

How to Become a Competent Medical Writer?

Dr Suhasini Sharma

ABSTRACT

Medical writing involves writing scientific documents of different types which include regulatory and research-related documents, disease or drug-related educational and promotional literature, publication articles like journal manuscripts and abstracts, content for healthcare websites, health-related magazines or news articles. The scientific information in these documents needs to be presented to suit the level of understanding of the target audience, namely, patients or general public, physicians or the regulators. Medical writers require an understanding of the medical concepts and terminology, knowledge of relevant guidelines as regards the structure and contents of specific documents, and good writing skills. They also need to be familiar with searching medical literature, understanding and presenting research data, the document review process, and editing and publishing requirements. Many resources are now available for medical writers to get the required training in the science and art of medical writing, and upgrade their knowledge and skills on an ongoing basis. The demand for medical writing is growing steadily in pharmaceutical and healthcare communication market. Medical writers can work independently or be employed as full time professionals. Life sciences graduates can consider medical writing as a valuable career option.

Key words: Medical writing, Regulatory, Publication, Technical guidelines, Skills, Resources

NEW knowledge and information is constantly being added to the field of medicine by way of an ever increasing number of research studies, growing clinical experience, and new ideas and thoughts. All this information needs to be effectively communicated to different audiences, e.g. the physicians and other healthcare professionals, patients and consumers and the drug regulators. Medical writing is the discipline of writing scientific documents by writers in the field of medicine – the “medical writers”. Medical writers may not be the original scientists who did the actual research, but work with the physicians/scientists involved in the generation of data, and help present the information in an appropriate manner. The importance of good medical writing cannot be ignored as science depends on clear and accurate reporting – an otherwise meticulous research can appear flawed if it is poorly presented.

The medical writer needs to have a clear understanding of the medical concepts and ideas, and be able to present the data and its interpretation in the way the target audience will understand. Medical writers combine their knowledge of science and their research understanding to present information at the right level for the target audience. Moreover, the writing needs to meet the specific requirements for different types of documents. Medical writing has become established as an important function in the pharmaceutical industry, because it requires specialized knowledge and skills to be able to write scientific documents which are well-

structured, and presented in a clear and lucid manner.

The demand for medical writing has gone up considerably in the last few years. The reasons are many – more research studies are being conducted today in the biomedical field; pharmaceutical companies are developing more new drugs and medical devices, and various scientific documents need to be generated for submission to regulatory authorities during their approval process; the number of biomedical journals has gone up considerably and many more scientific articles are now published than before; similarly, with the addition of a new and a powerful medium like the ‘internet’ a lot of medical information is generated as ‘web content’ for medical professionals as well as for the general public.

According to the CenterWatch analysis the medical writing market has doubled in size in the last five years, increasing from an estimated \$345 million in 2003 to \$694 million in 2008. Moreover, according to a separate survey, medical writing is also the fourth most frequently outsourced service.¹ As pharmaceutical companies outsource more and more work to Asia, Indian graduates can look at medical writing as a valuable career option, and develop knowledge and skills required to take this up as a full-time profession.

Types of Medical Writing

Medical writing involves writing different types of documents for different purposes, and for different audiences. Following are examples of different kinds of medical writing:

Medical Journalism

- Newspaper & magazine articles. These are mostly for general public and lay people and need to be written in simple, non-technical language.

Dr Suhasini Sharma
 Director, Medical Writing & Medical Review, Sciformix Corporation

How to Become a Competent Medical Writer?

Medical Education

- For Physicians – textbooks, Continued Medical Education (CME) programs, slide decks, e-learning modules
- For Patients - patient education material

Medical marketing of healthcare products

- Promotional literature targeted at healthcare professionals, product monographs, brochures, handouts
- Sales force training manuals, e-learning modules
- Internet content for physicians and patients (consumers)

Publication / Presentation

- Journal articles / manuscripts (research articles, case reports, review articles)
- Abstracts
- Posters & presentations for scientific meetings and conferences

Research Documents

- Clinical trial protocols
- Investigators' Brochure
- Informed Consent Documents
- Study reports
- Research proposals

Regulatory Documents

- Package Inserts (prescribing information) & Patient Information Leaflets
- Clinical study reports, web synopses
- Subject narratives
- Regulatory submission documents – Common Technical Document (CTD) modules such as nonclinical and clinical overviews & summaries, expert reports, safety & efficacy summaries; Aggregate safety reports such as Periodic Safety Update Reports (PSURs), bridging reports, Periodic Adverse Drug Experience Reports (PADER), Annual safety reports (ASR)s; policy papers etc.

