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Hetal Shah, Ph.D.



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.

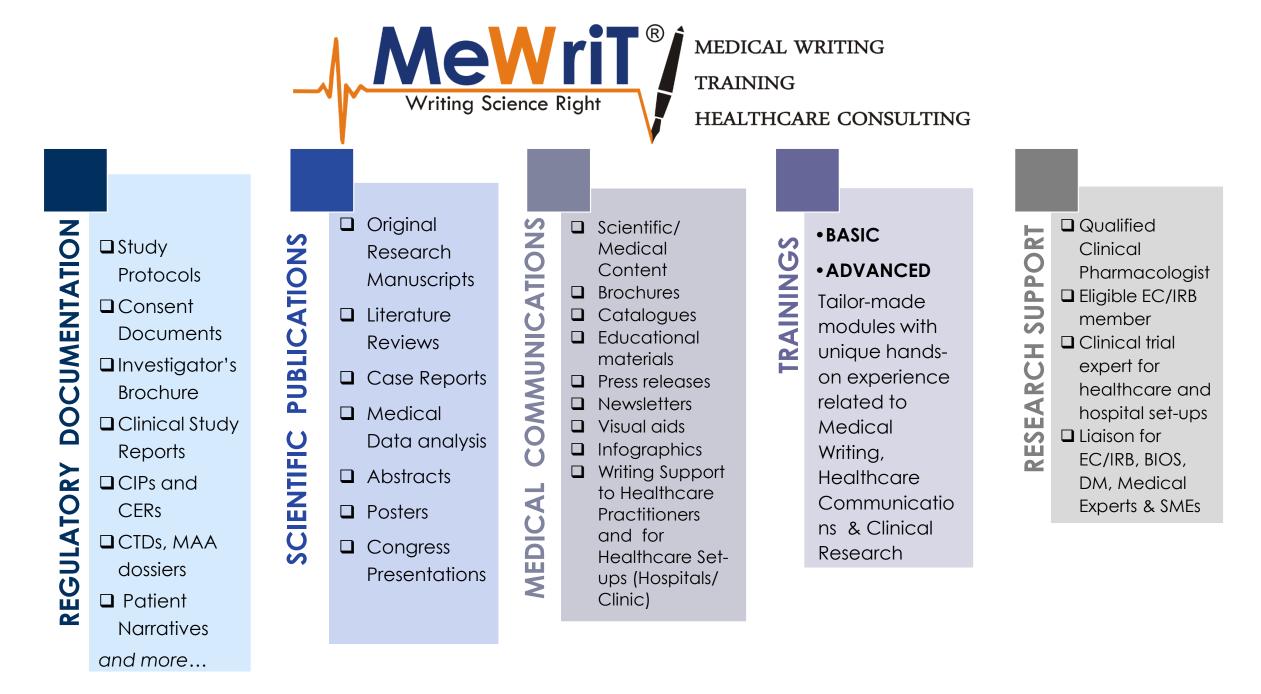




DR. HETAL SHAH M.Pharm.(Gold Medalist) Ph.D.(Pharmacology)

[Founder – Director]

- Independent Medical Writing Consultant & Trainer, based at Ahmedabad, since 2003.
- Over 17 years of first-hand experience in developing submissionready regulatory documentation and scientific publications for multinational Pharma & CROs.
- Over 60 scientific publications, presentations and professional acknowledgements at national and international forums to her credit.
- An adept and experienced Medical Writing trainer & faculty for medical writing workshops and events.
- Recipient of 'Woman Entrepreneur in Pharma & Healthcare' Award by AIC – LMCP Foundation (supported by Atal Innovation Mission, Government of India) in January 2019.
- Active Member of ISMPP, ISCR, executive committee member for the Society of Medical Writers of India (under formalization)



PROFESSIONAL EXPERTISE

WORK PORTFOLIO:

Regulatory Writing | Scientific Publications | Trainings & Workshops | Pharma & Medical Communications

- First-hand drafting, reviewing and finalizing research documents across three major portfolios: regulatory, publication and educational.
- **Therapeutic area** experience including, but not limited to: oncology, cardiology and cardiovascular, respiratory disorders (including COVID-19), autoimmune diseases, gastroenterology, metabolic disorders, diabetic, infectious diseases, orthopaedics, gynaecology, vaccines, paediatrics, ophthalmology, medical devices and nutraceuticals.
- Experienced primary writers/authors for various clinical trial documents protocols, IBs, CRFs, ICFs, other patient/study materials; CTD/drug submission dossiers; clinical study reports (ICH E3 compliant); event narratives; medical publications including original research manuscripts, literature reviews, clinical case reports, scientific abstracts, posters and presentations; scientific review and editing of documents; developing SOPs, and related.; and medical communications including web content, medical and healthcare content writing, infographics and posters, slide decks, promotional content, medical congress contents and alike.

• Workshop Leadership/Trainers for various medical writing and clinical research topics

- **Basics** of medical writing including literature search, writing basics, ethics, biostatistics, reviewing
- Advanced training in publication writing, original and review articles, case reports, event narratives, CTD modules, clinical study designs, clinical study reports, and related.

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