Review Article

Development of medical writing in India: Past, present and future

Suhasini Sharma

Medical Affairs, Sciformix Technologies Pvt. Ltd., Mumbai, Maharashtra, India

Abstract

Pharmaceutical medical writing has grown significantly in India in the last couple of decades. It includes preparing regulatory, safety, and publication documents as well as educational and communication material related to health and health-care products. Medical writing requires medical understanding, knowledge of drug development and the regulatory and safety domains, understanding of research methodologies, and awareness of relevant regulations and guidelines. It also requires the ability to analyze, interpret, and present biomedical scientific data in the required format and good writing skills. Medical writing is the fourth most commonly outsourced clinical development activity, and its global demand has steadily increased due to rising cost pressures on the pharmaceutical industry. India has the unique advantages of a large workforce of science graduates and medical professionals trained in English and lower costs, which make it a suitable destination for outsourcing medical writing services. However, the current share of India in global medical writing business is very small. This industry in India faces some real challenges, such as the lack of depth and breadth in domain expertise, inadequate technical writing skills, high attrition rates, and paucity of standardized training programs as well as quality assessment tools. Focusing our time, attention, and resources to address these challenges will help the Indian medical writing industry gain its rightful share in the global medical writing business.

Keywords: Medical communication, medical writing in India, outsourcing, regulatory writing challenges, safety writing, writing skills

Address for correspondence:
Dr. Suhasini Sharma, Sciformix Technologies Pvt. Ltd., Akruti Softech Park, 2nd Floor, Crossroad No. 21, MIDC, Andheri (East), Mumbai - 400 093, Maharashtra, India. E-mail: suhasini.sharma@sciformix.com

INTRODUCTION

Medical writing is the science (and art) of communicating health and health care-related information to various stakeholders. Medical writing, in a broad sense, is not new to India. Ancient Indian texts such as the *Atharva Veda*, *Sushruta Samhita*, and *Charaka Samhita* are well-known medical treatises. However, in a more contemporary sense, medical writing means preparing scientific documents of different types for communicating biomedical information to specific target audiences. It encompasses preparing documents required for research, development, regulatory approval, and continuance of drugs in the market (regulatory medical writing); writing journal articles and manuscripts (publication writing) that communicate research findings or new medical ideas to health-care professionals; and preparing medical literature for educational and promotional use (medical communication).

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Medical writing is critical for the pharmaceutical and health-care industry for approval, continuance, and promotion of their products. It is also extremely important for the medical profession for enhancement and communication of knowledge, propagation of new ideas, and betterment of therapeutic practices. For patients and the general public, it is the source of all health-related knowledge, information, and education. Thus, in modern times, medical writing is a very important instrument for communicating vital information that helps us lead a healthy, meaningful life.

Globally, a large part of pharmaceutical medical writing is still done in-house by companies themselves. However, a compelling need to gain efficiencies and reduce costs in the last couple of decades has prompted the pharmaceutical industry to look at "outsourcing" as a viable option for some of its noncore activities. The CenterWatch survey on the pharmaceutical services industry reported that medical writing is the fourth most frequently outsourced clinical function, and its market size had doubled in the period of 2003–2008.[1] Although much of this outsourcing of clinical services occurs to service providers within the developed regions of the USA and Europe, countries such as India have gained from this trend and have been able to capture a foothold in this industry. It is estimated that the cost of generating medical writing in India is around 40–60% of the cost in the developed markets of the USA and Europe, and around 10–20% lower than that in other emerging economies.[2] This cost advantage, in addition to its large pool of science graduates trained in English, gives India a substantial advantage over similar emerging economies in the medical writing business.

Medical writing as a service industry began in India around 2005 and has grown steadily since then. It has tremendous growth potential, although it faces some unique challenges and issues. This article looks at the spectrum of contemporary medical writing in India and how it began and grew to its current size and state. It also discusses what the challenges faced by the medical writing industry in India today are that impact its growth potential, and it tables some thoughts on how to overcome these challenges.

