JUHI CHAVDA

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PROFILE SUMMARY

A Clinical Research Professional with a total experience of 05 years in Clinical Operations. Demonstrated ability to support management, drive remote teams and coordinate the tasks of multiple clinical research studies.

WORK SUMMARY

Feb 2021- till date – Team Leader (Jr. CRA Team) & eTMF Specialist

CBCC Global Research LLP, Ahmedabad

Key Responsibilities (As a Team Leader):

- Manage the Jr. CRA team
- Overseen the Training Session, Personal training records of the team
- Ensure staff utilization meets Project requirements
- Monitor staff performance and regularly meets employees to discuss queries
- Ensure staff adherence to the quality expectation
- Conduct the meeting session with team for smoothing of process
- Assign resources and manages transition of ongoing process/workflow

Key Responsibilities (As eTMF Specialist):

- Perform eTMF periodic review of the documents for Content & Completeness check
- Perform eTMF Reconciliation tasks (Missing document, duplicates identification etc.)
- Oversee the Study reports & follow-up with action owners for open action items
- Compliance to TMF Completeness, TMF reviews & TMF Issue resolution
- Review & respond to eTMF content quality issues and identifies trends per study & across programs
- Maintain the eTMF in stage of audit ready

Mar 2017- Feb 2021 - Jr. Clinical Research Associate

CBCC Global Research LLP, Ahmedabad

Key Responsibilities:

- Identification & development of robust Site/Investigator Database for different indications
- To Perform Project specific site level feasibility assessment
- To Collect essential documents related to EC dossier and regulatory submission from sites
- To prepare and dispatch the EC Dossier to Sites
- EC & DCGI submission and approval tracking
- Project specific Clinical trial supply to the site like ISF, PF, and PK kits, Central Lab kits etc.
- To assist PM for getting the Site agreements executed
- Prepares site files, trial master files, trial related trackers etc.
- Review the TMF periodically & Study Reports and follow up with CRA and/or PM for any open action items.
- Resolve the QA audit findings in consultation with CRA/PM.
- Assist PM for the weekly/monthly project status report
- To work as per GCP and New Drugs and Clinical Trials Rules, 2019 and to ensures compliance for the same
- Other duties as assigned by CRA, PM, Head-PM and DO

Year	Designation	Company	Key Responsibilities
Sep 2016- Apr 2017	**Research Associate**	**Quest Care Pvt. Ltd, Kandala**	• Review of Pre & Post study related documents • In process and Retrospective review of raw data of the study, generate report & ensure compliance to response • Compilation of study documents for submission to regulatory and QA and subsequent archival.
Jun 2014- Jun 2015	**CRC**	**Kokilaben Dhirubhai Ambani Hospital**	• Conduct all the activities as per study protocol • Coordinate with Patient on daily basis • Maintain study files and EDC entry • Compile & monitor all study related logs & forms • Ensure the Patient Compliance & study adherence.

Educational Qualification

Apr 2014	**APGDCR (Advanced Post Graduation Diploma in Clinical Research)** IICR- Ahmedabad
Apr 2013	**Master of Science in Bioinformatics** (M.Sc) KSV University Gandhinagar, Gujarat, India
May 2009	**Bachelor of Science in Chemistry** (B.Sc) K.K.Shah Jarodwala Maninagar Science College, Gujarat, India

SCIENTIFIC PROJECTS, WORKSHOPS & TRAINING

Apr 2018: Basic Life Support Training, CBCC Global Research LLP.
Jun 2021: Good Clinical Practice, CBCC Global Research LLP

Miscellaneous

Electronic Platforms	IVRS
Microsoft Office	Good operational skills for Power point, Excel, Word
Guidelines and Regulations	New Drugs and Clinical Trials Rules, 2019, ICH –GCP E6 R2
Other Skills	Leadership and Communication skill Approachable, Organized and Efficient. Focused and Quality work, Manage Multiple tasks
Personal	**Gender:** Female **Marital Status:** Married **Nationality:** Indian **Mother Tongue:** Gujarati **Languages Known:** Hindi, English, Gujarati

Declaration

I, Juhi Chavda hereby declare that the details furnished above are correct to the best of my knowledge.
Ms. Juhi Chavda