**M.Chandrakriti Singh Email Id:** chandrakriti.maisnam@gmail.com

*M. Sc Biotechnology* **Contact No.:**+91 9205945228

**OBJECTIVE:**

To obtain a challenging position within a reputed organization where I can contribute towards the overall growth of the organization and achieve personal and professional growth.

**SUMMARY:**

Clinical Data Management professional with more **than 9 years of work experience** in data management, competitive intelligence and scientific insights domain. Expertise in designing clinical intelligence analytics platforms for real-time tracking of various clinical trials across multiple therapeutic areas, investigators and clinical trial sites.

**KEY KNOWLEDGE AREAS:**

* Clinical research fundamentals, data mining, research & analysis, clinical trials intelligence services
* Comprehensive knowledge of clinical data management processes & standards.
* Hands on experience on ORACLE CLINICAL 4.6 software and activities pertaining to:
  + 1. Planning &Designing a Study.
    2. eCRF designing including creating and testing Data Entry Screens.
    3. Designing Generating, Executing and Testing Validation Procedures.
    4. Discrepancy Management.
    5. Generation, Printing and Resolution of Data Clarification Forms (DCFs).
* Predictive Analytics, KOL Profiling and Identification, Quality Audit
* ICH GCP, GCDMP, ICMR guidelines & Schedule Y.
* Project Handling, Client Call Handling
* Mentor and train new hire staff
* Develop and Maintain Postive relationship with clients
* Roles & responsibilities of key stakeholders.

**PERSONAL PROFILE:**

* Hardworking, team player, results oriented with fast learning ability.
* Ability to meet timelines and to perform well under pressure
* Good writing and verbal communication skills.
* Emotionally mature, honest and dedicated with high personal integrity.
* Good time management skills.

**PROFESSIONAL SUMMARY:**

***Process Specialist – Data***

*Cognizant Technology Solution India (P) Ltd. Coimbatore, Tamil Nadu*

*April 22, 2015 to March 11, 2016*

**Responsibilities:**

* Responsible to plan, coordinate and manage the day-to-day clinical data operation that meet the goal and objective of the client while adhering to guidelines and policies
* Act as a primary liaison to client and regular communicate with team
* Coordinate all the project activities assigned by clients, monitor and track all the project metrics.
* Perform co-monitoring to ensure adherence to protocol, SOPs, GCP, ICH, GCDMP and regulatory requirements
* Ensure timely accurate and complete collection, completion and filling of study data
* Identify, address and resolve issues and problems as team might occur at data entry
* Design and maintain databases, queries, reports, graphics and data-analysis tools.
* Perform data entry, check reviews, database audits etc.
* Maintain audit readiness at the site level for any audits or regulatory inspections
* Maintain quality control on database according to required guidelines.
* Manage and integrate all query responses into clinical databases.
* Provide efficient support to team and evaluate all data collection activities.
* Obtaining input from Citeline team for clinical data management issues.
* Identification and remediation of issues arising that may affect the planned completion of client project including provision of support, guidance and assistance to clinical staff to meet project milestones
* Facilitate communication between all project stakeholders and ensure that regular updates are provide in accordance with each study plan.
* In consultation with senior management and clinical project managers, work towards the development of system (project management, work flow, resource tracking) to track project progress.
* Schedule and conduct regular team meeting and ensure appropriate distribution of minutes
* Participate client meeting, management meeting and audits as required
* Provide clinical QA input into project meeting and at operational management meeting.
* In consultation with team members and in conjunction with the director of quality and training, identify training needs, implement training programs and monitor training performance.
* Organize and train a project team who will assist in executing the clinical study
* Report performance status to off-shore client during weekly calls and to the management.

**Team Lead – Clinical Data Management**

*Point Perfect Transcription Service India Ltd., Coimbatore, Tamil Nadu*

*Feb.2007 to April 10, 2015*

**Responsibilities:**

* Coordinating various client request projects and services.
* Identifying process improvements for clinical data collection.
* Identifying trial sponsors, trial locations, study type, design and durations.
* Identifying the trial phases, drugs, investigators, sites.
* Maintaining accurately complete details of investigators& sites in the database.
* Maintaining primary and secondary outcome measures.
* Maintaining interim and final result reports of trials.
* Reviewing data effectively for completeness and inconsistencies.
* Quality auditing for whole department.
* Providing feedback to the frontline associates on their mistakes.
* Attending client calibration calls and team calibrations.
* Training the new hires, existing teams, managing and promoting them to next level.
* Training the team members on the process updates and failures.
* Diagnosing the team performance and to enhance the individuals and team performance.
* Member of the core team involved in the end-to-end content management of clinical trial data, data mining, updation and quality monitoring for key investigator & sites projects.
* Curating database of investigators involved in clinical trials, reporting, clients handling.
* QA Analyst for several Ad-hoc investigator and sites.
* Data mining, validating of global clinical trials information in database

**Customer Care Executive**

*Amtex System, Chennai, Tamil Nadu*

*Aug 2006 to Nov 2006*

**Responsibilities:**

* Working as a bridging force between the customers and the organization.
* Explaining the details about the new products to the customers.
* Resolving queries or problems about the products.
* Meeting the targets within the stipulated time frame.
* Analyzing customer feedback and sending reports to respective team leads.

**PROFESSIONAL ACHIEVEMENTS:**

* Quantity topper of the year
* 100% attendance of the year
* Won the Top notch award twice

**EDUCATIONAL SUMMARY:**

**Advanced PG Diploma in Clinical Research and Data Management (APGDCR-DM)**

*James Lind Institute, Hyderabad, Andhra Pradesh–Year 2013*

**Masters in Biotechnology (M.Sc. Biotechnology)**

*Periyar University, Salem, Tamil Nadu -* ***Year 2006***

**Bachelors in Biochemistry (B.Sc. Biochemistry)**

*Manipur University, Manipur -* ***Year 2004***

**TECHNICAL PROFICIENCY:**

**Computer Skills:**

* MS Excel, MS Word, MS Power Point, MS Dos, Internet, Basics of Hardware, Outlook etc.
* Fast learner of any new computer programs.

**Other Skills:**

* Knowledge of Chromatography, Centrifugation, Immune Techniques, Genetic Engineering, PCR, Spectrophotometer, Calorimeter etc.

**PROJECT: STEMI INDIA**

**STEMI INDIA** is an ICMR approved and funded project that is developing a pilot project in 4 clusters across Tamil Nadu.

**Responsibilities:**

* CRF data entry (manual, e-CRF)
* ICH-GCP, Clinical Safety Data Management, SOP’s Guidelines
* Source Data and Documents Verification
* CRF Pages Tracking and Correction
* Data review, Validation process, **Quality Control and Quality Assurance**
* Addressing discrepancies to the clinical team
* **Design and deliver agreed status reports at a global level and study level**
* Provide clinical data management support to Clinical Operations team and/or study project, Clinical data management team and biostatistics team
* Drive corrective actions as needed
* Participate in Client meetings and audits as required

**PERSONAL DETAILS:**

# Name : Mr. Maisnam Chandrakriti Singh

# Date of Birth : 11th April, 1982

# Sex : Male.

# Marital Status : Married

# Languages Known : English, Hindi, Manipuri and Tamil.

# Nationality : Indian.

# Mobile No : +91 9205945228

**Contact Address** : Kotla Mubakrakpur, Gurudwara Road, House No. 1408. New Delhi 110003

**REFERENCES:** Available on request

**DECLARATION:**

I hereby declare that all statements made above are correct to the best of my knowledge and belief.

Maisnam Chandrakriti Singh