THE SPECTRUM OF MEDICAL WRITING

The spectrum of contemporary medical writing spans from the most regulated, structure-driven common technical documents such as clinical study reports (CSRs), clinical and nonclinical overviews and summaries, research documents, namely, clinical study protocols, investigational brochures (IB), or product labels such as Summary of Product Characteristics (SmPC or SPC) to the relatively nonregulated, less-structured *Medical Communication* such as training and promotional materials, publications, and web content [Figure 1]. The former, regulation-driven documents are required for regulatory submission in support of approval or maintenance of health-care products, and this kind of medical writing is

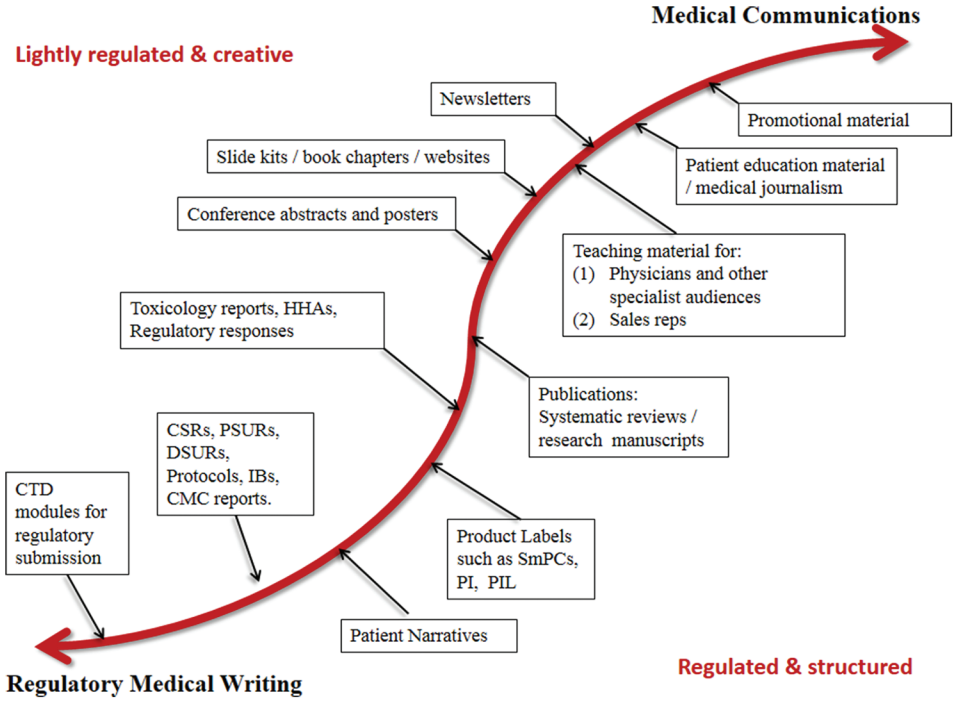

Figure 1: The spectrum of medical writing

known as *Regulatory Writing*. A specialized subcategory of *Regulatory Writing* is *Safety Writing* which includes pre- and post-marketing aggregate safety reports, benefit–risk analysis reports, and risk management plans (RMPs) for health-care products.

Writing clinical regulatory documents requires a deeper understanding of human physiology and pathology, how drugs work (pharmacology), and the drug development process. Whereas authoring safety documents requires a specialized knowledge of how drug safety is monitored and managed, various safety-reporting regulations and requirements prevalent in different regions of the world, in addition to the skill in analyzing and interpreting safety data, identifying new or potential risks, and planning appropriate measures to mitigate and manage those risks. *Medical Communication* is a specialized type of writing that is not as format-driven as regulatory writing but requires a greater degree of clinical and therapeutic understanding in addition to the ability to present scientific data and arguments in a logical, convincing fashion. It is more open to creative, innovative approaches and benefited by the use of multimedia. An understanding of statistical concepts is an added advantage for a medical writer.

Thus, medical writing requires a blend of capabilities: Medical understanding, writing skills, awareness, and the application of regulatory and scientific guidelines (such as ICH, GVP, COSORT, and ICMJE); knowledge of company-specific templates and style guides; the ability to understand, analyze, interpret, and present scientific data in the required format; along with the skill to interact and communicate with all stakeholders—reviewers, clinicians, statisticians, regulators, and clients.[3]

THE HISTORY OF MEDICAL WRITING IN INDIA

Pharmaceutical medical writing has been undertaken in India since the early 1960s, albeit on a much smaller scale and mostly by and for the use of the local pharmaceutical industry (or companies). This was mainly for the purpose of promoting pharmaceutical products to doctors or for training and informing the medical community and patients on health and health-care products. However, medical writing on a large scale or as a commercial enterprise began much later only after India signed the TRIPS agreement in 1994 and the new patent law took effect in 2005.

Medical writing saw a jumpstart in India post the CenterWatch report of 2008 on the rising demand for outsourced medical writing services, its market size of almost $700 million at the time and a growth rate of 15%.[1] By this time, the clinical trial industry had firmly established its roots in India. Clinical research organizations (CROs) as well as the information technology (IT)/business process outsourcing (BPO) industry started looking at medical writing as a possible extension of their current work as they were already handling a large amount of clinical trial data for their clients.

