college,chilakaluripet.
- **SSC** from SR public high school, chilakaluripet .

DOMAIN SKIL

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
- Informed consent Process, Reporting (AE, SAE), Case Report form
- Hands on experience on Oracle Argus Safety 7.0 Database - Data Entry, Case Processing
- MedDRA coding, SAE narrative writing.
- 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, SAE Reconciliation
- ICSR, SAE Reporting timelines, ICH- E2a, E2b, E2c guidelines
- PSUR, DSUR, Volume 9A, CIOMS, Black box warning
- Causality Assessment, Signal, Frequency of ADR, De-challenge, Re-challenge
- Hand on experience on **Oracle Argus Safety 7.0.3 Database** - Data Entry, Case Processing MedDRA coding, SAE narrative writing.

SKILLS:

- Database : Oracle Argus Safety Database 7.0
- 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** from Gratisol Academy of Clinical Research.

PERSONAL DETAILS

Date of Birth : 09th oct 1998
Father Name : Taj basha
Permanent Address : 32-77/22,SR-243, Seetaram nagar,beside JJ Talent School,
safilguda, Hyderabad-500056.
Sex : female
Nationality : Indian
Languages Known : English,Telugu,Hindi,Urdu.

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.

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