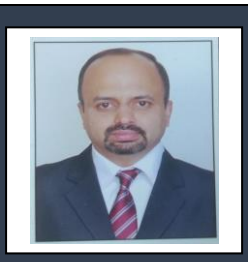

CORE COMPETENCIES

Clinical Research
Medical Writing
Medical Information & Data Analysis
Medical Monitoring
Safety Reporting
Medical Advisory Services
Publication / Scientific Writing
Team Management & Training

DR. NITIN SHANKAR JOSHI

Phone: +91-9820034002
Email: nibeeka2000@yahoo.co.in

A multi-faceted professional; targeting senior-level assignments in **Clinical Research, Medical Affairs and Drug Development** with an organisation of repute, preferably in **Pune / Delhi-NCR / Mumbai/Abroad**

PROFILE SUMMARY

- **An accomplished professional offering 12 years of experience** in **Clinical Research** and served for 15.5 years as Private Consultant Gynaecologist; skilled in Scientific Writing, Medical Affairs, Clinical Development, Medical Information & Communications, and Technical Communication
- The wealth of expertise entails Conceptualization of Study Designs, Medical Writing, Medical and Safety Monitoring, Medico-Regulatory Affairs and Clinical Trial Project Management
- Showcased expertise in key therapeutic areas like Biosimilars and Biologics, Vaccines, Metabolic Diseases, Dermatology, Ophthalmology, Endocrinology, Oncology, Neurology, Urology, Gynecology, Infertility, Contraception, Hepatology, GIT, Infections & Infestations, Andrology, Pediatrics, Allergy, Cosmetics, Devices, and Vaccines
- Skilled in directing clinical and administrative operations; steering the development and implementation of plans, operations, and programs within assigned service units

ORGANIZATIONAL EXPERIENCE

Since Feb'16 with DiagnoSearch Pvt. Ltd., Mumbai as Sr. Medical Advisor

Therapeutic Areas:

Vaccines and Oncology

Key Result Areas:
Medical Monitoring:

- Performing/Supervising:
  - Feasibility and eligibility assessment
  - Overall monitoring of trials from medical perspective
  - Medical monitoring of protocols in the TA of Vaccines, Biosimilars, Biologics, Oncology
  - Medical review of narratives, CSRs, and other documents
  - Training the site personnel and Investigators on study design & Protocol and safety data reporting
  - Conducting therapeutic area and protocol specific trainings to the Clinical Operations, Data Management, and Statistics Teams
- Addressing:
  - Protocol-related queries from Study Team
  - Medical and safety-related queries from site personnel (including protocol waivers and eligibility queries)
  - Queries from regulatory as DCGI
- Monitoring trial related activities on on-going basis
- Conducting medical monitoring visits at the sites during clinical trials

Safety Reporting:

- Proving guidance and training to CRAs and site personnel on safety data reporting
- Managing safety submissions to DCGI and other regulatory authorities (as applicable)
- Performing:
  - Review of safety data from clinical trial on an on-going basis
  - Medical review of SAE forms and safety information received from site.
  - Trend analysis of AEs/SAEs
  - Expectedness analysis for SAEs
- Interfacing with the Data Management team for safety data reconciliation

Medical Writing:

- Reviewing and providing inputs on statistical documents as SAP/SAR
- Reviewing and approval of:
  - Investigator's Brochures, Protocols, Case Report Forms and Informed Consent Forms
  - Mock TLGs, Sattistical Summary Reports
  - Clinical Study Reports, Safety Narratives for clinical studies
- Preparing templates for Protocol Development, Case Report Forms, Informed Consent Forms, Statistical Reports etc.
- Mentoring and training Medical Writers and Medical Coders
- Writing Clinical study report/ CRF/ICF/Package Insert (NCE for dyslipidemia and diabetes mellitus)
- Developing the summary of safety and efficacy for NDA
- Responding to the RFP in the TA of leukaemia, Oncology, Neurology
- Mentoring and guiding the junior associates
- Training the team on:
  - Medical Writing
  - Therapeutic area and protocol

Medical Consultancy:

- Concept Paper: background, various study designs including rationale, advantage & disadvantage, key study population etc.
- Study Feasibility (Feasibility Questionnaires and Feasibility Reports)

Representations to DSMB, SEC, SAC of BIRAC and DBT

- Safety data presentations to DSMB, PSRT
- Presentations to SEC and DCGI
- Presentations to SAC of BIRAC, DBT and ICMR

Currently working as Global Medical Monitor for a vaccine study conducted in AU.