With the advantage of a ready pool of medical and life sciences graduates trained in English and lower pricing, medical writing projects started coming to India in larger volumes. The initial assignments included work at the lower end of proficiency—assembly of CSRs (rather than actually authoring them), preparing clinical trial safety narratives (often in set templates), preparing and updating IBs, generating line listings for CSRs or safety reports, or conducting data quality checks on reports authored by other service providers.

Around the same time, another outsourcing industry was trying to find its feet in India—the pharmacovigilance or drug safety industry. IT/BPOs and knowledge processing organizations (KPOs) built large teams of drug safety professionals and relevant technology platforms (safety databases) and began offering "Case Processing" services from India. A natural extension of safety services is preparing aggregate safety reports, known as periodic safety update reports (PSURs). A few mature BPOs and KPOs with a higher degree of safety domain expertise started offering "safety writing" services—preparing PSURs, Periodic Adverse Drug Experience Reports, Canadian Annual Reports, IND Annual Reports, and Annual Safety Reports (ASRs) for submission in different geographies. This was followed by Chemistry, Manufacturing, Control reports, stability and quality documents for approval, and license maintenance of products globally. Companies that specialized in medical communication began offering documents of greater complexity by hiring PhDs and medical professionals in increasing numbers.

However, despite such a steady growth in the scope and volume of medical writing work in India, high-complexity documents such as clinical trial protocols for developmental studies, complex CSRs, integrated efficacy and safety summaries, regulatory briefing documents, publications in international journals, benefit–risk analysis reports, and RMPs are still a miniscule part of the medical writing we do from India.

MEDICAL WRITING IN INDIA—THE CURRENT SCENARIO

Medical writing has expanded significantly in India since it began as a commercial activity around 15 years ago.

The number of medical writers engaged in different types of medical writing and employed across various types of organization (IT/BPOs, KPOs, CROs, and communication companies) could be in the range of 1000–1500. As of July 2016, the Indian Medical Writers Association (IMWA), which is an academy of medical writers in India, mentions a membership of over 1500 on its LinkedIn page.[4] There are other similar, though smaller, professional bodies with listed members such as the All India Medical Writers Association. Many of these writers are pharmacy or life sciences graduates or postgraduates—some of them even with PhDs. A sizable number of graduates of alternative systems of medicine (homeopathy and Ayurveda) have taken up medical writing as a career and are doing well in the profession. Allopathic medicine graduates and postgraduates (MBBS or MDs) have entered the field mainly as medical reviewers or subject matter experts. Their role is primarily to review the documents prepared by the writing teams and provide clinical inputs and medical interpretation of data or prepare specific sections of documents that require greater medical insight, such as the benefit–risk analysis of a product. With the slowdown in the clinical trial industry in India in recent years, medical writing as a profession seems to have come into its own, and many life sciences graduates have taken up careers in medical writing.

There are different types of organizations employing medical writers in India—both service providers and pharmaceutical sponsors. A guesstimate based on the author's industry insight suggests that of the total pool of medical writers in India today, a large percentage (60–65%) could be employed with IT/BPOs, KPOs, or communication companies (such as TCS, Cognizant, Accenture, Sciformix, Indegene, Cactus Communications); around 25–35% in CROs (Quintiles, Paraxel, Icon, Siro Clinpharm, etc.) and 5–10% may be working in pharma companies (Novartis, Eli Lilly, Sanofi-Aventis, GSK, etc.).

Currently, there appear to be two strong medical writing streams in India—a regulatory writing stream and a "safety writing" discipline. While regulatory and safety writing services are primarily offered by the BPOs/KPOs and CROs, medical communication services (including publication writing) are offered by specialized companies and are still on a lower trajectory. Compared to developed markets, the demand for freelance writers is much less in India.

A major part of the business that the industry currently handles is from global biopharmaceutical companies. However, we are also witnessing a rising demand for outsourced medical writing from Indian pharmaceutical companies who aspire to take their products to developed and emerging markets globally. Hence, there is a growing demand for experienced medical writers who can prepare complex regulatory documents for global submission.[5]

It has been estimated that India handles 5–7% more regulatory writing than the USA in volume. However, in terms of revenue, the figure is much smaller, and globally, a significant part of writing is still done from high-cost destinations such as the USA and Europe, with most being done in-house.[6] In the field of promotional medical writing, only a small volume of work is done in low-cost regions such as India. The global market for medical writing was estimated to be around $1.3 billion in 2013.[6] No hard data exist on the annual volume of the medical writing business delivered from India. However, compared to the global medical writing business, this figure could be small ($50 to $70 million), and there is tremendous scope for the growth of this business in India, provided we overcome the challenges we currently face.

