Dr Hetal Shah, *PhD*

Subject Matter Expert – Medical Writing

FOUNDER - DIRECTOR

MeWriT® Writing Science Right
MEDICAL WRITING
TRAINING
HEALTHCARE CONSULTING

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Dr Hetal Shah is a **PhD Pharmacologist** and **Subject Matter Expert – Medical Writing** with over **2 decades of first-hand experience** in the field of **clinical research and medical writing**. She is the **Founder of MeWriT® Healthcare Consulting** – an independent medical writing and training consultancy service based at Ahmedabad, India.

Gold medalist for her manifold academic achievements, **Dr Shah also has > 70 publications to her credit including book chapters, research papers, review articles and presentations at national as well as international forums**. As an SME with high standards for quality and work ethics, Dr Shah is extensively in developing integral regulatory documentation & publications for pharmaceuticals & research organizations.

A **trained clinical research professional**, she is well-versed with various national and international regulations governing clinical trials and good clinical practice. Dr Shah has a rare combination of first-hand experience in handling varied clinical studies, both, at investigative sites as well as CROs. She has in-depth knowledge of GCP and its implementation, clinical trial operations, trial monitoring as well as overall clinical project management. She serves as a **Pharmacologist and Clinical Expert** for various areas of clinical study design and protocol development, study reporting and regulatory responses.

As an **independent medical writing expert**, she takes full accountability for first-hand writing, editing and finalizing of submission-ready documents for various therapeutic areas. Her writing sphere currently ranges from preparation of **clinical trial documents to clinical study reports**; compilation of drug authorization dossiers to **scientific publications for journals**. Dr Shah is also an **experienced trainer** with practical approach to coaching, and independently conducts medical writing & Clinical Research workshops and trainings customized for various topics and audiences' needs. She is a member of the **International Society of Medical Publication Professionals (ISMPP), Indian Society of Clinical Research (ISCR),** executive committee of All India Medical Writers Association (AIMWA) and an ex-member of the DIA Medical Writing group of India.

An accomplished professional herself, she effectively collaborates with therapeutic area experts, bio-statisticians, auditors, QA personnel, as well as in-house and allied clinical research teams to ensure a complete, accurate, cost-effective, and timely solution for your clinical projects or writing needs, with the best of quality and ethics.

On a personal front, Dr Shah is highly passionate about dance and fitness. She is a trained Bharatanatyam performer, has honed various Indian folk-dance forms and is currently pursuing her training in Kathak. She is yoga enthusiast with her eternal love for suryanamaskaras.

Dr. Shah has been felicitated as 'Woman Entrepreneur in Pharma & Healthcare' by the AIC-LMCP foundation (supported by Atal Innovation Mission, Government of India) at Ahmedabad, on 12 January 2019.

Dr. Shah has received the 'Hall of Fame' Awards, thrice in a row, from the Indian Society of Clinical Research (ISCR) in 2021, 2022, and 2023 for her contributions to the Medical Writing Council activities.

A brief account of Dr Shah's Profile is mentioned below for a quick reference. Full detailed CV is also included further here.

***Expert support for Scientific & Regulatory Documentation**: including clinical trial protocols and study designs, informed consent forms & other trial related documents, clinical study reports (ICH-E3 compliant), CTD modules, drug application dossiers, event narratives, ICMJE compliant scientific publications including original articles, scientific reviews, short communications, conference & educational materials, SOPs, and much more…*

***Pharmacologist and Clinical Expert** support for study design aspects, reporting issues, independent expert reviewer for drug/device dossiers, regulatory responses and resolutions.*

***Workshop Leader & Trainer** for various medical writing & clinical research needs.*

***Clinical Research Support** for clinical study management and related activities.*

Dr Hetal Shah, *PhD*
Subject Matter Expert – Medical Writing

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BRIEF Curriculum Vitae

Name:	Dr Hetal Amit Shah
DOB:	29 Feb 1980
Age:	43 years
Gender:	Female

Academics:

Academic Qualifications: PhD (Pharmacology); M. Pharm (Gold Medalist)

Language Proficiencies:

- English (IELTS: 7.5/9 bands; Writing – 8/9, Speaking-7.5/9)
- Gujarati, Hindi (Fluent)
- French (Introductory)

Publication Credentials: **50 odd** scientific presentations and publications

- 4 book chapters
- 5 original research articles
- 8 literature reviews
- 30 original research presentations at international/national scientific meetings

Professional Acknowledgments: Acknowledged for professional medical writing support in **20 odd scientific publications and presentations** in national and international journals and congresses.

