Medical writing on an accelerated path in India

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Abstract
The medical writing industry is on an upwards growth path in India. This is probably driven by an increasing urgency to have high-quality documents authored to support timely drug approvals, complemented by the realization that the competencies required are available in emerging geographies such as India. This article reviews the business landscape and the opportunities and challenges associated with outsourcing medical writing work India. It also analyzes the core competencies that a medical writer should possess and enlists various associations supporting learning in this domain.

Key words: Benefits, challenges, competencies, medical writing associations, medical writing outsourcing

INTRODUCTION
Medical writing is about presenting clinical and scientific information in a variety of formats for communicating medical information to different audiences. The need and the demand for medical writing have been continually increasing over the past few years. Pharmaceutical companies across the globe are investing money on research for novel drugs, new medical devices, and novel diagnostic techniques. An increasing number of new drugs are going through the intricate process of clinical trials that in turn has given rise to an increase in the demand for the submission of documents to regulatory authorities. Stringent regulatory requirements have raised the need of thorough documentation. Apart from regulatory submissions, several pharmaceutical companies such as Glaxo SmithKline[1] Janssen Pharmaceuticals,[2] Roche[3] and others have also committed to disclose results of all clinical trials in the public domain in support of the data transparency initiative. Several leading pharmaceutical companies have been continually publishing their clinical trial data in scientific journals and on clinical trial registries. The number of publications based on clinical trial data and the number of biomedical journals has increased significantly during the past decade. There has been a huge increase in the number of downloads for scientific information[4] indicating that increasing number of healthcare professionals and researchers are reading and making use of clinical trial data that is available in the public domain. This has increased the demand for medical writers who can write standards-compliant documents. Pharmaceutical companies have also recognized medical writing as a distinct function, imperative in the drug discovery process.

Due to the recently revised regulations issued by the Drugs Control General of India,[5] there has been a significant drop in the number of clinical trials conducted in India. Though, this has severely affected the Indian clinical research industry with respect to clinical operations, business in other areas of the clinical research industry such as medical writing, pharmacovigilance, and clinical data management has been growing steadily.

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COMPETENCIES OF A MEDICAL WRITER

Medical writing demands special skills to produce well-structured documents that present information clearly and concisely. Medical writers require knowledge of therapeutic areas, the drug development process, pharmacology, drug safety, statistics, and regulatory guidelines (e.g. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH], Consolidated Standards of Reporting Trials [CONSORT]). They also need to have the ability to interpret and present complex clinical trial data, should have an understanding of ethical and legal issues, should be aware of literature search techniques and should have a strong command over the English language. While a medical qualification is not critical, deep seated understanding of how to interpret and present clinical data is important. While, other skills are more easily developed, honing foundational medical and scientific knowledge is more difficult. Medical writers are also required to possess good project management and coordination skills as they need to work with different stakeholders like trial investigators, scientists, statisticians, trial managers, medical officers and other subject matter experts while working on different documents. Co-authoring, avoiding the duplication of efforts especially when working with global teams, and generating lean documents is a skill that needs to be acquired, especially in the current scenario of global outsourcing to emerging geographies. Medical writers ensure that the documents written by them comply with regulatory or other guidelines in terms of content, format, and structure. Medical writing required for nonregulatory purposes; that is, information published in the public domain includes publication writing, medical communication, promotional medical education and continuing medical education. These types of medical writing include but are not limited to publishing information (in the form of websites, blogs, newsletters, journal articles, abstracts, etc.) about clinical studies, surveys, disorders, therapeutic areas, health care products, and diagnostic tools. Medical information available on the web serves as a ready repository of information for researchers, medical professionals and the general public. Though these nonregulatory types of medical writing have a substantial contribution to the medical writing business in India, the scope of this article is restricted to the status of regulatory medical writing in India.

Business landscape for medical writing

Medical writing is an established business in geographies like the United States of America and United Kingdom, primarily due to English being a native language for these countries and also as many major pharmaceutical companies are based in these geographies. The outsourcing of medical writing services has been on the rise globally over the past decade and has taken a significant leap from the year 2005. Though the recent statistics are not available, it is important to know that the global medical writing market has more than doubled in size during the years 2003-2008. The estimated medical writing market revenue has increased from $345 million in 2003 to $694 million in 2008 and were growing steadily.

The Indian pharmaceutical industry has shown a compound annual growth rate of >20% from 2005 to 2011, according to the Confederation of Indian Industry. It is likely to be among the top 10 global markets in the coming 10-20 years if growth continues at the same rate. The contract research market in India is growing at a rate of 25% a year and it should be noted that the medical writing business, while not representing a significant part of the market share, stands as a key element in the value chain. The medical writing business in India is more than a decade old and has taken a stride over the past 5 years. According to a report published in 2010, a market analysis review has estimated that the global medical writing market size would be around $800 million in next few years, and that the India-based medical writing service providers are expected to gain significant market share in this area, needless to mention that they will be having competitors from China, Japan, Ireland, Philippines, Brazil, Russia and other countries. Among the low-cost destinations for medical writing, India will also have to compete with its Asian counterpart, China, which is making a consistent upward move in the medical writing business. By having many manuscript writers and translators in biomedical fields, who can easily adopt regulatory writing skills after adequate training, China offers a large pool of potential regulatory writers.

