



MEDICAL WRITING

TRAINING

HEALTHCARE CONSULTING

Office Address:

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Hetal Shah, Ph.D.



**M.Pharm.(Gold Medalist);  
Ph.D.(Pharmacology)**

<https://mewrit.com/pdf/cv.pdf>

## Founder & Principal Consultant



- **Subject Matter Expert – Medical Writing**
- Over 20 years of first-hand experience in medical writing & clinical research, since 2003.

### WORK PORTFOLIO:

- Regulatory Writing
- Scientific Publications
- Trainings & Workshops
- Pharma & Medical Communications
- Qualified Pharmacologist / Clinical Expert for Regulatory & Strategic Inputs



**PhD Pharmacologist and Subject Matter Expert (SME) – Medical Writing** with almost 2 decades of first-hand experience in the field of clinical research and medical writing.

- CBCC Global (erstwhile VIBGYOR), IQVIA (erstwhile Quintiles), Trilogy Writing (Germany), Arkus Research (for PharmaLex, Germany), Clinipace (UK) and independent affiliations
- Versatile roles: Clinical Site Coordinator, Site Manager, Project Manager, Medical Writing Lead and Expert Medical Writer

**Founder of MeWriT® Healthcare Consulting, - Independent Medical Writing & Training Provider based in Ahmedabad, India.**

- **As a medical writing SME:** full accountability for first-hand writing, editing and finalizing of submission-ready documents for various therapeutic areas. Writing sphere currently ranges from preparation of clinical trial documents to clinical study reports; compilation of drug authorization dossiers to scientific publications for journals, and related scientific communications.
- **A GCP-trained professional,** with a rare combination of hands-on experience in handling global clinical studies, both, at investigative sites as well as CROs.
- Serve as a **Pharmacologist and Clinical Expert** for various areas of clinical study design and protocol development, study reporting and regulatory responses.

**Gold medalist** for manifold academic achievements; an **experienced Author with > 70 scientific publication credentials** including book chapters, journal articles, and presentations at national and international forums.

Part of the landmark COVAXIN Trial Team in India during the COVID-19 pandemic.

Recipient of '**Woman Entrepreneur in Pharma & Healthcare**' Award by AIC – LMCP Foundation (supported by Atal Innovation Mission, Government of India) in January 2019 for her entrepreneurial venture

Recipient of the "**Hall-of-Fame**" Award, **thrice in a row, in 2021, 2022 and 2023** by the Indian Society for Clinical Research (ISCR).

An adept and experienced **Medical Writing Trainer & Faculty** with a practical approach to coaching; a frequent speaker at scientific events.

- **Trained > 2000 participants** including medical and pharma students and clinical research professionals since 2008!

**Active Member** of ISCR – medical writing Council, DIA medical writing India group, and the Medical Writers group of India.

- *On a personal front, a trained Bharatanatyam dancer performing multiple Indian dance forms; a yoga fanatic, a travelholic, and a culinary enthusiast !.*



## The 'merit' in Medical Writing & Training

### **Medical Writing, Scientific Communications and Healthcare Consulting**

Pharmaceuticals, Device and Biotech  
companies, CROs, HealthCare Set-ups and  
Healthcare Professionals

*Delivering excellence through technically sound, tailor-made,  
adaptive and innovative solutions, with unwavering focus on  
quality, ethics and data integrity.*



## REGULATORY DOCUMENTATION

- ❑ Study Protocols
  - ❑ Consent Documents
  - ❑ Investigator's Brochure
  - ❑ Clinical Study Reports
  - ❑ CIPs and CERs
  - ❑ CTDs, MAA dossiers
  - ❑ Patient Narratives
- and more...*

## SCIENTIFIC PUBLICATIONS

- ❑ Original Research Manuscripts
- ❑ Literature Reviews
- ❑ Case Reports
- ❑ Medical Data analysis
- ❑ Abstracts
- ❑ Posters
- ❑ Congress Presentations