CHALLENGES IN MEDICAL WRITING AND POSSIBLE SOLUTIONS

The medical writing industry in India faces some tough challenges that need to be addressed if we want to gain further strength and win more complex writing assignments for India. These challenges are as follows:

Lack of proficiency in business and technical writing skills

Even though much of science education in India is in English, our writing skills in the language are far from adequate. We tend to use laborious language and long sentences, with less emphasis on grammar and little regard to punctuation. This sometimes results in text with unclear or ambiguous meaning and makes documents too long and laborious to read. There is also an inability to present scientific data and arguments in a logical flow, resulting in documents becoming just "data dumps." Our "rote" system of education is partly responsible for this state of affairs. We need to make conscious efforts to develop better language and data presentation skills in our writers. Therefore, in addition to screening for these skills at the recruiting stage, medical writing training programs must include rigorous courses in business and technical writing.

Inadequate domain expertise with lack of global experience

Our writers are still new to the field of global medical writing and relatively inexperienced. They often lack domain expertise and have to depend heavily on internal and client experts for providing subject matter expertise. The experience will, of course, come with more years of writing documents of

increasing complexity across different domains. The incubation period for becoming an expert medical writer in any domain is long and requires conscious self-learning. This has to be supplemented at the organizational level by way of encouraging writers to attend internal and external training programs in specific domains, giving them a chance to attend national and international conferences, and even providing opportunities to work on-site at global locations. Moreover, India has a diverse, internationally trained, and competent pool of academically oriented practicing physicians. We must utilize this locally available clinical expertise to supplement our writers, provide valuable therapeutic insights, and enhance the value of our high-complexity documents.

High attrition rate

Medical writing is a growing discipline, and like many young industries, it is fraught with a high attrition rate of over 15%. The lure of a better job with a higher salary and a fancy designation is very tempting, and a little frustration with the current work setup or a feeling of stagnation can prompt youngsters to switch jobs. At an individual level, this may result in the loss of continuity in the development of functional expertise in the domain. At an organizational level, this results in the loss of trained resources which can have an impact on the quality of deliverables. Organizations must keep their attrition levels in check by creating an enabling workplace and a work culture that appreciates and rewards employees for their achievements, gives them opportunities to learn and grow in their field of interest, and by having compensation policies commensurate with industry norms.

Quality issues

There has been a consistent perception with global clients that although we may be good at assembly of documents, there are many "quality" issues when documents are authored in India. This is also one of the main obstacles in not getting more complex writing work done from India. Hence, in addition to improving our writing skills, we need better tools to monitor and improve the quality of our writing. However, there are no standardized quality metrics that can be consistently applied across various document types. Each type of document has a specific purpose, with specific data and format requirements, and needs an appropriate, standardized metric to judge its quality by way of a specific checklist that will go a long way toward improving the overall quality of our medical writing.

Paucity of standardized training programs

Medical writing is a skill that can be developed if one has the basic qualifications and qualities to become a good technical writer. Unfortunately, there are no standardized training curricula in medical writing and institutes consistently delivering such programs in India. We can do a lot here by (a) setting up certified, industry-led training programs with controlled curriculum; (b) providing internship to potential writing aspirants in reputed companies; and (c) actively collaborating with global organizations such as the European Medical Writers Association or American Medical Writers Association for regular skill enhancement and certification of our writers.

In summary, medical writing is a fairly young discipline in India. It is still evolving and will take a few more years to mature into a true industry. Despite having the advantages of a large, scientifically qualified workforce trained in English and low cost of delivery, the quantum of the current medical writing business delivered from India is a small fraction of the global business. To capture our due share of that business, we need to address the crucial challenges currently facing the industry. Some of the corrective measures are developing more functional expertise in various domains, honing our technical and business writing skills, training and rewarding our writers and providing them opportunities for growth, designing standardized training and certification programs in medical writing in collaboration with global organizations, and evolving better quality standards to improve the technical quality of documents. We must also leverage the vast clinical expertise available in India to deliver high-complexity work. India has the potential to become a destination for global medical writing, provided we commit our time, energy, and resources to address the current challenges by designing effective and sustainable solutions.

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I, Dr. Chandrashekhar N. Potkar, hereby declare that the particulars given above are true to the best of my knowledge and belief.

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