

Medical writing in India at a crossroads

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Abstract

Pharmaceutical regulatory medical writing for document submissions to Western health regulatory agencies has been undertaken in India for almost 10 years. From humble beginnings in a couple of non-Indian pharmaceutical multinational giants – Novartis and Sanofi-Aventis (as it was) – this activity has now expanded into multiple companies and almost a dozen information technology firms and contract research organisations. The biggest advantage is the cost, although this often comes at a ‘price’, in terms of document quality. However, medical writing in India may be turning a corner for the good as a result of the rapidly increasing body of experience in the field.

Keywords: Medical writing, India, Outsourcing, Quality, Cost arbitrage

Few people understand what medical writing is all about, even within the scientific community. Often, it is an excruciating experience for a medical writer to explain what they do in the pharmaceutical development world. Also, the broad range of medical writing activities adds to the problems. This range extends from regulatory writing for submissions to the health regulatory authorities worldwide to writing intended for publication in scientific journals and for presentation at conferences. So it can be quite challenging to articulate to the ‘native’ English speakers of the world the full scope of this professional activity within India (with its ‘non-native’ English-speaking population).

India, according to some estimates,¹ has the second largest English-speaking scientific force in the world after the USA. With hundreds of thousands of graduates with master’s and PhD degrees (achieved in English) adding to that pool every year, India presents a formidable cohort of young life science graduates entering the job market. All

they need to become fully ‘employable’ is appropriate in-house training by the many global big pharma innovator companies that have an Indian presence.

According to an Ernst and Young report published in 2009,² India offers significant cost arbitrage to service providers and sponsors when compared with developed and emerging economies. The cost of services, such as medical writing, in India is typically 40–60% lower than in developed economies and around 10–20% lower than in other emerging economies.² Medical writing services would typically include writing documents such as clinical study protocols, investigator brochures, clinical study reports, patient narratives, and various safety reports. Since almost all pharmaceutical companies are under increased cost-cutting pressure and look to outsource their development functions, such as clinical data management, statistical programming, medical writing, and pharmacovigilance, India is the natural choice for most of them. Of the functions listed above, medical writing requires a unique skill-set: the abilities to apply scientific knowledge and to create sense and order out of the gargantuan sets of data generated in clinical studies.

In a special report published in 2009,³ the authors discuss the history, current state, and projected future growth of biological research in India. They consider the establishments that churn out hundreds of thousands of young life scientists, many of whom will turn to the pharmaceutical industry for employment because of the lack of well-developed and well-paid research jobs in academia. Some established chains of institutes, such as the Indian Institutes of Science Education and Research, offer 5-year combined bachelor’s and master’s degree programmes, some of which include scientific writing in their curricula. The report’s authors opine that in order to realise its aspirations, India needs to educate, recruit, and develop its next generation of scientists. Similar challenges exist in the

developed world, but they are particularly acute in developing countries that are racing against time to achieve globally accepted standards.

Traditionally, Indians may not have formal English writing courses in schools and colleges, although the medium of instruction may very well be English. And although India has a large number of people who may know how to speak in English, albeit incorrectly some of the time, writing is a whole different ballgame. As Reeves noted,⁴ professionals in the fields of science and medicine are expected to write well in English, but most often they do not. A significant mass of 'educated' and urban Indians learn English at school with little emphasis on grammatical correctness. If a major effort is made at school to lay strong foundations in written English, instead of just spoken English, most students will eventually become better writers, regardless of their chosen career. Apart from the grammatical perspective, most Indians tend to construct tortuous sentences, which fail to convey their intended meaning. Learning to write short, crisp sentences would likely help them to clarify their messages.

The current scenario offers better prospects than did the 'teething' years for the quality of medical writing in India. Now that it is approaching a decade since regulatory medical writing began in India, a good number of writers have gained valuable experience as a result of working in different companies that undertake medical writing. Such companies include Western pharmaceutical companies, Indian information technology (IT) companies, Indian subsidiaries of Western IT companies, Indian

contract research organisations (CROs), or Indian subsidiaries of Western CROs.

Indian medical writers and their employers have one more challenge to overcome, that of the relatively high attrition rates. Writers switch jobs in search of quick pay rises and people management roles. In the process, they neglect to hone their writing skills and become a true expert in the field, which usually takes a few years spent just writing. At the same time, employers need to give their writers adequate recognition and timely rewards so that they continue to develop their key skill – writing.

Conflicts of interest and disclaimers

The author declares no conflict of interest. The views expressed by the author in this article are personal and do not necessarily represent the views of any organisation with whom the author may be associated.

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briefing books, and regulatory responses. His prior experience in medical writing in India is with a large Indian IT company, and a large non-Indian pharmaceutical multinational company. Salil has a Bachelors' in Human Biology and a Masters' in Pharmacology and also studied toward his PhD in Cancer Biology.