## MEDICAL COMMUNICATIONS

- ❑ Scientific/ Medical Content
- ❑ Brochures
- ❑ Catalogues
- ❑ Educational materials
- ❑ Press releases
- ❑ Newsletters
- ❑ Visual aids
- ❑ Infographics
- ❑ Writing Support to Healthcare Practitioners and for Healthcare Set-ups (Hospitals/ Clinic)

## TRAININGS

- **BASIC**
  - **ADVANCED**
- Tailor-made modules with unique hands-on experience related to Medical Writing, Healthcare Communications & Clinical Research

## RESEARCH SUPPORT

- ❑ Qualified Clinical Pharmacologist
- ❑ Eligible EC/IRB member
- ❑ Clinical trial expert for healthcare and hospital set-ups
- ❑ Liaison for EC/IRB, BIOS, DM, Medical Experts & SMEs

# REGULATORY Documentation & PUBLICATIONS

- **> 100 High quality essential CT documents** for all types of clinical studies including BA – BE, phase I to IV, post marketing surveillance studies and registries, IITs.
  - Clinical study protocols, investigators' brochures, informed consent documents, patient cards, paper case report forms.
- **Special expertise in developing clinical study reports (CSRs)** compliant to the ICH-E3 guidance
  - > 50 CSRs for various drug classes, vaccines for Indian & global submissions including NDA/IND/BLA and EMA
- **CTD modules** – over 50 clinical and non-clinical overviews and summaries, for various categories of drugs/products and marketing authorizations
  - NDA, ANDA for the FDA; generics, bibliographic, hybrid and related for the EMA region compliant to the EU directives and NTA 2B guidelines, as well as for the Asian and emerging markets as per the ASEAN CTD guidelines.
- **50 odd Publications (as Author/Co-author) and 20 odd Professional Acknowledgements** for Publications supported by MeWriT

# TRAININGS

**> 15 years**

as an adept workshop leader and trainer for various medical writing and clinical research topics

**Trained > 3000 participants**

including medical practitioners, PG residents, medical and pharma students and clinical research professionals

## ACADEMIA

- Nepal Cancer Hospital, Kathmandu
- National Forensic Sciences University, Gandhinagar
- Delhi Pharmaceutical Sciences and Research University (DPSRU), Delhi
- Institute of Pharmacy, Nirma University, Ahmedabad
- L. M. College of Pharmacy, Ahmedabad
- Chitkara University, Punjab
- Indira IVF Centre, Udaipur, Rajasthan
- Sri Jayadeva Institute of Cardiovascular Sciences, Bengaluru
- Tata Memorial Hospital, Mumbai
- SRM Medical College, Chennai
- Lovely Professional University (LPU), Jalandhar, Punjab

## INDUSTRY [Pharma/CRO]

- TatvaCare at Zydus Wellness, Ahmedabad
- Alceon Medtech Consulting, Vadodara
- Cliantha Research, Ahmedabad
- Veeda CR, Ahmedabad
- Syngene, Bengaluru
- Serdia Pharma, Mumbai
- Meril Life Sciences, Vapi, Gujarat
- Docplexus, Pune
- IQVIA, ILS, India
- Lupin Pharma (with ISCR for Post-Graduate Respiratory Medicine professionals)

## OTHER

- Indian Society for Clinical Research (ISCR) workshops
- DIA Medical Writing Group
- Open Workshop with CT Quest, Delhi (at Pune)
- Open Workshop with Arkus Research & ISPE, Mumbai

FORMAL  
TRAININGS





# **CREDENTIALS FOR DOWNLOAD:**

## **MeWriT – Company BROCHURE:**

<https://www.mewrit.com/pdf/brochure.pdf>

## **MeWriT's PUBLICATION Credentials:**

<https://www.mewrit.com/publications.html>

## **FOUNDER's CV [Dr. Hetal Shah]:**

<https://www.mewrit.com/pdf/cv.pdf>

# DR. HETAL AMIT SHAH

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*For more details, visit: [www.mewrit.com](http://www.mewrit.com)*

