

## Medical Writing Outsourcing: Opportunities and Challenges in India



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## Medical Writing Outsourcing: Global Status

The global demand for medical writing services has shown a considerable rise in the last few years. The use of professional medical writing services has been shown to be beneficial to the researchers in presenting their research accurately and precisely [1, 2]. Pharmaceutical companies prefer to outsource the medical writing tasks to knowledge service providers in order to control the research and development cost, get high quality documents under tight timelines, and save the investment and time needed to train the writers on regulations, guidelines, right skill set, *etc* [3].

A recent report by Transparency Market Research estimated that in 2013, “Global Regulatory Affairs Outsourcing Market” was 1559.7 million USD. The report also forecasted the growth of the market for 2014-2020 to be at a compound annual growth rate (CAGR) of 14.6% and reach 4490.4 million USD by the end of 2020. Regulatory writing and publishing were the major areas of outsourcing and are expected to be same in the forecasted period (2014-2020). In 2013, North America was reported to hold the major share of regulatory outsourcing market; however Asia Pacific is expected to show significant growth in the forecasted period [4]. The Center watch analysis of the medical writing market from 2000-2008 estimated that it has doubled from 345 million USD to 694 million USD [5]. The increase in the number of clinical research organizations (CROs), medical writing service providers also indicates a rise in the demand of medical writing. A survey reported medical writing to be the fourth most frequently contracted service from CROs in 2005 and 41% participants responded that they used outsourced medical writing services [5].

Major business for medical writing is located in the United States of America and the United Kingdom. These regions have a core niche of medical writers marked by English being a native

language and presence of major pharmaceutical companies [5, 6]. In recent times, the pharmaceutical market has expanded significantly in Asia. Pharmaceutical companies are now targeting Asia due to a large population, aging population and strong economic growth. However, the complex and stringent regulatory landscape in countries such as China, Japan, India, Taiwan and Korea impose obstacles for foreign pharmaceuticals. Thus, outsourcing of regulatory compliance services business to third parties in Asia is a key option for the foreign pharmaceutical companies. China is reported to be the top most and best outsourcing destination followed by India, Korea and Taiwan [7]. More than 5000 members from China are registered with the American Medical Writers Association (AMWA), and around 1000 with the European Medical Writers Association (EMWA) [8].

### **Medical Writing Outsourcing: India**

As per Ernst & Young (EY) report 2015, medical writing outsourcing has become one of the major information technology (IT) outsourcing services in India and is likely to be among the top 10 global markets in the coming decades if the growth is consistent [9]. Revenue for the medical writing domain in India is mainly earned from multinational IT companies, CROs, global pharmaceutical companies, research institutes and independent researchers/ physicians and Indian subsidiaries of western IT companies [10]. India is reported to have around 500 regulatory medical writers. India's clinical development activities also target Europe and the U.S. market, thus there is need of medical writers who can prepare complex regulatory documents. In addition, India also has a pool of medical writers who have an expertise in the pharmacovigilance sector. They can prepare and aggregate safety reports, including Periodic Adverse Drug Experience Reports (PADERs), Periodic Safety Update Reports (PSURs) and

Periodic Benefit-Risk Evaluation Reports (PBRERs) [8]. The outsourcing of medical writing business to India is associated with several key opportunities and challenges (**Figure 1**).

**Figure 1: Key Opportunities and Challenges of Outsourcing Medical Writing to India**



### Opportunities for Outsourcing Medical Writing Business to India

**Low cost:** Pharma companies are restructuring to cut down the cost and the medical writers in these companies are quitting jobs to work as freelancers. Thus, there is an increasing demand of medical writing services providers by the pharma companies [5]. Pharma companies are now opting the strategy to outsource the medical writing and other clinical development activities (including clinical data management, pharmacovigilance and statistical programming) to such knowledge services providers [10, 11]. It helps them to control the research and development

cost, get high quality documents under tight timelines, and save the investment and time needed to train the writers on regulations, guidelines, right skill set, *etc* [12].

India offers significantly low cost to service providers and sponsors as compared to developed and emerging economies. The costs of services for medical writing in India is estimated to be 40–60% lower than in developed economies. It is even 10–20% lower in comparison to the other emerging economies [13].

