

Pharmaceutical writer or CRO writer – choosing the right path

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Abstract

The career choice is an unavoidable topic for those scientific graduates or experienced professionals in the areas of medicines or the pharmaceutical industry. The career of medical writing offers a series of career possibilities for the individuals with degrees in sciences or experienced professionals in the areas of medicine or the pharmaceutical industry. This article offers insights on starting and developing a medical writing career from the perspective of a writer in China who has worked in both clinical research organisations (CROs) and pharmaceutical companies. The variety of business needs, the requirements of key stakeholders, and project goals in the pharmaceutical companies and CROs lead to differences in the work styles and paces, prospects for career development, and pathways that allow talents to flourish in the field of medical writing. Similarly, the various writing roles lead to more opportunities of career choices and transitions.

Background information

The area of medical writing is still an unknown area for many professionals who have a wealth of experiences in the pharmaceutical industry or clinical practice, even though China experienced important developments over the past 20 years in the area of medical writing. When you ask your medical peers to describe the position of medical writer, it has been my experience that medical writers are described as a group of people who are only familiar with copying and pasting data and text from others' works, correcting spelling

errors, or drafting tables or figures without being proficient at writing original scientific papers or regulatory documents. As a scientific writing professional, I fully understand that what we can do is sometimes completely beyond people's expectations and imagination.

However, as medical writers, there is little doubt that we have opportunities in a burgeoning industry. The needs of the global medical writing market have shown continuous growth, and the writing business in 2008 doubled since 2003, reaching \$694 million in 2018.¹ In a report that was published by the Nature Index 2015 – Asia-Pacific – Japan, South Korea, and Australia lead the way in the number of original scientific papers, followed by China, which has significantly more than that of India.² Although we have no published statistical data on the business market size of medical writing in China, the importance and weight of the career have already been fully endorsed by those peers with collaborative experiences.³

My writing journey

For me, being a scientific writer has proved to be an important career choice after graduating from medical school. Even after more than 10 years, I can still recall the images of being in the classroom of the annual meetings of EMWA and learning how to present data in a figure when I was just a junior medical writer. I feel fortunate to be able to do what I love. Work experiences in the pharmaceutical industry and clinical research organisations (CROs) have allowed me to understand the values and potential of the career. These developments have brought me lifelong growth and positive collaborations with peers and key opinion leaders in clinical practice. Here I would like to share some of my experiences and my understanding of the roles and responsibilities of writing professionals who work for the pharmaceutical companies or CROs. I hope that the information can be “road signs”, particularly for those who are interested in exploring the areas that may once have seemed to be “scientific writing deserts”.

With regard to the business needs and technical skills, potential options can include both pharmaceutical writers or CRO writers.⁴ Medical writers in pharmaceutical companies

offer technical supports on preparing regulatory or regulatory-related submission dossier documents and scientific publications. The pharmaceutical companies – as the research and financial sponsors – are responsible for developing product pipelines and are the purchasers of technical services. Therefore, in pharmaceutical companies, medical writers are responsible for monitoring project progression and quality of writing projects. Most writers in pharmaceutical companies have master's or doctoral degrees in a medical or biological field, and some have developed expertise in clinical practice or medical research before pursuing a professional role. In preparing manuscripts and regulatory documents, writers collaborate with physicians, researchers, statisticians, or other medical professionals from start to finish.

The responsibilities of the medical writers in pharmaceutical companies include writing documents while serving as project coordinators, process controllers, and decision makers on writing topics. As per the business needs of the writing projects, the writers need to be equipped with regulatory or publication knowledge. In the past 10 years, given the confines of budgets and changes in general in the structure of research organisations and the pharmaceutical industry, more and more pharmaceutical companies prefer to delegate some parts of research and development (R&D) works to third-party service providers.⁵ The third-party service providers (CRO companies) employ professional scientific teams to work with the pharmaceutical companies on accomplishing regulatory, operational, and statistical goals, or on writing projects. For writers in a CRO, the job mainly focuses on drafting documents, coordinating review cycles, and working with the sponsor contacts to finalise and archive the documents.