Each of the above types of medical writing is meant for a distinct set of audience, e.g. medical professionals, patients & general public, medical sales representatives or drug regulators. Hence, the language used and the level of technical information has to be appropriate to the level of understanding of the respective audience. For example, while documents meant for medical professionals and regulators can be highly technical and can include scientific data and its explanation, those meant for patients and general public need to be simple and free of technical jargon. In addition, documents for regulatory submission are required to fulfill set formats and structures, and their contents are guided by regulatory rules and guidelines. Hence, a medical writer involved in the preparation of these documents needs to be conversant with the regulations and prescribed formats for such type of documents.

It is possible, therefore, that the knowledge and skills required for writing different types of medical documents are different, and one may decide to specialize in a specific type of medical writing, depending on one's aptitude and liking.

Who requires medical writers?

Medical writers mostly work with the pharmaceutical industry. However, there are many other settings in which medical writers are required:

- Pharmaceutical / healthcare product companies including medical device companies
- Contract Research Organizations (CROs) & Business/Knowledge Process Outsourcing companies (BPOs / KPOs)
- Scientific content and healthcare communication companies (Functional Service Providers)
- Media & Publishing companies and Medical Journals
- Academic medical institutions, Medical/scientific societies
- Healthcare Websites

The scope for medical writers is therefore tremendous and growing. This is also a profession which one can practice either independently as a freelancer, or as an employee in an organization, depending on one's experience, level of expertise and liking. So, learning medical writing can be the beginning of a life-long profession.

Requirements for becoming a Medical Writer

The basic pre-requisite for becoming a medical writer is of course, familiarity with medical concepts and terminology. An academic qualification in one of the life sciences such as medicine, or paramedical sciences such as pharmacy, microbiology, nutrition and dietetics, biochemistry, biotechnology can provide the right background which makes the writer familiar with scientific concepts and research data.

Another important pre-requisite is the ability to write. As the basic requirement on the part of a medical writer is to communicate scientific information to the target audience, some degree of command over the language, reflected by an ability to write grammatically correct text, and an ability to express and present information clearly and succinctly is most important.

In addition to the above basic requirements, one needs domain knowledge & language skills.

Domain knowledge

- **Medical & therapeutic area knowledge** - since the medical writer communicates scientific information related to the medical field, it is needless to say that he/she understands medical terminology and concepts. Writing technical documents related to specific therapeutic areas e.g. cardiology or neurology, can be greatly facilitated by knowledge in that field.

How to Become a Competent Medical Writer?

However, since medical writers seldom work in a single therapeutic area, it may not be possible for one to have a prior thorough knowledge of each therapy area. It would be a good strategy to have basic knowledge of different medical specialties, and build upon that as one goes on writing documents in different therapy areas.

- **Drug development process , pharmacology, drug safety** – medical writers involved in the preparation of clinical research and regulatory documents such as trial protocols, investigator brochures, clinical study reports of different phases (I -IV) of clinical trials, efficacy and safety summaries require a thorough understanding of the drug development process, the clinical research and various guidelines related to these. Those writing reports of early clinical development also require a good grounding in pharmacology and an understanding of pharmacokinetic concepts. Similarly, medical writers writing safety reports need to understand the drug safety process and requirements of safety reporting prescribed by different regulatory authorities.
- **Statistics** – Medical writers come across statistics when they write about clinical trials and when they write about research studies. The statistical results of clinical research must be communicated in a manner that allows clinicians to assess critically the quality and reliability of both the study design and any conclusions that might affect clinical practice. Every medical writer has to deal with confidence intervals, regression analyses, randomization schemes, P values, and t-tests. An understanding of statistics is necessary for good medical writing. One of the ways of developing this is attending workshops on medical statistics conducted by professional statisticians.
- **Technical guidelines** - EU, USA and Japan have evolved a set of common guidelines (International Conference on Harmonisation [ICH] guidelines) related to drug development and registration. In addition, the national regulatory authorities have their own specific requirements. Numerous guidelines are available on how to write clinical study reports (ICH E3), investigator's brochures, patient information leaflets, clinical overviews, periodic safety reports (ICH E2C) and other documents required for regulatory submission. These instructions require thorough reading. Information about these technical requirements is usually available on the ICH website or websites of the Regulatory Authorities. Knowledge of these guidelines is a “must” for a regulatory medical writer. Moreover, new guidelines emerge, old ones are revised, and a medical writer has to keep up to date. Publication guidelines like Good Publication Practices, guidelines for reporting clinical trials (e.g. CONSORT), the International Committee

of Medical Journal Editors' (ICMJE) guidelines for manuscripts are available. In addition, all medical journals have their own instructions for authors.

