

CURRICULUM VITAE

LALIT N. GORE (WANI)

Email: techligament@gmail.com & lalit@ambemedical.com

Mob. No. : - + 91- 99967596296/9167920553

OBJECTIVE:

To Serve the organization with utmost sincerity and sharpen my skills, put forward some innovative thoughts for organization's development.

Working as Independent GCP Auditor in Tehligament Life Care Group for Pharmaceutical Industry support for Bio-Equivalence/Clinical Studies & Pharmacovigilance Sector (June 2020 to till date)

Major Hand in handling difficult projecst in DCGI & CNB Department.

TECHNICAL EXPERTISE

Over **13 years of experience** in Clinical Research Division as Clinical Research Auditor/Monitor for Bioequivalence & Clinical Studies, Pharmacovigilance & CRA in CRO.

More than 36 Bioequivalence CRO audit experienced in across the India.

Monitored more than 300 BE/BA & Clinical Studies

As Internal Quality Monitor faced Regulatory External & Internal Audit

Faced USFDA, DCGI, MCC RA audit & Sponsor (US and UK Indian) Audit.

Software Skill: --

LIMS, Biometric, MedDRA, Safety database, eCTD, SAS/Winlonin eCRF, eCTD Software (Advent / Sapphire/ARISg).

- Plans & conducts clinical trial site & Clinical Research organization (CRO) audit as per GCP, GLP, Schedule Y, Applicable regulatory & 21 CFR part 11.
- Conduct the monitoring visits to check compliance to GCP, study protocols, Standard Operating Procedures (SOP), Source document verification (SDV) & other regulatory requirements. (Used own prepared checklist).
- Knowledge of guidelines for clinical trials such as ICH-GCP, Indian GCP & Schedule Y.
- Expertise in handling Bio-Equivalence & Bioavailability studies (Well acquainted with documentation & report preparation for submissions to various national & international regulatory agencies).
- Preparing & Reviewing Protocols, CRFs, ICFs, TMFs, eCRFs, Narratives, AEs, SAEs, eCTD & Clinical Study reports.
- Generate the Audit report along with categorizing the findings within the given timelines & report to CRO.
- Support to RA department for eCTD Submission, DCGI, Module 2 & 5 dossier preparation.

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WORK EXPERIENCE:

Independent GCP Auditor for Pharmaceutical Industry- especially for clinical trial projects encompassing Phase-I, II, III, /PK projects including Bio availability and Bioequivalence. (June 2020 to till date)

Monitored more than 300 BA/BE studies and Clinical Studies

- Selection and Identification Clinical Research Organization based on Molecules and Submission Regulatory Authorities
- Plan System Audit of CRO as per Client Requirement
- Capabilities to Handle export or import of medicine
- Handle Comparator Drug Sourcing Parts
- Supply of Medical Literature to more than 30 companies.
- Monitoring of Clinical/Bioequivalence studies as per GCP, GLP & Schedule Y
 - **CRO Qualification Audit- System and Facility Audit**
 - **Clinical Study Monitoring**
 - **Site Initiation Audit**
 - **Site Close Out Visit**
 - **Conduct System Audit strategy meeting with internal team**
 - **Monitoring Visit Report Preparation**
- DCGI Regulatory works –NOC on faster tracks.
- To review all Clinical trials documentation like Protocol, SOP, Case Report Forms, Informed Consent Forms, Medical Screening Records, AE/SAE reporting methods, Investigational Products Documentations, Clinical Study Reports, eCTD Submission documentation as per Regulatory like ANDA requirement, GDP/GCP compliance.

