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| Resi: D-203, Pushpak Appt.,  Opp. Smruti Mandir,  Ghodasar,  Ahmedabad - 50.  Tel.; (Mobile) : 09825961390  (Resi) : 079-25895834  (Email) : bipinjha3774@yahoo.com |

**Full Name :** Jha Bipinchandra Digamber

**Date of Birth :** 3rd July 1974

**Nationality :** Indian

**Language Known :** English, Gujrati, Hindi and Maithili

**Sex :** Male

**Marital Status :** Married

**Computer Literacy :** Ms-Word, Excel, Power Point and Internet

**Hobby :** Surfing net and reading

**Area of Interest :** Translation, Clinical Trials and Regulatory Affairs

**Educational Qualification :** BA with Hindi from Gujarat University in 1997

MA with entire Hindi from Gujarat University in 1999

B.Ed. with Hindi and Social Studies from Gujarat University in 2002

**Technical Qualifications :** Certificate Course in Computer Science from LCC

**PROFESSIONAL EXPERIENCE:**

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| Clinical Research Professional with over ten years of experience in different Contract Research Organization (CRO) involved in bioavailability / bioequivalence and phase – I clinical trials on healthy human volunteers. |

* As a part of clinical research team prepared more than 100 ICF in English, translated more than 300 ICF in Hindi and Gujarati and presented more than 500 ICF of Bioavailability / Bioequivalence trials and phase-I trial.
* Specialized in ICF preparation, ICF Translation, and Presentation to volunteers in more uniform and simplified way.
* Having enough awareness to various regulatory guidelines / ICH-GCP requirements for smooth and quality work in clinical research trials.
* Involved and developed and updated various systems and SOPs within the department and also training of the SOPs to study personnel.
* To look after the auditors, sponsors, & investigators visiting to the organization.
* To communicate with IEC, QC/QA for ICF related issues and resolve queries.
* Faced various regulatory audits such as ANVISA, AFSSAPS, WHO, USFDA, and CAP.
* Attended several conference and workshop related to basic and Advanced GCP, regulatory affairs and other guidelines
* Given presentation as a faculty in basic and Advanced GCP workshop on ICF.
* Handling of complete check-in activity in consultation with the Principal Investigator and Head-Clinic Operations.
* Actively involved in various trial-related activities including screening and handling volunteers’ recruitment as per protocol requirements in consultation of PI and Head of the Department.
* Enhancement of the volunteer data bank & Electronic Data Management.
* Planning, Organizing, and Conduct of the Screening process and addressing to overall volunteer management during the study.
* Handlings of both inter and intra-department project related communication through proper channels.
* Performing quality control checks for the works done in the department.
* To develop a culture of accurate and quality work.
* An effective communicator with good presentation & leadership skills.
* Also worked as a freelance translator on different subjects.

Bipin Jha