

AMRITA CHOWDHURY



CONTACT

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LANGUAGES

English

Hindi

Bengali

PROFILE SUMMARY

Presently working as Junior Data Analyst in Cognizant Technology solutions, having over 2.5 years of experience as a Review Specialist in Clinical Data management and 1.7 years of experience in medical device data management study as a project coordinator. Core strengths include knowledge of Medical Device Reporting, Profound knowledge of regulations related to Data Management and clinical research, Good Clinical Practice, Good Documentation Practice, In-depth knowledge of data collection, medical terminology, and Clinical trial processes, internal audit, documentation and surveillance, Good communication skill, Computer knowledge.

WORK EXPERIENCE

Junior Data Analyst, Cognizant

Jan 2017- Present

Responsibilities:

1. Clinical Data Management- Review Specialist

- Complete review and validation of clinical data to ensure consistency, integrity and accuracy according to Study specific guidelines.
- Review, Update and Correct data in the Clinical database based on the resolved data queries. Perform additional data review activities to provide high quality data.
- Coordinating with the CRAs to ensure that the sites update the data as per eCRF completion guidelines and resolving issues regarding the clinical trial data.
- Performed Query management with the basis of manual listings review.
- SAE Reconciliation (With respect to start date and stop date and the AE term).
- Vendor Reconciliation.
- Preparation of study status (open, answered queries, overdue data in missing page missing visit data) on weekly client meeting.
- Perform the pass one pass two entry of the paper CRF into the database.
- Discrepancy done based on manual listing review, manual query with respect to normal lab value ranges and adverse event.
- Manual tracking of the CRF pages.
- Performed manual QC of the data entered into the data base.
- Running status report forms (Metrics reports) and providing update to the study leads.

2. Medical Device - Project Coordinator

- Coordinating process handling functions.
- Ensuring that complaints are evaluated to determine whether they represent a Potentially Reportable Experience.
- Establishing and maintaining procedures for reviewing and evaluating cases.
- Perform Adverse Events (AE) identifications.
- Completes assigned workload within established performance standards in accordance with Process

timelines.

- Perform Data analysis and review in accordance with SOPs.
- Review and clean data errors for consistency and accuracy according to study guidelines and conventions.
- Prepare data and information for making regular report data analysis
- Supervising all process related activity, root cause analyses, and Process-related corrective and preventive action activities.
- Review and clean data errors for consistency and accuracy as per guidelines and conventions.
- Participate in FDA audit or ISO audit as per requirement.

3. Further Responsibilities:

- Participating in study meetings and team discussions.
- Participating in knowledge sharing session with the team members.
- Updating and maintaining the Issue logs.
- Providing Study status updates to the Study Leads on a weekly basis.

QC Analyst, Richcore Lifesciences
2016

Jun 2016- Oct

Responsibilities:

- Instrument calibration, Documentations, Protein estimations, Enzyme activity analysis, Raw material testing.

INTERNATIONAL CERTIFICATION

The Biocon-KGI Certificate Program in Bio-sciences from Biocon.

ADDITIONAL TRAININGS

- Hands on training on HPLC and Fermentation techniques from Siddaganga Institute of Technology
- Hands on training on Molecular Biology from Institute of Bioinformatics and Applied Biotechnology (IBAB)
- Zoological field excursion on aquatic vertebrates and invertebrates in coastal area of West Bengal, 2012.

EDUCATION

- M.Sc. (Microbial Gene Technology) from Madurai Kamaraj University, Tamil Nadu in 2015, with 75.33%.
- B.Sc. (Zoology) from Jogamaya Devi College in 2013, with 63%.
- 12th Standard from St. John's Diocesan, Affiliated to West Bengal Board of Higher Secondary Education with 74% in 2010.
- 10th Standard from Shri Ritam Vidyapith, Affiliated to West Bengal Board of Secondary Education with 80% in 2008.

Project undertaken as a part of academic curriculum(M.Sc);

Project name:

Genetic Characterization of a Novel Mutation Capable of Suppressing Ion Mutant Phenotypes (Isp) in Escherichia coli

- Key Skills Acquired: Transduction, β – galactosidase assay, Gel elution, relative viability test of bacteria in different concentrations of MMC and MMS, Sequential spotting analysis of bacteria in particular concentrations of MMC and MMS in different time intervals (liquid survivability).

ADDITIONAL SKILLS

Computer skills: Proficient in MS office, Advanced Excel, Power point

Communication Skills: Client interaction skills, Email Comprehension, Global Culture, Business Writing Convention.

REFERENCES

References available on request

Conclusion

I hereby state that all the information provided are authentic to the best of my knowledge.

Amrita Chowdhury