Professional Experience:

Over 20 years of consolidated professional experience in the field of Clinical Research & Medical Writing

- **Clinical Research Project Management** – 9 years
  - Clinical site study manager – Investigative Site (via SMO): 2 years
  - Clinical research manager – SMO: 3 years
  - Regional team leader– CRO project management: 3 years
- Line Management – CRO: 5 years
- **Medical Writing** – 15 years
- **Independent Pharmacologist & Clinical Expert** – 15 years

Experience in Medical Writing

- First-hand experience in 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, autoimmune diseases, gastroenterology, metabolic disorders, diabetic, infectious diseases including COVID-17, orthopaedics, gynaecology, vaccines including COVID vaccines, medical devices and nutraceuticals.***
- Experienced primary writer/author 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.

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- **Workshop Leader/Trainer** for various medical writing and clinical research topics including, but not limited to: clinical trials basics, good clinical practice, Ethics committee aspects, 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. Workshops are customised and conducted based on the audience's need and interest.

Experience in Clinical Trial/Project Management (Clinical Operations)

Clinical Site Study Manager

- End-to-end clinical study management at investigative site including site coordination, clinical study and patient management, CRF completions, overall trial conduct as site personnel; overlooking clinical site coordinators and collaboration with CROs and sponsors.

Clinical Research Manager

- Overall responsibility of clinical study planning, protocol discussions, regulatory and project management planning, drafting monitoring plan, coordination with sponsors, managing CRA teams and day-to-day activity, oversight for on-site as well as in-house monitoring, matrix-driven performance management, training of CRAs, ongoing support and SPOC for sponsors.

Regional Team Leader

- Regional team leader overlooking start-up of large phase III trials in India and Asia pacific regions. Primarily involved with leading study start-up phase, collaboration with sponsors managers, participation in overall project management planning and discussions, primary approver for IP packet release and site hand-overs.

Experience in Clinical Pharmacologist / Expert

Clinical Study Design inputs

- Study Design Discussion and Development with Clinical Team for all phases of clinical trials; finalization of study outlines/synopsis for medical writers.

Independent Review of Clinical Study Reports

- Review and Expert inputs for clinical study reports – all phases. Collaboration with medical writing team for revisions and finalization for CSR submissions.

Responses to Regulatory Queries

- Thorough & Independent Reviewer for Clinical regulatory queries. First-hand drafting and finalization of responses to Regulators in line of study results and available supporting documentations; with a strong and assertive presentation of responses.

Pharmacologist

- Serve as pharmacological experts for aspects of drug/device trial designs and reporting, and confirmation of compliance to regulatory requirements.

Experience in People Management

Line Management Experience

- Handling direct line and in-direct functional reports, overlooking day-to-day activities, project planning, time management, team leadership and overall team building. Ensuring CRA trainings and ongoing support, overseeing KPIs, and matrix-driven performance appraisals.
- Managing extended teams of expert consultants – medical writers; therapeutic area experts, biostatisticians as part of team MeWriT.

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Current Professional Portfolio:

Independent Consultant – Pharmaceutical organizations & CROs

- Clinical Writing Expert
- Pharmacologist
- Clinical Research Expert

Founder & Director – MeWriT Healthcare Consulting
Providing professional support across three major segments:

- **Medical Writing** for pharma regulatory documentation, scientific publications, drug dossiers, educational and related.
- **Workshops & Training** for various medical writing & clinical research aspects – customized to audience's interest.
- **Clinical research support** for clinical trials/project planning and management, sponsor collaboration and representation, team meetings and training, people management and related consultations.