General Knowledge and Skills

- **Language & grammar** – a medical writer has to communicate scientific information. In addition to understanding the scientific aspects, the writer needs to present the information in a clear manner and at a level of understanding appropriate to the target audience. Use of grammatically correct language, simple and short sentences, active voice, appropriate punctuation marks, and a logical flow of ideas can go a long way in making the information understandable to the readers. Avoiding the use of highly complex technical jargon also makes the writing more lucid, especially for nonmedical audiences.
- **Literature / reference searching** - huge amount of scientific information is now available in the public domain. In addition to the books and medical journals, databases like Medline, PubMed, EMBASE, Micromedex are commonly used for sourcing medical information. Searching through all medical databases and healthcare websites for information relevant to your purpose is like searching for a proverbial needle in the haystack. Keeping in mind what exactly you are looking for, knowing where to search and selecting only the authentic sources, planning your search strategy, use of correct keywords for searching and then carrying out the search as per the set plan is more likely to bring up useful information. Reviewing your search results to consider if the information is relevant, and systematically classifying and filing useful information for later retrieval is equally important.
- **Interpretation and presentation of research data** – writing scientific documents involves review and interpretation of research data, presentation of those data in text, tables, and graphs, and developing logical discussion and conclusions as to what the data means. Medical writers must have sufficient knowledge of the research topic, and should be able to understand the research design and data so as to interpret and present it to their readers. Presenting data in the form of tables and graphs is a skill which needs conscious efforts to develop.
- **Ethical & legal issues** – issues of concern to medical writers are - giving truthful and complete information including negative findings, following copyright laws, not indulging in plagiarism, following authorship criteria for research manuscripts, and respecting journal review process.

So, what makes a good medical writer? The following

How to Become a Competent Medical Writer?

qualities distinguish a good medical writer from a mediocre one:

- Ability to understand the purpose and requirements of the project
- Ability to write at a level appropriate to the target audience
- Thorough research of the subject
- Ability to think, logical organization of thoughts and ideas
- Scientific accuracy
- Attention to details
- Ability to work across teams (often remotely) as well as independently
- Good communication & coordination with various people involved in the process
- Good time management, and meeting deadlines and commitments

Steps in writing scientific documents

- **Understanding the project brief** – Before starting to write, it is necessary for the medical writer to understand the purpose of the document being written and what the sponsor wants to achieve through it. In addition, it is necessary to know the timelines to follow, data that would be required to be studied and the review/approval process to be followed.
- **Literature search & review of information**—adequate planning and time spent on literature search and review can yield valuable information which a medical writer can use appropriately to support the document being written. A correct search strategy and classifying retrieved information in usable chunks is very important.
- **Authoring & compiling the document** – drafting the first version of the document usually takes up most time. Familiarity with the type of document, its purpose and contents is necessary to build the draft. Use of a pre-defined template makes the work easier. Apart from the scientific part of the content, having adequate language skills and following the in-house or client style-guide at this juncture is useful to reduce subsequent review and revision time. In addition to the main text, the document may contain a number of appendices. These are usually supplied by the sponsor. However, it is the responsibility of the medical writer to ensure that correct and current appendices have been compiled in the final version of the document.
- **The review process** – the review process for scientific documents involves review of contents and editorial/formatting review. The former is usually undertaken by a senior medical writer with more experience, and

a subject matter expert who may be a clinician or therapy area expert. Quality check (QC) of contents involving cross-checking all verifiable information with the source data is also required. This is usually done by a peer medical writer. However, every medical writer must do a thorough ‘self review’ of the first draft of the document before it goes for further review.

