Dr. Yashwant D. Gome

Team Leader in Transitional Quality and operation team with experiences in CRO

PROFILE

A dynamic professional with over **10+ years** of experience in Pharmacovigilance (PV) and in CRO as a Clinical Research Coordinator/Associate.

Self-motivated with good communication and excellent interpersonal skills.

An excellent team member to help enhance the quality and

CONTACT

Address
Flat No. E-401, Sun Exotica Society, Near yewalewadi kaman,yewalewadi, Kondhwa Bk.
Tal.Haveli, Dist. Pune 411048
Email
yash.gome346@gmail.com
Mobile
+91 9890112869
+91 9987150289

HOBBIES

Listening Music.

Playing Cricket.

Learning New Things.

OBJECTIVE

To achieve good positions in company management that offers challenging responsibilities and a constant learning environment. I want to use my experience and deliver analytical which provides opportunities and scope for growth.

EXPERIENCE

- Currently designated as **Team leader of Transitional Quality team and operation** from Apr 2019.
- A dynamic professional with over **10 years o**f experience in **Pharmacovigilance** (PV) with Cognizant as Senior Process Associate (TQ– Transitional Quality) and Specialist in TQ (Transitional Quality).
- For **2 years and 8 months** worked in CRO as a Clinical Research Coordinator/Associate with Max Neeman International.

CARRER GRAPH

Apr-2019 till date	Cognizant, Pune	Team leader
Jan 2015 - May 2019	Cognizant, Mumbai	Specialist in Transitional Quality
Mar 2013 –Jan 2015	Cognizant, Mumbai	Senior Process Associate- TQ
May 2010 – Mar 2013	Max Neeman, Pune	CRC/CRA

PERSONAL SKILLS

- Dedications towards work and give my best to do it.
- Self-confidence, quick learning and adaptability.
- Leadership qualities and team spirit.
- Knowledge about technologies and interest to learn new technologies.
- Able to handle project independently.

PERSONAL DETAILS

- **Name** : Yashwant Dadasaheb Gome
- **Date of Birth** : 5th May 1985
- **Father Name** : DadasahebShankarrao Gome
- **Gender** : Male
- **Marital Status** : Married
- **Nationality** : Indian
- **Languages Known** : English, Hindi and Marathi
- **Passport No.** : L2523401(05/2013 to 05/2023)
- **PAN No.** : ARMPG1851C

HR DETAILS

- Total and Relevant Experience : 12 Years 8 Months
- Current Appraisal Cycle : April
- Notice Period : 60 Days

AREAS OFEXPOSURE

1) **Team leader of Transitional Quality team and operation (Cognizant Pune. Apr 2019 to till date)**
   - Handling all team activity for Transitional Quality and operation
   - Reporting out KPI to client
   - Reporting error trend to Client and Ops team
   - Taking session for top errors with resolutions
   - Communicating with client on day to day basis
   - Interaction with team, project leader and client.
   - Updating team on new information.
   - Preparing and sharing Late case and TAT missed cases RCA/CAPA with client

2) **Specialist in Transitional Quality (Cognizant, Pune. Mar 2013 – May 2019)**
   - Aware of individual case processing (**Spontaneous, Clinical trial and Observational trial)**
   - Data entry of cases, peer review of cases.
   - Working in Independent QC Team
   - Doing QC of Process Cases
   - Development of a narrative summarizing the patient's adverse event details as reported as per regulatory requirements.
   - Identify duplicate/invalid cases or reports and process accordingly.
   - Compliance with strict reporting timeframes to ensure adherence to international and domestic regulations.
   - Use medical dictionaries (MedDRA) and business guidance's to code medical history, drugs and serious adverse event and laboratory investigations.
   - Interaction with team, project leader and client.
   - Updating team on new information.
   - Communicating with client on day-to-day basis

3) **Clinical Research Co-Ordinator. (Max Neeman International Pune. May 2010to Mar 2013)**

   - Review research protocols and amendments, informed consent documents, CRF'S and other applicable business & project related documents.
   - To communicate with IEC for approval of protocol & ICF
   - Coordination and Consult with Clinical team to understand the nature of the scientific work to be covered.
   - To perform regular monitoring to ensure the compliance to ICH-GCP guidelines,local& international regulations (i.e.DCGI, FDA) and applicable SOPs
   - Verify the CRFs and source data according to the monitoring plan
   - Patient recruitment as per protocol, scheduling of patients according to protocol compliance.
   - Preparation of customized presentation for doctors
   - Counseling and interacting with patients.
   - Data Verification. CRF documentation within timeline with query validation.
   - Worked on Medidata Rave, Inform, Pheedit.
   - SAE Reporting within Timelines, Maintaining Follow-Up, Writing SAE Narrative.
   - Notification of CIOMS, SAE at the site, SUSAR's to the Ethics Committee.
   - Accountability and shipment of records.
   - Attended site initiation visit, site Monitoring,
   - Done Maximum Feasibilities and Identification of New PI.
   - Presentations to Ethics committee regarding new protocols.
   - Notification to Ethics Committee of new updates.
   - Handling financial aspect as per the Clinical Trial Agreement. Handling Con –Calls with the Clients related to the Study protocol.

CLINICAL RESEARCH EXPERIENCE:

SR NO	Therapeutic Area	Phase	Ecrf
1.	Oncology (2 trials)	III	Inform
2.	Diabetes (2 trials)	IV	Inform
3.	Cardiac (1 trials)	IV	

DECLARATION

I hereby declare that the above particulars are true to the best of my knowledge and belief. I assure you, that I will abide by the rules and regulation of the organization.

Yours faithfully,

Yashwant D. Gome