Dr. Hetal Shah has been felicitated as 'Woman Entrepreneur in Pharma & Healthcare' by the AIC-LMCP foundation (supported by Atal Innovation Mission, Government of India) at Ahmedabad, on 12 January 2019.

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FULL Curriculum Vitae

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1. PERSONAL

Name**:** Dr Hetal Amit Shah
DOB: 29 Feb 1980
Age: 43 years
Gender: Female

2. ACADEMICS

PhD (Pharmacology) **:** L M College of Pharmacy, Ahmedabad, India. April 2008
Thesis Title: Evaluation of Drugs and Devices in patients with Acute Myocardial Infarction, Chronic Refractory Angina and Heart Failure

M Pharm. (Pharmacology) **:** L M College of Pharmacy, Ahmedabad, India. Sept 2003
[Gold Medalist]

B Pharm. **:** L M College of Pharmacy, Ahmedabad, India. May 2001

3. ACADEMIC CREDITS

Two Gold Medals awarded at the Gujarat University, Ahmedabad for securing first position at M. Pharm level. Scored 75% at Gujarat University Examination of M Pharm-I in May 2002 and 73% in M Pharm-II and thus standing First in Gujarat University in M. Pharm Final semester (with specialization in Pharmacology).

Dissertation work submitted for the degree of M. Pharm at the Gujarat University consisted of the following subject: "Effect of combination of atorvastatin and fenofibrate in patients who have undergone Percutaneous Transluminal Coronary Angioplasty."

Awarded the **Jindal Prize (Gold Medal & Certificate)** at the Indian Pharmacological society (IPS) - Gujarat Chapter meet on 1st Feb, 2004 for standing first in M. Pharm (Pharmacology) at Gujarat University by the IPS Ahmedabad Brach.

Obtained **First Position & Gold Medal** in "Advance Diploma in Community Pharmacy Management (ADCPM)" Program at Institute of Pharmaceutical Education and Research (IPER), Pune in August 2004.

Oral Presentation at the O. D. Gulati Prize session at the Annual conference of Indian Pharmacological Society, December 2003, New Delhi.

Presented Poster entitled "Pharmacoepidemiology and risk factors of Hypertension in Western Gujarat" in the Poster Session of Annual Conference of Indian Pharmacological Society, November 2002, Gwalior.

Nominated as **Young Investigator's Awards Finalist** at the American College of Cardiology Conference ACC 2006 to be held in March 2006 at Atlanta, Georgia, US.

Participated in the annual conferences of Indian Pharmacological Society, Dec 2003, Nov 2002 and Jan 2002.

Participated in the annual meeting of the International Society of Heart Research (ISHR)-India section held at Chandigarh in Feb 2003.

Participated in the Joint International Conference of "International Society of Heart Research (ISHR)" and "International Academy of Cardiovascular Sciences (IACS)" Jan 2005 at Gandhinagar, Gujarat, India.

Participated in the European Society of Cardiology (ESC) Congress, 2005 held on 3 Sept – 7 Sept, 2005 at Stockholm, Sweden.

Participated in the 56th Annual Conference of the Cardiological Society of India on Dec 7-10, 2006 at Delhi, India.

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4. SKILLS & TRAININGS

"**ICH-GCP training**" by Aventis pharmaceuticals Ltd in November 2003.

Certificate course on "**Overview of Clinical Research & Foundations in GCP**" by Academy of Clinical Excellence, Bombay college of Pharmacy in April 2006.

"Emerging Trends in Clinical Trials and Clinical Research: **Role of Clinicians and Pharmacologists**" conducted by L M College of Pharmacy, Ahmedabad and National Institute of Medical Sciences (India) in October 2007.

Certificate in "**General Course on Intellectual Property**" from WIPO Worldwide academy, June 2007.

'Workshop on Scientific Paper Writing'- by Indian Pharmacological society Ahmedabad Branch in January 2007.

'Medical Writing Workshop'- conducted by Dr Barry Drees (Ex-Director, EMWA), held by Prescription Pharma Support, Mumbai in March 2007.