Feb'13 to Sep'15 with Biogenomics Ltd., Mumbai as Medical Director (Clinical Research)

Key Result Areas:

- Acted as Functional Head of the department of Clinical Research:
- Spearheaded the entire gamut of operations in management of clinical trial projects of new products, strategy development, from inception to completion
- Directed & implemented clinical development strategies for Biosimilar products
- Provided:
  - Inputs on regulatory guidelines for interferons, filgrastim and insulin analogues
  - Clinical inputs for study designs and implementation
- Conceptualized study designs for Biosimilar products like:
  - Insulin analogues (Phase-I and Phase-III)
  - Interferons (Phase-I and Phase-III)
  - Filgrastim (Phase-I and Phase-III)
- Developed pre-study documents as investigator's brochure, protocol, ICD and CRF for:
  - Insulin analogues Phase-I study
  - Filgrastim Phase-III study
  - Interferon Phase-I and Phase-III study
- Performed:
  - Identification of CROs for implementation of clinical projects in Biologics and Biosimilars
  - Due diligence visits to CROs and SMOs
- Managed CRO activities and ensured overall timelines for clinical projects are met through:
  - Site feasibility reports
  - Site qualification reports
  - Monitoring reports
- Presented protocol to the Gastroenterology NDAC which resulted in approval of the study
- Covered therapeutic areas which involved Oncology, Diabetology, and Hepatology

PREVIOUS EXPERIENCE

Dec'11 to Dec'12 with Karmiclifesciences Pvt. Ltd., Mumbai as Associate Director (Medical Affairs & Safety)

Jul'11 to Dec'11 with Zydus Cadilla Ltd., Mumbai as Senior Scientist

Highlights:

- Performed conceptualization of study design for development of Clinical Study Protocol
- Developed Protocol Synopsis, Clinical Study Protocol, Summary of safety and Efficacy for NDA of NCE
- Wrote Clinical Study Report / CRF/ ICF / Package Insert (NCE for dyslipidemia and diabetes mellitus)

Jul'08 to Jul'11 with Siroclinpharm Pvt. Ltd., Location as Assistant Manager and Lead CSR Writing/ Senior Medical Writer

Highlights:

- Completed:
  - 20 full Clinical Study Reports (Phase-1) in therapeutic area of Pain and 5 full Clinical Study Report in the area of Metabolic Diseases
  - 3 reports (Phase-3); 1 each in therapeutic area of Pain and Infections and 1 in the therapeutic area of Metabolic Disease (NCE)
  - 3 Phase IIb CSRs and 2 PMS reports
- Wrote about 500 safety narratives in therapeutic areas of Pain, Metabolic diseases, CVS and Psychiatry
- Developed protocol and ICF for Phase-IIb study in TA of metabolic disease
- Worked effectively with functional groups and teams to write and manage the production of accurate and complete clinical study reports based on ICH E3 guidelines and guidance material
- Implemented policies that promoted & protected health, safety, security, and the quality of work life
  Imparted continuous on job training to the workforce to enhance the productivity and operational efficiencies through knowledge enhancement and skill building

ENTERPRENEURSHIP

Jan'93 to Jun'08 as Private Consultant (Consultant Gynaecologist)

Highlights:

- Identified and treated problems of the female reproductive system such as infertility
- Advised on high risk problem in antenatal & gynaec patients and women healthcare
- Involved in ovarian pathology; checked and treated ovarian cysts and cancer of the female reproductive tract
- Resolved various cases pertaining to high risk pregnancy & delivery, operative obstetrics, infertility, gynaec malignancy and gynaec endocrinology

TRAININGS ATTENDED

- ICH-GCP
- Statistical principles for Medical Writing
- Focused Clinical Study Report and Narrative Writing by trainers from US
- Lean Six Sigma
- Advanced training on Data Interpretation in CSR writing by trainers from US
- Basic and Advanced Training in Pharmacovigilance
- USFDA and EU Essentials of Drug Safety and Pharmacovigilance by Steve Jolley
- Clinical Quality Assurance
- Audits and Inspection
- Corporate Grooming and Etiquettes
- Team Building Workshop
- Line Management
- Assertiveness and conflict management

ACADEMIC QUALIFICATION

2008	**PGDCR** from PEXA, Mumbai, CAHS
1991	**M.D.** from LTM Medical College, Sion, Mumbai University
1990	**D.G.O.** from College of Physicians & Surgeons, CPS, Mumbai
1987	**MBBS** from LTM Medical College Sion, Mumbai University

ACADEMIC ACHIEVEMENTS

- Secured **1st place** in:
  - Dr. B. M. Bhargava Memorial Examination in Anatomy, 1983
  - First M.B.B.S Examination, 1983
  - Biochemistry in 1st M.B.B.S. Examination, 1983
  - Microbiology in 2nd M.B.B.S. Examination, 1985
- Achieved **2nd place** in:
  - Pharmacology Competitive Examination, 1985
  - 2nd M.B.B.S. Examination, 1985
  - 3rd M.B.B.S. Examination, 1986

PUBLICATION

- First author of paper entitled, A study of Preeclamptic Toxaemia in Pregnancy published in August 1990 issue of the Journal of Obstetrics & Gynaecology of India

PERSONAL DETAILS

Date of Birth:	29th September 1965
Languages Known:	English, Marathi, Hindi, Kannnada and Tamil

Address:	301, Ambience Building, Prestige Garden, Nitin Casting Compound, Almeida Road, Panchpakhadi, Thane (W)- 400601, Maharashtra