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| Facility Audited and Monitored Bio-Studies Centers | | | |
|---|---|-----------------|---|
| Location | Name of CRO | Location | Name of CRO |
| Mumbai | Raptim Research Limited, | Ahmedabad | Accutest Research Laboratories (I) Pvt. Ltd., |
| Mumbai | Accutest Research Laboratories (I) Pvt. Ltd., | Ahmedabad | Cliantha Research Limited., |
| Mumbai | Enem Nostrum Remedies Pvt. Ltd. | Ahmedabad | Cadila Pharmaceutical Ltd. |
| Mumbai | Glenmark Research Centre, | Ahmedabad | Lambda Therapeutic Research Ltd. |
| Mumbai | Lambda Therapeutic Research Ltd. | Ahmedabad | Synchron Research Services Pvt. |
| Mumbai | Sitec Labs Pvt. Ltd., | Ahmedabad | Veeda Clinical Research Pvt. Ltd |
| Mumbai | Lifesan Clinical Research Centre | Ahmedabad | CBCC Global Research LLP |
| Mumbai | Reliance Clinical Research Services | Hyderabad | GVK Bioscience Limited |
| Mumbai | Panexcell Clinical Lab Pvt. Ltd, | Hyderabad | Vimta Labs Limited. |
| Vadodara | Accutest Research Laboratories (I) Pvt. Ltd., | Hyderabad | Axis Clinicals Limited, |
| Vadodara | Alembic Research Centre | Hyderabad | AnaCipher Clinical Research |
| Vadodara | Cliantha Research Limited., | Hyderabad | Aizant Drug Research solution Pvt. Ltd. |
| Mangalore | Ecron Acunova Limited | Hyderabad | ClinSync Clinical Research Pvt. Ltd. |
| Delhi | Jubilant Generics Ltd. | Hyderabad | RA Chem Pharma Ltd., |
| Chennai | Micro Therapeutics Research Labs Limited, | Hyderabad | QPS Bioserve India Pvt Ltd. |
| Chennai | Quest Life Sciences Pvt. Ltd., | Pune | Bioradius Therapeutic Research Pvt. |
| Pune | Synapse Labs Pvt. Ltd., | Coimbtore | Spinof Life Science Pvt ltd, |

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Worked as Senior Manager-Clinical Research in Enalte Lab Pvt Limited , Ambernath facility (Oct 2017 to May 2020)

- Handled independently CR division of Enaltec
- Develop and implement study management strategies for successful project delivery to Organization.
- Act as a medical resource to the company as a whole and particularly to the clinical research department (protocol, CSR writing/ review, adverse events, discussions with investigators, internal meetings).
- Lead clinical research program consistent with applicable regulation, guidelines & policies.
- Ensure high performance and efficiency of the clinical team through the scheduling of co-monitoring/accompanied site/visits and ongoing mentoring of CRA team.
- Write clinical development plans, develop budgets, & provide drug development inputs
- Responsible for implementation of best practices within Global Clinical Operations.
- Establish ongoing liaison with key opinion leaders and to ensure that significant developments in the field are identified and monitored.
- Provide input for the development of proposals for new work and manage project budgets.
- Identify quality issues within the study to implement appropriate corrective action plans.
- Assist Business development activities for the USA market.
- Co-ordination with CROs & Vendors for successful study conduct.
- Co-ordination with ADL, FRD, Regulatory & Project management
- Participate in the on-boarding, mentoring and training of new staff

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Worked as **Assistant Manager-Clinical Research in Indoco Remedies Limited**, Navi Mumbai (**May 2010 to Oct 2017**)

- Plans & conducts clinical trial site & Clinical Research organization (CRO) audit as per GCP, GLP, Schedule Y, Applicable regulatory & 21 CFR parts 11.
- To co-ordinate with CRO's for quotation & then after finalization of center for Protocol & necessary documents evaluation.
- Monitoring of Clinical/Bioequivalence studies as per GCP, GLP & Schedule Y (Before, During & after closeout visit)
- Co-ordinates with R&D for samples to be sent for clinical trials & with the quality area for identification & selection of CRO's & to support any related audits.
- Identifying clinical trial sites (CRO) that will be audited. Plans & conducts GCP audits, as auditor. Audits include clinical sites, vendors, internal trial master files & audit processes.
- Identify the problems in site during the audit, set the criteria & communicate with department head & relevant CRO.
- To support regulatory activities like eCTD format report for USFDA-ANDA submission.
- Reviewing the draft & final version of Protocol, CRF, ICF & Study Report (Clinical, Bioanalytical & Statistical) of Clinical Studies (**Hard and Soft copies**)
- Maintaining ongoing communications with CRO to provide information, queries resolutions, & overall progress of clinical studies & adherence to established guidelines.
- Supportive role to Regulatory department & Formulation Department to preparation of Dossier, which is submitted to different regulatory bodies etc: EU, Brazil, MCC, Health Canada, TGA, DCGI & USFDA.
- Prepared PSUR report for various existing Product sold in different regulatory market.
- Ensure that BA/BE or Clinical studies are conducted in accordance with the Study Protocols, SOPs, GCP & applicable regulatory requirements.
- Resolved & Answered Regulatory Authorities (eg. DCGI, MCC, EU) Audit queries.

