From researcher in Europe to medical writer in India

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Abstract

This is an article about my returning back to India from Europe and transition from research career to a profession of medical writing. I was introduced to medical writing through European Medical Writers Association (EMWA) while I was in Europe. After a PhD degree and postdoctoral experience in Europe, I returned to India and started anew as a medical writer at a knowledge process outsourcing company. My training period in the company involved introduction to company ethics and policies, different topics of medical writing, and functional approaches. Working on client-specific projects required training in their processes and business rules. In the company, I experienced an open work environment and helpful colleagues. On the projects I was able to use several skills that I learned while in research. I faced a steep learning curve in different therapeutic areas, reports, and client's expectations. Medical writing in India is still developing. The challenges include getting acknowledged for manuscript writing, standardization of rates for work, and for training courses.

Keywords: Medical writing in India, Knowledge process outsourcing, KPO

Genesis of a medical writer

Medical writing was an unknown profession for me until I discovered the European Medical Writers Association (EMWA) website during my PhD tenure in Germany. I took a chance and opted to undertake certification in medical writing with EMWA. The EMWA courses exposed me to the intricacies of drug development, clinical research, and medical writing. They also covered diverse topics including global healthcare facilities, regulatory compliance, and patients' rights and awareness in different countries.

As an Indian I could immediately see the advantages that India has in this field, not only as a big market for global pharmaceutical companies but also as an outsourcing destination, that can provide skilled and relatively inexpensive English-speaking talent for all stages of clinical research and documentation. I observed that there are reservations in Europe about outsourcing this type of work because of concerns related to the quality of the work and the impact of outsourcing on local job availability.

I took up a post as a postdoctoral researcher in the UK after completing my PhD in Germany, and my quest for medical writing continued during my full-time research jobs. However, my wish to shift to medical writing came true only on returning to India, my homeland. Luckily for me an article I wrote for *The Write Stuff* ('Going Home')[1] led me to my present position as a medical writer.

My first job as a 'medical writer'

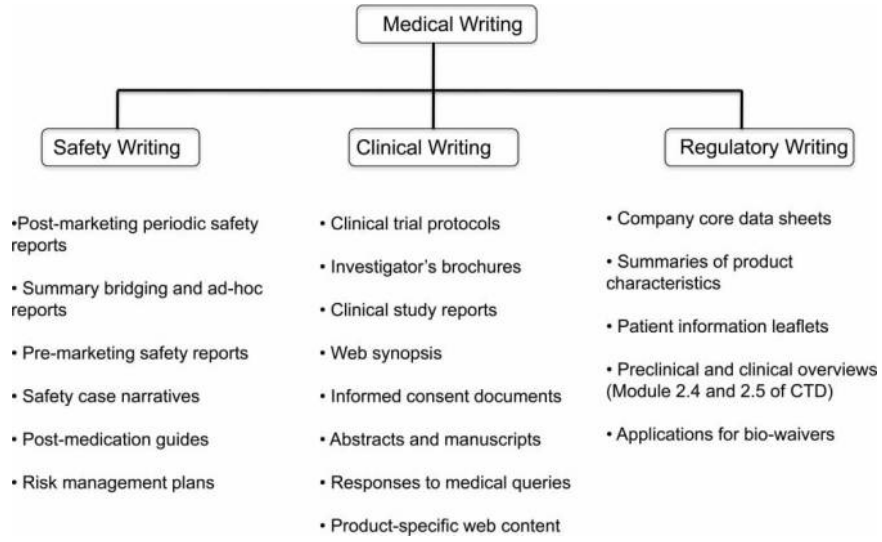
Armed with research experience in chemistry and a medical writing certificate from EMWA, I started life as a medical writer at Sciformix, India. Sciformix is a knowledge process outsourcing (KPO) company working specifically for global pharmaceutical and biopharmaceutical clients. I found it easy to blend in, as the organization is a close-knit group of about 250 people, from diverse backgrounds. We work in different fields such as biometrics, medical writing, safety and risk management, regulatory affairs, and clinical operations, but we all interact.

The medical writing team here is involved in preparing a range of clinical documents of varying complexity both for local and for global clients as shown in Scheme 1.

