POORNIMA S R

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Professional Summary

A well-rounded professional with experience in multiple areas of Clinical Research includingClinical Data Management, Clinical SAS programming, Medical writing, Pharmacovigilance, and Onsite-Clinical Oncology Trials etc.

Knowledgeable in industry procedures, data standards and guidelines. Good problem solving, communication and collaboration skills.

Work Experience

Senior Associate - Kinapse India Scientific Services, Gurgaon - January 2011- October 2011

Responsibilities

- Drafting/Reviewing/QC'ing narratives for subjects who discontinued due to AEs, SAEs, Death or any other Special Interest.
- Project management activities: Project Trackers, Working Instructions, Guidelines.
- Drafting Clinical Study Report shell.
- Involved in the quality improvement initiatives of the department. Training and mentoring new joiners to get on board.
- Worked on Reports as a part of On Job Training: Drafting/Reviewing/QC'ing of Clinical Study Report, PhRMA Web Synopsis, CTD Study Abstract, Synopsis CSR and Protocol registrations and results posting of clinical trials on clinical trial registries (clinicaltrial.gov).

Drug Safety Executive in Makrocare Clinical Research Limited, Hyderabad- December 2009- January 2011.

Responsibilities

- Writing case narratives for ICSRs & PSURs.
- Medical Information support: Responsible for providing medical information and scientific support for consumer healthcare products to Physicians and Consumers.
- Create and maintain project specific working files, case report files and project central files.

- Case Processing:
    - Triage of Incoming Reports for Completeness, Legibility and Validity
    - Data entry of case reports into Oracle AERS safety database
    - Adverse event and drug coding by using MedDRA and WHODD
    - Assessment of case reports for seriousness, causality and expectedness
    - Quality review of all SAEs for data completeness
    - Identify clinically relevant information missing from the case report and facilitate its collection (in consultation with medical staff as required) by preparing follow-up request as needed
    - Alert manager to potential safety signals based on incoming case reports
    - Perform Literature Searches to identify adverse events for inclusion in the worldwide safety database
    - Perform weekly consistency checks for Non-Serious line listings
    - Preparing and updating SOP's according to client's requirements
    - Involved in Oracle AERS Validation (OQ & PQ) and authored validation (OQ& PQ) documents.
    - Worked on Reports as a part of On Job Training: Drafting and reviewing of Periodic Safety Update Reports (PSURs)

Clinical Research Coordinator in Indo-American Cancer Institute & Research Centre, Hyderabad, from November 2008 to December 2009.

Responsibilities

- Review and familiarize with the **Oncology Trials** study protocol (which includes study flow and timelines, inclusion and exclusion criteria etc)
- Trained on EDC database systems- Inform and Rave.
- Maintain Study related documents (CRF, eCRF, Informed Consents, Source Documents, IRB)
- Coordinate in study initiation, monitoring visits and study close out
- Interact with patients - Recruitment of subjects, discuss protocol with the subjects and answer their queries, schedule visits, document patient experience, dispense study drug
- Assist in investigational product usage, accountability with study team and maintaining the essential documents for the study SMF and study logs
- Coordinate with Principal Investigator, Clinical Monitors and the Ethics Committee
- Serious adverse event reporting to sponsor and regulatory authorities as per the protocol requirements, IRB and DCGI guidelines.

Junior Clinical Microbiologist in Indo-American Cancer Institute & Research Centre, Hyderabad from June 2005 to November 2008.

Responsibilities

- Perform technical duties related to the work of the clinical microbiology service: bacteriology, mycology, parasitology, serology, and virology
- Maintain complete, accurate, legible, neat, organized, up-to-date records/logs/files,
- Assure the accuracy of all tests performed by adhering to the laboratory's Standard Operating Procedures
- Participate in the laboratory inventory program that provides adequate inventories of reagents and supplies
- Provide direction, training, and feedback on routine laboratory procedures, as assigned.

Certifications

- **SAS Certified Base Programmer for SAS 9**.
- Certificate of Completion was awarded by Clearright Drug Safety Solutions IT Services, Health Informatics for completion of training on **AE Case Processing with Oracle AERS.**
- Interactive Web Seminar on "**Introduction to Signal Detection & Data mining**" by Barnett educational services.
- Was awarded a Certificate of participation for attending the session on **ICH GCP** organized by Roche.
- "**Duke University** Health System Clinical Education & Professional Development" awarded certificate for undergoing "**Good Clinical Practice**" online training program.

Education

Master of Science, Osmania University, Hyderabad, Jun'03–May'05

Specialization: **Microbiology.**

Project Work: "Isolation, Characterization and Functional assessment of Splenocytes using mice as a model"

Institution: National Institute of Nutrition, Hyderabad.

Topics covered : Biochemical analysis of biological samples, Molecular biology techniques, Tests for cell viability. Basic handling of HPLC (High performance liquid Chromatography) and FACS (Flow Cytometer).

Bachelor of Science, Osmania University, Hyderabad, Jun'00–May'03
Specialization: **Microbiology, Botany, Chemistry.**

Project Work: "Project on Anti Pimple Cream"
Institution: St. Francis Degree College, Hyderabad.
Topics covered : Isolation of Microorganisms present in pimple and acne, Gram Staining and Anti-sensitive Disc Method.