***Increase in Clinical Trials:*** A total of 219,712 clinical trials have been registered at clinical trial registry of the U.S. National Institutes of Health, of which 101,471 (46%) are at non-U.S. location [14]. Since, India is a highly populated country with increase in the aging population; the pharmaceutical companies are targeting it to conduct clinical trials. Nearly, a fifth of all the global clinical trials are being conducted in India that provides a financial and scientific gain to the pharmaceutical companies [15]. The cost of clinical trials is more than 50% cheaper in India as compared to the developed countries [16]. India is reported to be the second country after China to provide the largest patient pool. Comparatively, the timeframe for getting regulatory approval is less stringent and faster in India [15]. Several regulatory documents need to be submitted for conducting trials, thus foreign companies prefer to outsource these activities to the native service providers based in India.

***English-speaking:*** More than 80% of the scientific articles published annually are in English [17]. India is ranked second largest English-speaking country in the world after the U.S. English is the business language of India and Indian managers are quite effective in using this skill for communicating and managing their international clients [18].

***Talent pool for medical writing:*** Every year thousands of graduates with master's and PhD degrees in science are added to the pool of medical writers in India [10]. As per a survey

conducted in 2008 by Cactus Communications, approximately two-thirds of the Indian medical writers were physicians and more than 90% were holding a life science degree [19]. Medical writing service providers offer in-house trainings to their teams on all the latest guidelines for medical writing including publication guidelines and regulatory writing guidelines. India has a highly skilled workforce which includes well qualified and experienced medical professionals. Experts in this field have thorough knowledge of all pharmaceutical manufacturing and regulatory guidelines, excellent command on the concepts of medical science, have rich industry experience of the clinical practices and drug development procedures and have good writing skills. An amalgam of all these traits qualifies them for a competent medical writer [20].

### **Challenges in Outsourcing Medical Writing Business to India**

Though there is a bright future of medical writing in India and there are many more upcoming opportunities for the medical professionals but still there are few challenges being faced by them:

***Less experience:*** Medical writing as a profession is just a decade old in India. Though, there are few ancient evidences of writing scientific books available in Indian history [21]. In a survey of 49 respondents, more than 60% had medical degrees, but only 21% had more than 10 years of experience in the field of medical writing, indicating that this field is still in early emerging stage in India, though growing very rapidly [19].

***Less trainings or degree courses available:*** There are hardly few training courses available in medical writing in India. Medical writing as a discipline has not yet been introduced as a part of study course for any pharmaceuticals or medical degree or post degree course. Training courses for individuals who want to join the medical writing profession are few. Considering these needs, the Indian Medical Writers Association was founded in 2007 by a small group of professional biomedical communicators with academic, industrial and medical affiliations. Their aim was to

provide a forum to promote standards of excellence in medical writing by promoting the professional development of members and increasing awareness of medical writing throughout India. Its development is still at an early stage and international associations like European Medical Writers Association (EMWA) can share their experience and help this association to give a strong platform for medical writers in India [20, 22]. Training young doctors during their graduation and life science graduates at university for the importance of good scientific research along with the ethics and technique of publication will definitely promote better medical writing [21]. Online training for medical writing is offered by the National Medicine Journal of India (NMJI). Few Institutes like the Christian Medical College at Vellore also conduct annual programmes on epidemiology and clinical trials, which cover many topics of interest to medical writers. [23] Generally, medical writers learn the actual writing in their jobs [21].

***Language command:*** Verbal and written communication skills are equally important for medical writing. The power of language reflects not only in the writing but in dealing with outsourcing partners, as most of the countries have English as their business language. Command on English plays a vital role in maintaining cross culture communications. Clients working in different time zones speak with different accents. It is necessary to take extra care with email etiquette and accent free English pronunciation while virtual communication with clients [22]. For the Indian writers to be recognized internationally; they must acquire global regulatory expertise and require trainings not only in the scientific principles but they must be equally good on communication skills as well. Also, it is very important to write the accurate though simple and grammatically correct English to make the draft understandable and meaningful by general public. Local medical writers, mostly pharmacy or life-science post-graduates being non-native

English speakers, need to be trained upon their language skills. More exposure to western writing and training will rectify this problem [21].

### **Conclusion**

Thus, we conclude that the medical writing business in India will show a significant growth in the future. The low cost, increase in number of clinical trials, use of English as a business language and talent pool for medical writers are the key driving factors for the outsourcing of medical writing to India. However, India will have several competitors including China, Korea, and Taiwan which hold a significant share in clinical research market. Increase in the number of experienced writers, in-house training of the writers on command over English in communicating with clients and incorporating courses and degrees related to medical writing will help in developing skilled and competent medical writers in India.

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