"**ICH-GCP training**" by Quintiles Research Pvt Ltd, India. June 2008.

Online Training on "**Human Participants Protection Education for Research Teams**" – By National Institute of Health (NIH), USA.

Soft Skills trainings – Line Management related trainings at Quintiles 2008-2010.

Train-the-Trainer: Quintiles 2009.

Adept user of MS office applications, SPSS Statistical Software, Corel Draw, Adobe Photoshop and related.

Sound insights of medical/therapeutic areas, drug and research processes and related subject matters, both, by qualification as well as experience.

Comprehensive understanding of all applicable regulatory guidelines including ICH, FDA, EMA, CDSCO-DCGI, and excellent grasp over interpreting them effortlessly for ensuring her documents are up-to-date with the regulatory requirements. She goes an extra mile to keep herself in pace with any new or revised guidance.

A unique capability of liaising with all relevant stake holders including therapeutic experts, biostatisticians, data managers, project members, administrators and supporting team to ensure an accurate and complete deliverable on time!

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5. LICENSURE & MEMBERSHIPS

Life Member of Indian Society for Clinical Research

Medical Writing – Council Member

Western Chapter – Governance Member

Life Member of Indian Pharmacological Society

Pharmacy Council of India: G-18516

Founder & Executive Committee member *of The All India Medical Writers Association (Under Registration)*

Ex-ember of International Society of Medical Publication Professional (ISMPP)

Ex-member of Drug Information Association (DIA) & DIA MW India Group

6. PROFESSIONAL STATISTICS

Over 20 years of consolidated experience as a Medical Writing and Clinical Research Professional.

- **Medical Writing**: Over 15 years of experience in Clinical and Regulatory writing.
- **Independent Pharmacologist & Clinical Expert** – 15 years
- **Clinical Research Project Management**: Over 9 years of experience on-site and in-house, SMO and CRO.
- Line Management: Over 5 years of experience in people management and team leadership.

Positions previously held:

- Sep 2003 to May 2008: VIBGYOR Scientific Research Pvt Ltd [now called CBCC Global] Ahmedabad, India.
  Last position held: Manager –Clinical Research & Medical Writing.
  Roles: Investigative site coordinator, site manager, study manager, clinical research manager, manager-medical writing, Expert Pharmacologist
- Jun 2008 to Jan 2012: Quintiles Research (India) Pvt Ltd. [now called IQVIA], Ahmedabad, India.
  Last position held: Manager – Site Startup.
  Roles: study team leader – India and Asia pacific, Team manager - India
- Part-time freelance medical writer – 2005 to 2012.
- Full-time Independent Consultant (Clinical Research & Medical Writing) since February 2012.
- Founded MeWriT in 2017.

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7. CURRENT PROFILE

Subject Matter Expert – Medical Writing

- Independent (Consultant) & Trainer – International & National Pharmaceutical Companies, Device Companies & CROs

  Involved in various roles, as:

  - Medical Writing Expert
  - Clinical Pharmacologist

Founder Director – MeWriT Consultancy, Ahmedabad, India.
MeWriT provides professional support across three major segments:

- **Medical Writing** for pharma regulatory documentation, scientific publications, drug dossiers, educational and related.
- **Workshops & Training** for various medical writing & clinical research aspects – customized to audience's interest.
- **Clinical Research Support** for clinical trials/project planning and management, sponsor collaboration and representation, team meetings and training, people management and related consultations.

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Dr. Shah has been received the 'Hall of Fame' Award from the Indian Society of Clinical Research (ISCR), thrice in a row, in 2021, 2022, and 2023 for her contributions to the Medical Writing Council activities.

