NANDAKISHORE.CH

Records Management Associate II, PAREXEL INTERNATIONAL Pvt. Ltd, Hyderabad.

Mobile: +919676615577, Email: nandakishore6362@gmail.com

Summary:

Currently working as Records Management Associate II with more than 4 years of experience in Clinical trial documentation, eTMF handling and maintenance from study set-up till export. Well versed with eTMF terminologies and Tools. Having overall knowledge of Clinical Trial process, ICH GCP knowledge and understanding about all the phases of clinical Trials.

Work Experience:

Records Management Associate II at PAREXEL INTERNATIONAL.

Date of employment 1st Aug 2016-Till date

Primary Responsibility

- Creating, maintaining and terminating user profiles on Inform database as per the SOPs.
- Perform InForm **EDC** and **RAVE (iMedidata)** User Management activities as required.
- Creating and deactivating Sites and associating\dissociating users to the same on Electronic Data Capture (EDC) system.
- Creating and updating the Rights groups.
- Performing Study start-ups whenever a new study goes live.
- Performing **Data Base lock** and Unlock as per the requirements of the study team.
- Performing Ad hoc requests and assigned tasks as per the requirement of client and organization.
- Entry of data into databases using relevant data entry tools.
- Review of study specific guidelines, as required
- Adherence to agreed timelines;
- Tracking and filing of study documents, including paper CRFs forms.
- Assisting with the archiving of study documents;
- Performing quality checks of study data. **Assist in query management**;
- Support administrative work for **Data Management Department**.

As RMA Role Responsibility

- Ensured that the investigators and site staff are aware of and comply with the study protocol, procedures and SOPs, GCP and other regulatory requirements.
- Ensure up to date study documents in tracking systems / document repositories.
- Coordinate flow of incoming and outgoing documents with project team members.
- Make necessary arrangements for internal and external audits.
- Perform archive procedures upon study termination: prepare copies of Central Files as required by Sponsor and
- PAREXEL Internal Records

Clinical Process Associate, Quintiles; Bangalore.

Date of employment 1st May 2015 - 20th June 2016.

- Ensured effective security, storage and retrieval of all proprietary and client information in Accordance with established procedures.
- Performed document Filing, Collection and Validation.
- Coordinated work flow through assignment of tasks and establishment of procedures like indexing of a regulatory document by using appropriate filing location in PSMT (Project Specific Matrix Tool).
- Assisted in the training of new team members on departmental procedures.
- Reviewed and QC of all document which are processed Core, Country, Site level clinical trial documents in eTMF

Trainee Clinical Research Coordinator; ICBio; Bangalore.

- Communicated with the sponsor, Ethics committee and update the Principal Investigator about the status quo and trial related events.
- Coordinated site management and clinical activities as per ICH-GCP.
- Coordinated and remind subject for all site visits which adhered to protocol requirements.
- Took active part ICF procedure explaining to subjects.

Educational Background:

Qualification	Board/University	Year of passing	Marks (%)

B. Pharmacy	Sri Krupa Institute of Pharmaceutical Sciences	2014	61
Intermediate	Vijwala Junior College	2010	62
SSC	Sri Nikhileshwara Nanda High School	2007	70

DECLARATION:

I hereby declare that the above-mentioned information is true to the best of my knowledge.

Date:

Place: Hyderabad **(Nandakishore.CH)**