- **Formatting & editing** – formatting (checking text font and size consistency, line and paragraph spacing, headers and footers, margins, page numbers etc) and editing (language e.g. US or British English, spellings, punctuation marks, correct use of tense, appropriate reference style etc) of documents is a skill which needs to be learned by every writer to make their document more presentable and acceptable. Documents that are required for publication or electronic publishing need to be rigorously copy-edited, proof-read, and checked for formatting requirements.
- **Approval and sign off** – all scientific documents need approval and a sign-off from the designated approver, usually an expert. The approver may be in-house or external and adequate time must be allowed for the approver to review and sign-off the document.
- **Electronic publishing** – electronic publishing involves making the material available in digital format for on-line access. A number of software tools are now available for e-publishing, and a modern day medical writer may need to have some familiarity with their use.

Training and Professional Resources for Medical Writers

There is no formal degree / diploma or certification course in medical writing. Training in this discipline usually involves

- In-house training – organizations that employ medical writers generally provide the necessary general and project-specific training to new recruits. This may involve training in drug development process, exposure to drug safety and medical statistics, different kinds of regulatory documents and their requirements, and in-house templates, work processes and style guides.
- Short courses / workshops by professional bodies – one or two day training courses or workshops may be organized by professional bodies on specific topics e.g. CSRs, protocol writing or statistics etc.
- On-the-job ‘mentor-guided’ training – this is usually given by a senior medical writer more experienced in writing different kinds of documents. Training is more focused on specific type of documents the organization is handling.
- Motivated “self-study” – this is the mainstay of a medical

How to Become a Competent Medical Writer?

writer's training. A writer who is self-motivated and curious can do a lot in training himself/herself on different types of medical writing.

In addition, the following organizations represent professional bodies for medical writing.

- European Medical Writers Association (EMWA) – www.emwa.org/
- American Medical Writers Association (AMWA) – <http://www.amwa.org/>
- Australian Medical Writers Association (AuMWA) – www.medicalwriters.org

The aim of these organizations is to:

- a. Create a forum where medical writers can meet and share knowledge and experience
- b. Promote career opportunities and professional development of medical writers
- c. Promote standards of excellence in biomedical communication
- d. Offer training in the fundamentals of medical writing

Medical writers can gain a lot by becoming members of these organizations, subscribe to their journals, attend conferences, training courses and workshops organized by them. For Indian writers, this may not be a feasible or economical option.

Conclusions

Medical writing is both a science and an art. It requires an understanding in medical science and an aptitude for writing. In addition, a thorough knowledge of specific requirements for different types of medical documents, and keeping up to date with the relevant guidelines is a must. The demand for medical writing is growing steadily over the years. The pharmaceutical and healthcare industry offers number of job opportunities for medical writers. Graduates and post-graduates in life sciences who have the right skills and aptitude can consider taking up medical writing as a full-time profession.

References

1. Korieth K, Demand for Medical Writing Continues to Rise. *The CenterWatch Monthly*, Vol. 15, Issue 12, December 2008, Pg1, 8-13.

Resources

- Some books and style manuals
 - The A-Z of Medical Writing by Tim Albert (editor), B M J Books, (May, 2000)
 - Robert J. Bonk, PhD, *Medical Writing in Drug Development: A Practical Guide for Pharmaceutical Research*, Haworth Press, 1998.
 - Chicago Manual of Style*, 14th edition. Chicago and London: University of Chicago Press, 1993.
 - American Medical Association Manual of Style*, 10th edition. New York, NY: Oxford University Press, 2007.
- Websites
 - Centers for Disease Control and Prevention (<http://www.cdc.gov/>)
 - International Conference on Harmonization (<http://www.ich.org/>)
 - Food and Drug Administration (<http://www.fda.gov/>)
 - European Medicines Evaluation Agency (<http://www.emea.eu.int/>)
 - National Institutes of Health (<http://www.nih.gov/>)
 - Pub Med (searchable database of journal articles) (<http://www.ncbi.nlm.nih.gov/>)
 - Mayo Clinic (<http://www.mayoclinic.com/>)
 - Web MD (<http://www.webmd.com/>)
 - The Merck Manual (<http://www.merck.com/mmpe/index.html>)
 - Full-text journals (<http://www.welch.jhu.edu/services/fulltext.html>)
 - Instructions to authors in Health Sciences (<http://mulford.mco.edu/instr/>)
 - Pharmaceutical Information Network (<http://www.pharminfo.com/>)
 - Vancouver Guidelines (<http://www.icmje.org/index.html>)

**All life is an experiment.
The more experiments you
make, the better.
— Ralph Waldo Emerson**