Here readers who are new to this industry may wonder what the key differences are between the careers of medical writing in the pharmaceutical companies and the positions of the CRO companies. I would answer this question by first describing the relationships between the two types of organisations. When a pharmaceutical sponsor decides to outsource writing projects, they would first generally screen, evaluate, and recruit potential service providers.



After all the resource allocations are settled with a formal business contract between the pharmaceutical sponsor and the service provider(s), a writing project kick-off meeting would be held before the project is initiated. In the meeting, all the project procedures, timeline, stakeholders, and splits of responsibilities would be determined. Afterwards, the offsite medical writers would be responsible for drafting documents, coordinating their reviews, consolidating comments, and updating/finalising the documents. On the other side, the responsible project manager(s) or medical writer(s) from the pharmaceutical sponsor would serve as the contact for coordinating the external clinical investigators' review comments and those comments from the internal teams of the pharmaceutical sponsor. Once the paperwork is finished, the sponsor will electronically archive all the drafts and the final version of documents with traceable version numbers and dates.

The key differences in the career of medical writing are reflected in business and research needs, technical requirements, and career development. From the perspective of the pharmaceutical sponsors, they prefer cost-effective service providers who can offer high-

quality writing, while CROs prefer to maximise revenues when they negotiate project fees with pharmaceutical companies. Within pharmaceutical companies, medical writers are expected to understand compound strategies, regulatory affairs or publications, be skilled in time or project management, and budget planning, etc., while CRO writers may need to be more detail-oriented and possess a higher level of writing skills. The CRO writers should be capable of performing multiple writing tasks within a short time; they should be able to learn new topics quickly by themselves and work efficiently with sufficient document quality under pressures from picky clients. Additionally, CRO writers need to have good emotional intelligence, be adept at building positive customer relationships with the pharmaceutical sponsors, and be able to negotiate project timelines and prices. The career development track in the pharmaceutical companies offers the prospect for junior medical writers to become

technical experts/leads or performance managers/directors. Those who are not interested in the writing aspect after their initial experiences could have other opportunities to accept other positions (e.g., project manager, or regulatory affairs specialist). In CROs, there are similar

writing career pathways as those of the pharmaceutical companies. The

main difference is that CRO writers have a better chance at branching out into business development or taking on a consulting role if their talents lead them there.

Regarding career recommendations, I can offer some personal reflections to those newcomers in the field of writing with what I have experienced in over a decade. I advanced

from a junior writing role in the pharmaceutical companies after I completed a clinical medicine degree and a master's degree in molecular pharmacology. At the beginning of my career, I focused on a single therapeutic area and was responsible for drafting documents of simple clinical study reports and scientific publications.

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After 5 years, I became a writer in multiple therapeutic areas and found opportunities where I could be involved in those complex projects. After 9 years of deep involvement and being familiar with rapid work paces in the diverse therapeutic areas, I received a job offer from a prominent CRO. During the initial 6 months of my CRO journey, I was frustrated with the differences between the pharmaceutical companies and the service providers, due to rather accelerated work paces (even for an experienced writer), completely various business perspectives, and diverse client tastes. Therefore, in my point of view, I do not necessarily recommend that new writers initiate a writing career from a CRO since you may not have the opportunity to develop writing skills and gain a deep knowledge of compounds and diseases. Instead, you would move from one project (client) to another very quickly without adequately “digesting” what you learned. If you do have to begin your writing career from a CRO, you should take stock of your career progress at regular intervals to make sure that you are not burned out before you become a well-rounded writing professional.

At the beginning of a career, I suggest junior writers focus on understanding the industry, developing basic skills of writing, and increasing their knowledge of (pre-clinical or clinical) research and diseases, at the same time, working on building up long-term collaborative relationships with your colleagues, clients, or clinical investigators. The experiences would give you

more confidence on the career track of medical writing and these valued relationships could bring in more businesses and potential clients, benefitting you down the line. If writing for pharmaceutical companies is your first job, I suggest that you place equal weight on increasing your knowledge as on developing your writing skills. Given that the pharmaceutical writers have opportunities to experience all facets of the R&D process, being versatile is important for your career development.