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8. PROFESSIONAL EXPERIENCE

8.1 Principal Medical Writer & Clinical Pharmacologist

Over 20 years of neat first-hand experience as expert pharmacologist and clinical writing expert in compiling, organizing, writing, editing and preparing a wide range of submission-ready regulatory and research documentation; details as below:

- Medical writing experience aligned to a broad range of therapeutic areas and therapies, including but not limited to: oncology, hematology, cardiovascular diseases, respiratory disease, endocrinology including diabetes, autoimmune diseases, nephrology and urology, infectious diseases, dermatology, gastroenterology, orthopaedics, women's health, neurosciences, biological therapies, anti-viral, antibiotics, herbals and nutraceuticals, homeopathic therapy, disinfectants and sterilizers, medical devices – diagnostic and therapeutic, immunology and vaccines.
- Drafted > **70 high-quality peer reviewed publications** across multiple therapeutic areas, eventually published in national and international journals, including research manuscripts, reviews, case reports, abstracts and posters for global congresses. *See 'Publications' above for more details.*
- Compiled close to **100 high quality essential documents** for all types of clinical studies including BA – BE, phase I to IV, post marketing surveillance studies and registries. These include investigators' brochures, protocols, consent documents, patient cards, paper case report forms.
- Special expertise in developing clinical study reports (CSRs) compliant to the ICH-E3 guidance, derived from experience with more than **50 CSRs** for various drug classes, vacccines, study phases and regulators.
    - *Principal Medical Writer for the landmark COVAXIN (Covid-19 vaccine) Trial in India.*
- Compilation of event narratives, experience of more than **5000 narratives**– specifically for serious/significant events and deaths compiled for CSRs and other regulatory purposes.
- Select experience compiling CTD modules – **over 50 clinical and non-clinical overviews and summaries**, for various categories of drugs/products and marketing authorizations viz. 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.
- Understanding of pharmacovigilance related writing including the risk management plans (RMPs), development safety update reports (DSURs), periodic safety update reports (PSURs/PBRERs) and annual safety reports (ASRs).
- **Expert Support [as Pharmacologist and/or Clinical Reviewer]** in interpreting, drafting, revising and finalizing strong and assertive responses to regulatory queries (including FDA/EMA/MHRA/TGA, and alikes) in a systematic response format.
- **Expert Reviewer** for all medical writing deliverables across multiple clinical studies. A sharp eye-for-detail and performed high-end scientific reviews and editing/proof reading for various scientific and regulatory documents for in-house junior writers or extended sponsor teams.
- Educational communications including preparations of educational materials, slide kits, short communications, standard operating procedures, research grant writings, blog content, content for HCPs, and more.

Credit of 50 odd Publications (as Author/Co-author) and 20 odd Professional Acknowledgements for Publications supported by MeWriT *[for details see 'Publications'].*

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8.2 Trainer & Speaker for Medical Writing

Over 15 years as an adept workshop leader and trainer for various medical writing and clinical research topics of interest to the pharmaceutical and medical device corporates, clinical research organizations, students and academic institutes.