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- Preparation and submission of Module 2 and Module 5 (attached Reference research Article) for dossier submission to applicable regulatory submission.

Worked as **Drug Safety Specialist (Pharmacovigilance Division) in Tata Consultancy Services (TCS), Vikhroli Mumbai (Jan 2009 to May 2010)**

- Processing & reporting of **AE/SAEs reports**. (Clinical & Spontaneous cases)
- Gathering relevant information from source documents & entering in **safety database (Advent / Sapphire/ARISg)**.
- Analyzing & evaluating individual cases & collecting, collating & reporting adverse event data & **drafting narrative** for each case.
- Coding of Adverse Events, patient history, product indication, suspect & concomitant drugs using Medical dictionaries (**eg. MedDRA**).
- Conducting internal QC, maintaining various project trackers for entire team & reporting to Team Leader.
- Preparation of **Periodic Safety Update Report (PSUR)**, providing medical evaluation comments & submission to regulatory authorities as per timeline.

Worked as **Internal Quality Monitor** in Synapse Labs Pvt. Ltd. Pune (**Jan 2008 to Jan 2009**)

Worked as **Clinical Research Associate** in Raptim Research Ltd, Navi Mumbai (**Jul 2007 to Jan 2008**) -----Both Bioequivalence CRO experience:

- Preparing & Reviewing the Study Protocol, draft ICF (Both Marathi & English), CRF, Project specific raw data & final Study Report.
- Handling online Healthy volunteer screening & registration process (**Biometric Technique**).
- Handling **LIMS software** for BA/BE documentation process & Data archival system (Soft as well as Hard Copy)
- Inspecting & overseeing clinical study related activities to ensure compliance to Protocols, SOPs, GCP, GLP & applicable regulatory guidelines.
- Preparation of **eCTD document for various regulatory authorities (USFDA)**.

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- Coordinating with QA department for issue of documents like SOPs, Forms, Log Book, Protocols, CRF's & ICF's according to requirement & maintain the accountability records.
- Preparing Training Schedule, coordinating with the trainees & trainer, conduct the training, evaluating & maintaining the training records.

EDUCATIONAL QUALIFICATION:

- **M.Sc in CR (Clinical Research)** from Institute of Clinical Research, India, Cranfield University (UK) (61.00 %)—**Year 2007**
- **PG in Pharma Management** from Institute of Clinical Research, India (61.00 %)-**Year 2007**
- **B.Pharmacy** from R.C.Patel College of Pharmacy, Shirpur (NMU Jalgoan) (3rd & 4th Year) (59.28 %)- **Year 2005**
- **H.S.C** from Jaihind Junior College, Dhule (Nashik Board) (63.33 %)- **Year 2001**
- **S.S.C** from New English School, Jamner (Nashik Board) (73.06 %)- **Year 1999**

THESIS WORK

My project work as a part of curriculum (M.Sc in CR) on the topic “**Better Monitoring & Improvement of quality in BA/BE trial in CRO**” at ICRI, **Cranfield University (UK)**

My project work as a part of curriculum (PGDPM) on the topic “**Contract Research Organization as New Business Opportunity in India**” at ICRI

COMPUTER EXPERTISE

- Computer skills - Microsoft Office (Microsoft Word, Microsoft Excel, Power Point, Internet) & other basics of Computer.
- Handled **Biometrics & LIMS system software** to generate eCRF.

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PERSONAL PROFILE:

Name : LALIT NILKANTH GORE

Date of Birth : 08/03/1984

Gender : MALE

Marital status : Married

Language : ENGLISH, MARATHI, HINDI.

Passport No. : R0804718 (China Visit)

Notes: References will be provided upon request

DECLARATION:

The information furnished above is correct & true to the best of my knowledge.

Sincerely Yours

MR. LALIT N. GORE (WANI)