My training period

On joining the company I spent a few weeks as a trainee. Along with other new employees, I was given general training on company background and ethics. Senior medical writers provided training on aspects of medical writing ranging from the general (ICH-GCP overview) to the specific (editing and proof reading). Thanks to the EMWA

DOI: 10.1179/204748112X13303569555628



courses, the terminology and processes involved in medical writing were familiar.

First assignment

I was assigned to an ongoing project and was given time to understand the processes before starting production. I had to go through style guides and business rules provided by the client and the references related to the therapeutic area assigned to me. My first draft was carefully reviewed by my project leader and coach. By now, I was getting to know the importance of the client's template, subject content, scientific balance, style guides, and the importance of 'word count'. The document was reviewed by a subject expert who provided the necessary medical input. On incorporation of all the comments and after another level of peer review, my draft went through rigorous editing and proof reading before being sent to the client. As a result of the continuous evolution of the processes involved in medical writing, I can see that external workshops and training at client sites will form part of a continuous learning process.

Work environment and colleagues

I find it helpful that I can approach anyone in the team, just as in Europe, and that extra care is taken to synchronize the interests and knowledge of individual writers with the requirements of a project. Work pressure is evident as maintaining 100% time compliance is a very important criterion for a service provider. Every day I plan my time for expected deliverables but I also need to be open and flexible, especially when contributions from various authors and reviewers are required for regulatory documents. I am learning methods of tracking metrics in real time. Filling up time sheets at the end of each day provides a reality check of how much time is required to prepare a document and how much more goes for communication with the team (internal and external), literature search, planning, etc.

Interacting with colleagues constitutes a major part of working life. I see many colleagues at a time and they come from different backgrounds such as medicine, pharmacy, clinical research, statistics, and software. It is refreshing to work with people who see the world from a different perspective. I find working in a KPO to be truly multifaceted.

Projects coming my way

While working on postmarketing periodic safety reports, company core data sheets and responses to medical information queries, the skills honed during my research career proved helpful – literature searching, analysis, and review of articles on the basis of evidence, sorting out relevant articles, understanding them and their systematic presentation are required in all these projects. An eye for detail (another skill acquired during my research career) is coming in very handy in medical writing. I am also learning to modify my writing according to the target audience, which ranges from regulatory officials and healthcare professionals to the general public.

Learning curve

In a client-servicing company, I often face a steep learning curve in terms of my ability to draft and review complex documents, and to understand the different therapeutic areas. I am keen to develop

my understanding of required therapeutic areas and documents types, and to start contributing to projects as early as possible. I go back to the material and resources from the EMWA courses to refresh the basics before starting each new project.

Working with clients in different time zones who speak with different accents is a common challenge in a KPO. The relationship with the client is primarily based on virtual communication so it is essential to take extra care with email etiquette and accent-free English pronunciation.

Current challenges faced by the pharmaceutical industry compound the challenges faced by the service provider industry due to uncertainty about project scope and timelines. In spite of that, it is important that everyone keeps working diligently and builds a level of confidence and understanding with clients for future projects. Deadlines in a KPO are certainly more stringent than in academia.

Medical writing in India

Medical writing is still maturing as a profession in India. Regulatory writing is primarily done according to client specifications. In the case of manuscript writing, however, authorship roles and acknowledgement of medical writers are still under consideration. EMWA[2] has clear guidelines about the role of a medical writer in a publication. However, the acknowledgement of a medical writer's role in manuscript writing is still a challenge in India. Freelancers, KPOs, and clinical research organisations in India need to come together to start a trend of acknowledgement. A national platform for medical writers was much needed in India to raise questions and solve issues of authorship and standardization of remuneration rates in medical writing. Moreover, training courses for individuals wanting to join the medical writing profession are few and far between, and are sorely needed. Looking at these needs the All India Association of Medical Writers (www.freewebs.com/aimwa/) has been founded recently.

Its development is still at an early stage and international associations like EMWA can share their experience and help this association to give a strong platform for medical writers in India.

Disclaimer

All the views presented in this article solely belong to the author.

Acknowledgement

I acknowledge Ms Sushama Natu (Sciformix) for her suggestions and comments during the preparation of this article.

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Chandrima Pal received her PhD in Biophysics from University des Saarlandes, Saarbruecken, Germany. She did postdoctoral research from University of St Andrews, St Andrews, UK. She is an EMWA certified medical writer. She worked as a freelancer for a short period and is now working as a medical writer with Sciformix Technologies Private Limited, Pune, India.