- ***Speaker** at the Medical Writing Track for the **ISCR Annual Conference held on 01-03 Feb 2024 at Hyderabad*** for the session on "Collaboration between CDM, Bios, and Medical Writing' at the pre-conference workshop, and presentation on 'Continued Professional Development for Medical Writers: One size doesnot fit all' in the main conference.
- ***Speaker** at the Scientific Writing Workshop* organized by the Institute of Pharmacy, ***Nirma University on 06 Jan 2024, Ahmedabad,*** on the topic of 'Essentials of Biomedical Publications'.
- ***Emcee for the Clinical Research Conclave 2023*** organized by the ***Indian Society for Clinical Research (ISCR), on 07 Oct 2023 at Ahmedabad. Panelist*** for the discussion on 'Changing Landscape of career prospects in clinical research with digitization and AI/ML - Skills for today v/s future Scenario'.
- ***Workshop Leader*** for 'Original Research Publication Writing' – a 1-day program for Novobliss Research, at Ahmedabad on 25 Aug 2023, conducted by MeWriT.
- ***Workshop Leader*** for 'Scientific Writing Style'– a 2-day program for Alceon MedTech Consulting, at Vadodara on 28 – 29 June 2023, conducted by MeWriT.
- ***Workshop Leader*** for 'Essentials of Scientific Writing' – a 1-day program for Cliantha Research, at Ahmedabad on 31 May 2023, conducted by MeWriT.
- ***Workshop Leader*** for 'Clinical Study Reports' – a 2-day program for Veeda Clinical Research, at Ahmedabad on 03-04 Apr 2023, conducted by MeWriT.
- ***Faculty** at the Medical Writing Track for the **ISCR Annual Conference held on 25 & 26 Feb 2023, Delhi. Speaker*** for the session on "Independent Medical Writing Providers: Finding Your Niche!", and ***Panel Moderator*** for a discussion on 'Cross-functional Collaboration: Challenges and Opportunities for Medical Writers (MW)' at the conference.
- ***Local Organizing Committee Member*** for the 15th Annual Conference of the ***Indian Society for Clinical Research (ISCR),*** held virtually in ***Feb-Mar 2022.***
- ***Panelist*** for the Discussion on 'Freelancing in Medical Writing and Work-From-Home Opportunities in the New Changed Scenario' at the ***ISCR Annual Conference on 11 Mar 2022 (virtual).***
- ***Workshop*** for ***Medical Writing for Clinical Project Managers*** conducted virtually for a clinical research organization on 29 Nov 2021.
- ***Keynote Speaker*** at an international ***United Conference of WOMEN IN PHARMA*** held virtually on 15 Jul 2021.
- ***Organizing Committee Member*** at the ISCR Workshop on Clinical Study Protocols held virtually on 27 – 28 Aug 2021.
- ***Workshop Leader*** for 'Medical Writing' training conducted virtually on ***22 Apr 2021*** for a closed group of clinical experts of reproductive medicine from ***SRMC, Chennai.***
- ***Workshop Leader*** for a ***Medical Writing Mini-workshop Series 2021*** organized by ***MeWriT*** over January to May 2021.
- ***Workshop Leader*** for the pre-conference ***Medical Writing Workshop*** on 'Effective Authoring of Clinical Study Reports in the Evolving Landscape of Data Transparency'

conducted as part of the annual conference of the Indian Society for Clinical Research (***ISCR 2021***), held virtually on ***12 Mar 2021***. Also delivered a session on 'Critical Appraisal and Practical Implementation of CSR Guidances' in this workshop.

- ***Organizing Committee Member*** at the annual conference of Indian Society for Clinical Research (ISCR 2021) held virtually on 19-20 Mar 2021**.**
- ***Workshop Leader*** for 'Medical Writing' training conducted virtually on ***24 Oct 2020*** for a closed group of Clinicians from ***Tata Memorial Hospital, Mumbai.***
- ***Panelist*** for the discussion on ***'Clinical Trials - past, present and future'*** at the international virtual conference on clinical research -INCRES2020 - organized by School of Bio Science and Technology, Vellore Institute of Technology on ***03 Oct 2020.***
- ***Workshop Leader and Organizer*** for a ***2-day ONLINE program on 'Essentials of Medical Writing' for a corporate team of Medical Communications'*** professionals from ***Pune*** on ***20 & 21 June 2020.***
- ***Workshop Leader*** for 'Medical Writing' training conducted on ***11 Mar 2020*** for a multinational pharma team – primarily non-writing audience – at ***Mumbai***.
- ***Speaker at the annual conference of Indian Society for Clinical Research (ISCR 2020) on 24-25Jan, at Mumbai.*** Delivered a session on 'Importance of Continuing Medical Education for Medical Writers' in the form of Careers and Competencies in the Medical Writing Forum.
- ***Workshop Faculty*** at the ***national workshop for 'Adopting the CORE reference for writing disclosure-friendly CSRs',*** organized by the Indian Society for Clinical Research (***ISCR***) at ***Noida*** on ***11 Nov 2019.***
- ***Workshop Faculty*** at the national workshop of '***Research Manuscript Writing'*** organized by the Indian Society for Clinical Research (***ISCR***) at ***Ahmedabad*** on ***18 & 19 Oct 2019.***
- ***Workshop Leader and Organizer*** for a ***2-day program on 'Essentials of Scientific Writing Skills'*** for a corporate team of Bioanalytical professionals at ***Bangalore*** on ***24 & 25 Sep 2019.***
- Expert Faculty for a scientific session on 'Medical Writing – The Pharma and Healthcare Industry Perspective and Prospects' for research scholars and students of ***Lovely Professional University (LPU), at Jalandhar, Punjab*** on 06 Sep 2019.
- Workshop Leader for 'Medical Writing Workshop' at ***Sri Jayadeva Institute of Cardiovascular Sciences, Bengaluru*** in association with IQVIA and Merck, conducted on 27 April 2019.
- Expert Faculty for a scientific session on 'Medical Writing – The Pharma and Healthcare Industry Perspective and Prospects' for faculties and students of ***Delhi Pharmaceutical Sciences and Research University (DPSRU) at Delhi*** on 14 February 2019.
- Served as an expert industry panelist for the discussion on 'Startup and Investment Opportunities in Pharma and Healthcare' at Alumni meet, ***L. M. College of Pharmacy, Ahmedabad*** on 12 January 2019.
- Workshop Co-leader for 'External Medical Communications' session at the 2-day National workshop on the 'Essence of Medical Writing' organized by the ***Indian Society of Clinical Research (ISCR) at Bangalore*** on 23-23 November 2018.
- Workshop Leader for 'The art and science of publication writing' workshop organized by CTQuest LLP., at ***Pune***, India on 26 October 2018.
- Workshop Leader for 'Medical Writing Workshop' at ***Nepal Cancer Hospital, Kathmandu*** in association with IQVIA and Merck, conducted on 10 October 2018.