India as a destination for the outsourcing of medical writing: Benefits and challenges

Most of the giant pharmaceutical companies are headquartered in western geographies, and India is preferred by these for clinical research outsourcing due to its lower cost and infrastructure equivalent to international standards. India is also a promising option for outsourcing the medical writing work, owing to the availability of a huge talent pool of skilled clinical research professionals and owing to English being the business language of the country. Differences in time zones also prove to be beneficial as the turnaround times for projects are shorter. Many leading pharmaceutical companies maintain in-house medical writing divisions, and a few of them have developed their captive medical writing teams in India, to make use of experienced medical writers available locally and to cater to the needs of the growing clinical trials market in India. However, most pharmaceutical companies
prefer to utilize combination (in-house and outsourced) business model where they have a core in-house medical writing team and an external medical writing service provider who can help them to manage their work peaks.

The industry is observing an upward move for regulatory writing in India in the past few years and Indian medical writers have evolved to become key players and members of the clinical study teams in the drug development process.[14] India has been steadily receiving medical writing business from pharmaceutical companies across the globe, primarily from companies based in US and UK. Most of the top 20 global pharmaceutical companies outsource their medical writing work to India. Global sponsors look for dedicated teams to support their medical writing requirements so that these dedicated teams develop a good understanding of their products, requirements, standard operating procedures, processes, etc., which in turn significantly reduces the oversight required by the sponsors. Indian Contract Research Organizations, Knowledge Process Outsourcing and Business Process Organizations have responded to these needs favorably and have maintained skilled dedicated teams to cater to various sponsors. Though many global pharmaceutical companies are outsourcing their medical writing work to India, most of them have restricted the outsourcing to low complexity, low criticality and low priority documents. The primary concerns being the lack of experience of Indian medical writers in handling complex documents, costs involved in training Indian medical writers to handle highly complex documents and the continuous oversight and rework required during the initial months. Confidentiality of data is also another area of concern for sponsors, while outsourcing their critical documents to vendors. Different writing styles and interpretability can also pose a serious problem, while writing critical documents. Since the medical writing industry in India is still evolving, medical writers who understand project management, strict adherence to timelines and quality are not readily available in the market, which makes sponsors apprehensive while outsourcing their high-priority documents. Currently, most of the sponsors are outsourcing the writing of template-driven documents that involve minimal data analysis and interpretation. In addition, a huge number of documents are outsourced for performing stand-alone quality checks. Nevertheless, Indian medical writing service providers are continuously working towards overcoming these issues, and there has been a gradual increase in high-complexity and high-priority documents being outsourced to India by global sponsors. Initial requests from sponsors for performing the stand-alone quality check of medical writing documents are gradually being replaced by request for authoring increasingly complex documents.

Most of the medical writers in western countries have established themselves as freelancers. However, this model is still not well adopted by Indian medical writers. Indian medical writing business is in its growing phase, and not many medical writers have the versatile experience of working on various types of documents, for various regulatory authorities and for varied therapeutic areas. The experience earned by Indian medical writers over the past few years is still in a primitive stage, and there is a lot to learn. Although Indian medical writers still need to be groomed to a greater extent to meet international standards and to grow as independent or freelancing medical writers, there is a growing pool of experienced medical writers with a combination of good authoring skills with a core understanding of the clinical space. The current trend is very promising and soon India will have a huge pool of highly experienced medical writers who can establish themselves as independent writers.

### Medical writing: A preferred choice for a career

Rapid growth in the medical writing business has also translated into a huge increase in the number of institutes offering medical writing courses. Life sciences and pharmaceutical sciences postgraduates and PhDs have started moving from the research and development sector to medical writing. A number of medical professionals are seeking medical writing as the preferred choice for their careers. Growing number of aspiring medical writers are trying to become certified medical writing professionals. A few Indian medical writers have already been certified as medical writing professionals on an international platform.

### Medical writing associations

Leading countries in the medical writing business like the US and UK have established professional organizations for medical writers. The American Medical Writers Association (AMWA),[15] an organization for writers, editors, and other communicators of medical information was founded more than 70 years ago. AMWA has grown since 1940 and had more than 5000 members in the US, Canada, and 30 other countries. The European Medical Writers Association (EMWA),[16] founded in 1989 has over 1000 members from 39 different countries, including 12 countries outside Europe. The All India Medical Writer’s Association (AIMWA)[17] is comparatively very recent. It has been founded in 2007, by a group of medical writers from India and currently has more than 175 members associated with it. AIMWA work toward supporting and strengthening the medical writing service in India to meet global standards, providing a platform of acknowledgment for professionals in medical writing, establishing co-operation and linkages among various individuals, groups and organizations engaged in medical writing in India and across the world and promoting and facilitating training and certification in
the field of medical writing. AIMWA offers an opportunity for Indian medical writers to interact with other writers and discuss medical writing topics and get guidance from experts in the field. The Drug Information Association India Medical Writing Community is also a group of medical writing professionals that provides extensive networking and learning opportunities.

CONCLUSION

The pharmaceutical industry is observing an upward move for regulatory writing in India in the past few years and Indian medical writers have evolved to become key members of the clinical study teams in the drug development process. The Indian Medical writing market has been steadily growing, and the current circumstances clearly indicate that this trend will continue.

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