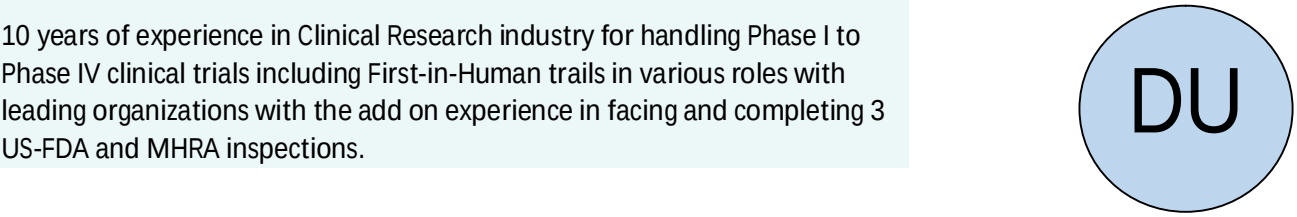
Curriculum Vitae

10 years of experience in Clinical Research industry for handling Phase I to Phase IV clinical trials including First-in-Human trails in various roles with leading organizations with the add on experience in facing and completing 3 US-FDA and MHRA inspections.



DARSHAN UKANI

Clinical Research Professional

H-203, Akash Elegance, Near Sola overbridge, Science city, Ahmedabad- 380060 Gujarat, INDIA

Work Experience

- **2016 – Till date** — Clinical Process Specialist in Clinical Research/Clinical Trial
  IQVIA, Ahmedabad (Work from Home)
- **2015 - 2016** — Quality Assurance- Auditor in Clinical Trials
  LAMBDA Therapeutics Research Ltd, Ahmedabad
- **2010 - 2015** — Clinical Research Associate (CRA)
  CADILA Pharmaceuticals Ltd, Ahmedabad
- **2008 - 2010** — Clinical Research Coordinator (On-site)
  Sheth V S Research Foundation Trust, Ahmedabad
- **2007 - 2008** — Clinical Research Coordinator (On-site)
  VIBGYOR Scientific Research Pvt Ltd, Ahmedabad

EDUCATION

- **2006 - 2007** — Post Graduate in Clinical Research & Clinical Data Management from PUNE University
  Grade: A
- **2004 - 2006** — Master In Biotechnology from Bangalore University
  Grade: A
- **2001 - 2004** — Bachelor In Biotechnology from Saurashtra University
  Grade: B

Personal	----------
DOB	: April 27, 1984
Nationality	: Indian
Gender	: Male
Civil Status	: Married

Language	----------
English	: Expert
Hindi	: Native
Gujarati	: Native

Skills and Competences: ----------

- Project Management
- Working Under Pressure
- Team Work
- Time Management
- Emotional Intelligence
- Presentation
- Analytical Thinking

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Responsibilities:

2016 – Till date **(as Clinical Process Specialist)**

- review and approval of Site Visit Reports (SVRs) for global clinical trial sites in Clinical Trial Management System (CTMS)
- to ensure quick turnaround time and timely finalization of SVR
- follow up with CRA/Site Managers to ensure timely follow up of open AIs and complete resolution of AIs
- Review Protocol Deviations (PDs) and corrective and preventive actions (CAPAs)
- To analyze and identify site level, CRA level, Country level PDs and provide project level inputs for preventive actions.
- Identification, escalation and discussion of study specific quality issue & safety concerns in appropriate and timely manner with PM/CPM/study team along with proposed solution
- To provide ongoing training and lesson learned sessions to CRAs on SVR writing, AIs writing and PDs writing
- Facilitate and respond to company, client and regulatory audits
- Mentoring new members, assisting in preparation of project tools and sharing ideas and suggestions with team members

2015 - 2016 **(as QA auditor)**

- Performing QA audit for activities for clinical trials as mentioned for CRA role

2010 - 2015 **(as Clinical Research Associate)**

- Clinical Monitoring and Site Management: Identify potential investigators, Performing Study start-up activities Site Selection (SSVs) & identification of potential investigators, Organizing IMs, Site Initiation Visit (SIVs), Site Monitoring Visit (SMVs), Booster/Training visit, Site Close out visit (SCVs) as per ICH-GCP guidelines
- Review Subject Recruitment Plan and site support in facility and storage
- Routine Monitoring visit to ensure subject safety, right & data creditability
- Evaluating the quality and integrity of site practices – escalating quality issues as appropriate, submitting quality Site Visit Report in timely manner
- Monitoring of IP accountability, inventory and compliance
- Preparing study specific Project Management Plan, Safety Management Plan, IMP plan, Risk Management Plan, DSMB charter
- Managing the Patient Data, in eCRF & paper CRF, query resolution, Investigator Site File (ISF), Site Master File (SMF), Trial Master File (TMF), SAE/AE management
- Ensure the proper essential documents are in place prior to trial start up and on an ongoing basis throughout the study
- Providing trial status tracking and progress report to

In-Silico Competencies

- Operating Platform:
  Windows, Mac OS
- Office Tool:
  MS-Office
- Web:
  Internet, eCRF tools (Medidata Rave, InForm, Oracle RDC, CTMS), IWRS, IVRS

Hobbies:


Outdoor


Travelling


Calligraphy


Yoga


Cycling


Badminton & Squash

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darshanukani

2007 - 2010 **(as Clinical Research Coordinator)**

RESPONSIBILITIES:

- Coordinate International (USFDA, MHRA) as well as Domestic (DCGI) clinical trials
- Patient screening, Randomization, Study Visits, Follow-ups
- IVRS, IWRS, Oracle RDC.
- Communication with Ethics Committee (IRB/IEC)
- Site feasibility questionnaire
- Internal Monitoring of Clinical Trials

CONFERENCES & SEMINAR ATTENDED

- "**Clinical Excellence Programme**" workshop in clinical research organized by SANOFI- AVENTIS Pharma on 09 Sep 2009 at Hotel President, Ahmedabad
- **Clinical Excellence Programme** on Good Clinical Practice by Sanofi Aventis India Limited, on 10-May-2008 at Heart Care Clinic, Ahmedabad
- **Clinical Excellence Programme** by Sanofi Aventis India Limited, on 06-Oct-2007 at Heart Care Clinic, Ahmedabad
- Investigator Meeting for **CHAMPION PLATFORM** clinical trial on 16, 17 Nov 2007 at Hilton Tower, Mumbai organized by The Medicines Company, NJ, USA.

Declaration: I hereby vouch that all the above information given by me is true to my consent.

Darshan Ukani

Darshan Ukani

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