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- Workshop Leader for 'Medical Writing Workshop' conducted for the ***Indira IVF Centre, Udaipur, Rajasthan*** in association with IQVIA and Merck, on 12 October 2018.
- Workshop Faculty at the 'National Workshop on Scientific Writing' organized by the ***SRM Medical College, Chennai*** in association with Medical Pharmacologist Society of India and ISCR on 09 Mar 2018.
- Conference Resource Person at the 'Evidence Based Medicine and Clinical Research Conference' organized by the ***SRM Medical College, Chennai*** in association with Medical Pharmacologist Society of India and ISCR on 10 Mar 2018.
- Medical Writing Trainer at ***Meril Life Sciences*** for 'Medical Writing and Literature Search Training' organized on campus on 13 Jan 2018.
- Workshop leader for *'**Medical Writing Workshop'** in **June 2017*** by Arkus Research Pvt Ltd., at Ahmedabad.
- Visiting ***External Expert Faculty*** *for* ***'Clinical Trials'*** at Institute of Pharmacy, Nirma University, Ahmedabad, Mar – Jun 2016.
- Workshop leader for '***Narrative Literature reviews'*** conducted in December 2014 for BMS, Mumbai.
- Conducted a web tutorial on 'Writing overviews: module 2.4 and 2.5 in the EU context' for the ***Medical Writing working group, DIA India*** in June 2014.
- ***Workshop facilitator and coordinator for a two-day basic and advanced medical writing*** workshop, covering an array of medical writing aspects, held on 15-16 ***Nov 2013 by ISPE*** at AMA, Ahmedabad, with audience from academia as well as Industry.
- Workshop leader for 'Poster Presentation' Workshop conducted by ***All India Medical Writers' Association at Bangalore in June 2008.***

8.3 Clinical Research Project Management

Over 9 years of exhaustive experience on-site and in-house clinical (trials) project management at previous affiliations. Experienced in providing overall guidance and oversight for large multi-site, multi-protocol clinical projects in various roles viz. site coordinator, site manager, clinical research manager, clinical study manager, start-up team leader. Responsibilities undertaken as below:

- Served as a Clinical research coordinator / site manager for investigative site and handled > 10 phase III/IV clinical studies
- Experienced in clinical trial monitoring at Indian sites & also supervised team of CRAs.
- For investigator-led/small scale studies, assumed overall responsibility for the preparation of protocols and Case Report Forms, finalization of monitoring and data management options (either in-house or contracted to a Contract Research Organization), ethics committee approval, development of recruitment strategies to increase patient randomization into the trial, the provision of clinical trial materials, and management of the trial.
- As a start-up team lead, participated in developing budget, timelines, quality guidelines, risk management planning, project strategic planning for start-up and execution, identification & selection of sites, regulatory submissions and approvals, project monitoring, overseeing startup CRA teams, conducting internal and external team meetings, & project handovers.
- Establish appropriate clinical tools and processes for the study team to support the execution of clinical deliverable and study timelines.
- Manage clinical study set-up and follow-up study activities through ongoing tracking and review of study progress. Report progress to appropriate clinical management and project management forums.

