MEERA BHASKAR

#### Seeking a suitable position that can utilize my domain knowledge, ‘soft’ skills and experience

**PROFILE**

* **Four plus years experience** in various aspects of **CDM in CRO’s and in clinical trial**
* Good understanding of **CDM** processes from **study initiation**, **study conduct** **and study** **closure**
* Provided **training in Clinical Research\*** as a part of study/work curriculum
* End to end understanding of **Data Management processes for** **Phase I to IV studies**
* Have demonstrated knowledge of **FDA, ICH-GCP, GCDMP** guidelines
* Hands on experience in **CRF Designing and Annotation with CDISC SDTM Standards**
* Deft in **Database Testing, Dummy Data preparation, Data Validation, AE/SAE, LAB Data Reconciliation, Medical Coding and Query Management, in Oracle Clinical 4.5 .1 & EDC systems namely Inform 4.6,Medidata Rave and Medrio**
* Experience in handling **external data** namely **Lab, IVRS, ECG, PK, Diary data**
* Experienced in preparing **DM Plan & DV Plan/SV Plan**
* Experienced in developing **Quality plans and guidelines**
* Experienced in handling **External and Internal study audits**
* Experienced in working with clients **globally** for Clinical Data Coordination
* Motivated and creative with the **ability to self-manage**
* Attending **SAS and PL SQL** training

**EDUCATIONAL QUALIFICATION**

#### **2005 PG Diploma in Clinical Research from York College, Toronto, Canada**

#### *through* Inter-ed Faculty of Clinical Research, Cochin, India

#### **2004 M.Sc Microbiology**

#### Bharathiyar University, Coimbatore, India

#### **2004 Advanced Diploma in Bio informatics**

#### Bharathiyar University, Coimbatore, India

#### **2002 B.Sc Microbiology**

#### Madras University, Chennai, India

**PROFESSIONAL EXPERIENCE**

**2009 – 2011 Consulting & Training (Dec 09 to till date)**

Providing training to Clinical Data Management / Clinical Research aspirants. Topics include:

* Introduction to Clinical Research
* Bioequivalence and Bioavailability studies
* Clinical Monitoring and Site Management
* Ethical and Legal issues in Clinical Research
* Introduction to Clinical Data Management
* Introduction to Pharmacovigilance

**2007 – 2009 Clinical Data Manager I (Oct 07 – Dec 09)**

**Paragon Biomedical India Pvt Ltd -** [**http://www.parabio.com/**](http://www.parabio.com/)

*Paragon Biomedical is a full-service clinical research organization (CRO) providing high quality Phase I - IV clinical trial support to the world’s pharmaceutical, biotechnology, and medical device companies.* ***Location:*** *United States, United Kingdom, Poland and India.*

**Responsibilities included:**

* Data Entry, Data Validation, Edit check writing & testing, Database testing and Query Management in Oracle Clinical 4.5.1., Inform 4.6,Medidata Rave and Medrio
* SAE, AE, and Lab data Reconciliation in Oracle clinical and Inform 4.6
* External data handling namely Lab data, IVRS, ECG, Diary data
* CRF Designing and review as per protocol
* CRF annotation using CDISC standards
* Participating in start-up activities which included development of Data Management Guidelines and specification and review of database set up
* Reviewing Guidelines
* Performing Medical coding and review using Medra and WHODD
* Participating in assigned study finalization activities including Database close out, Reconciliation, Critical Item Review, Quality control and archiving
* Participating in external audits
* Working as Internal auditor for different in-house projects

**Year 2007 Clinical Research Coordinator (May 07 – Oct 07)**

**Quintiles India Pvt Ltd –** <http://www.quintiles.com/>

*Quintiles is fully integrated bio and pharmaceutical services provider offering clinical, commercial, consulting and capital solutions.* ***Locations:*** *Africa, Asia, Europe, America, Australia and New Zealand.*

**Responsibilities Included:**

* Ethics committee submission and approval
* All study related documentation
* Maintaing TMF
* eCRF filling
* Scheduling and maintaining patient visits
* Drug accountability
* Diary review
* Part of Internal and external audit

**2006 – 2007 Clinical Data Coordinator (Jun 06 – Apr 07)**

**Manipal AcuNova Pvt Ltd**

*Manipal AcuNova Presently known as* ***Ecron AcuNova*** *is a Contract research organization that provides end to end services for Phase I - IV Including clinical trial management, Clinical data management, PK/PD services and Lab services.* ***Location:*** *United States, Europe and India.*

**Responsibilities included:**

* + - Designing CRF
    - CRF Annotation using CDISC standards
    - Writing Edit checks
    - Validating edit checks
    - SAE, AE, and Lab data Reconciliation
    - Reviewing Guidelines for assigned projects
    - Conducting QC of data for assigned projects
    - Medical coding using WHO DD and MeDRa
    - Part of Quality audit team and have done internal audits for different projects as per ICH GCP guidelines
    - Part of Training team for AcuNova certified clinical research course

**Therapeutic Fields worked on:**

|  |  |  |
| --- | --- | --- |
| * PAH – Pulmonary Arterial Hypertension | * Ophthalmology | * Diabetes |
| * Gynaecology | * Infectious diseases | * Pain Management |
| * Cardiology | * Neurology | * Dermatology |
| * Oncology | * Nephrology | * Vaccine studies |
| * Medical Devices | * Paediatrics | * Orthopaedics |

**Clinical Trial Phases worked on:**

* Phase I (Dose Escalation study)
* Phase II (IIa and IIb)
* PhaseIV
* PhaseIV

**2004-2005 Lecturer: Subject - Microbiology (Jun 04 – May 05)**

***Presentation college of Applied Sciences*** *in Cochin, India affiliated to Mahatma Gandhi University.*

**Platforms/Applications worked on:**

* Clinical Database Management Systems
  + Oracle Clinical 4.5.1, Inform 4.5 (EDC), Inform 4.6 (EDC),Medidata Rave (EDC) & Medrio(EDC),SAS
* MS Office

**Personal Details:**

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Mob: 949 607 7940 (Secondary)

Email: [**meera.bhaskar1@gmail.com**](mailto:meera.bhaskar1@gmail.com)

Visa Status: **L2** / Possess **EAD** & **SSN.**