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- Collaborate with other functional groups within the company such as data management, pharmacovigilance, and biostatistics where necessary to support milestone achievement and to manage study issues and obstacles.
- Track clinical budget consumption through regular review of project budget reports.
- Escalate out of scope requests to applicable higher line and implements corrective action wherever necessary to manager clinical costs.
- Establish customer service relationship with applicable client representative(s) through regular communications.
- Serve on clinical operations task forces and participate in department/corporate initiatives. Ensure adherence by project team to Standard Operating Procedures, Work Instructions, and Project Instructions.
- Serve as program lead, coordinate and establish consistent practices across all protocols which may include resourcing plans.
- Participate in sales presentation and proposal development; provide input into budget development.
- Participate in mentorship and training of more junior staff. Identify and record non-conformity with Company procedures, SOPs and internal QC program.
- Serve as a Regional and Global Lead which would include coordinating activities across regions.
- Ensure overall project efficiency and adherence to project timelines and financial goals.

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8.4 People Management

Over 5 years enriching experience in people management and team leadership. Experienced in handing direct and in-direct line reports at previous engagements, and has been involved with:

- Ensuring the operational integration of departmental goals & objectives
- Managing staff in accordance with organization's policies and applicable regulations.
- Responsibilities including planning, assigning, and directing work; appraising performance and guiding professional development; rewarding and disciplining employees; addressing employee relations issues and resolving problems. Approve actions on human resources matters.
- Participating in the selection and on boarding process for new staff by conducting candidate review and participating in the interviewing process. Conduct on boarding training for new staff in conjunction with human resources and training programs.
- Accountability for staff efficiencies and adherence to SOPs, work instructions, and project instructions and timelines.
- Participating in the allocation of resources to projects by assigning staff to projects that are appropriate to their experience and training.
- Managing the quality of assigned staff's work through regular review and evaluation of work product.
- Identifying quality risks and issues; and creating appropriate corrective action plans to prevent or correct deficiencies in performance of staff.
- Ensuring that staff is meeting defined workload and quality metrics through regular review and reporting of findings as outlined by operations management.
- Also participated in operational quality or process initiatives.
- Identifying and making recommendations to resolve ongoing training and development needs of the staff.
- Monitoring KPIs, matrix-driven performance appraisals and team building

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Acknowledgements: *We acknowledge the medical writing support provided by Subhajit Hazra (ISCR member) in revising and finalizing this manuscript. We thank Anushila Vaishali (MW Council Chair) and Dr. Hetal Shah (MW Council Member) for their efforts in the overall planning and execution of the publication activities for the DCT Position Paper initiative.*

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Acknowledgements: *We thank the ISCR Medical Writing Council – Anushila Vaishali (MW Council Chair) and* ***Dr. Hetal Shah (MW Council Member)*** *for their efforts in planning and execution of the publication activity for the DCT initiative; and contributing as principal medical writers in the development of this position paper content…*

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Acknowledgements: *The authors would also like to acknowledge the medical writing and editorial support provided by Dr. Hetal Shah, Founder & Principal Consultant, MeWriT™ from Ahmedabad, India, in the preparation and revision of this manuscript in collaboration with all the authors and reviewers, and in styling the article as per journal requirements. Medical Writing Support was outsourced to Dr. Hetal Shah, Founder and Principal Consultant of MeWriT (Ahmedabad, India).*

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***Acknowledgements:** We thank Dr Hetal Shah, Consultant Medical Writing Expert from Ahmedabad, India, for her professional service in drafting this manuscript.*