For instance, in pharmaceutical companies, you have the chance to be a part of planning scientific publications, interacting with colleagues from marketing and regulatory affairs departments, consulting on product launches and indication applications, or post-market product reimbursements. You can also participate in compound developments via writing projects in collaboration with third-party service providers. Working independently in the field of medical activities depends on how much you can invest in your career development and what your career expectations on your writing roles are in the coming 5 to 10 years.

Identifying clear career goals should be a priority for aspiring writers. With approachable career milestones in mind, junior writers are recommended to ask your managers or bosses for a reliable writing coach wherever you work, set a series of growth plans with your coach, and have a system of follow-up actions on your career progress. If your rate of growth exceeds your

bosses’ expectations, you will have more opportunities to be involved in complex projects with higher priorities. At that time, please stay focused, do not overestimate your capabilities, and remember to develop your career strengths, rather than trying to be a jack-of-all-trades. In addition to developing your writing ability, please join one or more writing communities or organisations to stay in touch with industry developments and network with your peers. The regular communications offer you more career possibilities and a sense of being part of a collaborative family.

“Rome wasn’t built in a day.” Through a medical writing career, you are developing as an assistant in medical research, as a leader in scientific communications, and as a valuable contributor to pharmaceutical businesses. In China, most writers prefer to develop their careers in pharmaceutical companies, rather than CROs because of the size and growth of the pharmaceutical company employment market. In recent years, the CRO industry has been growing substantially faster than global forecasts, but growth in R&D spending in the pharmaceutical industry has been especially strong, and is estimated to reach \$39.3 billion in 2022.⁶ Along with an increase in the R&D budgets, the employment market of the CRO industry will expand and a number of R&D positions will be available for scientific graduates or experienced professionals. The need for medical writers will increase along with the trends, which will also

result in more career opportunities in CRO companies.

As the industry evolves, the employment possibilities will continue to expand. As scientific graduates, junior writers, or senior professionals, we should seek to improve our individual capabilities, broaden career visions, and be prepared for any changes in the profession. As a 14-year practitioner, with similar goals as other medical writers, I am confident that the profession will become even better known and well-regarded and it will definitely have a bright future in the century filled with historic changes.

Conflicts of interest

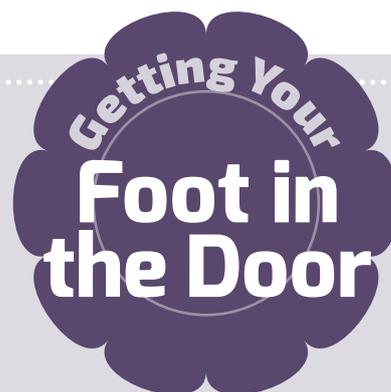
The author declares no conflicts of interest.

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Yan Zhou, MD, MSc, PMP, ISMPP, has been a scientific writing professional since 2005, a witness to the expansion of medical writing in China during this time.



How Janet Douglas did it

Before I got into medical writing, I worked as a veterinary surgeon in universities and referral institutions, did research (and hence wrote scientific papers), and wrote on veterinary topics for animal owners. But after finishing my PhD I was at a career crossroads. I loved to write and wanted to stay involved with science, but I didn't feel cut out for a future in research. This coincided with a move to a country where I couldn't practice veterinary medicine and the arrival of a baby, which made working part-time and freelance an attractive option.

Luckily for me, a veterinary colleague who had moved into the pharmaceutical industry needed a writer to prepare a series of manuscripts describing the primary clinical trials of a new veterinary product. I worked on these papers for almost a year, and realised that this blend of science and writing suited me well. Unsure where to find more writing work, it became apparent that the veterinary writing market was small but that medical writing was in demand.

Feeling wholly underqualified (because I am a vet, not a medic), I approached a medical communications company (medcomm) who evidently saw something they liked in my rather unusual background. Unwilling to commit to a full-time job, I held out for work-from-home – i.e., freelance work. As a trial, I wrote a review manuscript for them that evidently passed muster, and I subsequently worked for this company for many years.

Working for the medcomm, I quickly realised that you don't need to be a medic to do this job well – you just need to be



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able to figure out what you don't know, then go and find it out! I have been figuring out what I don't know, finding it out and writing it down for over 20 years now, and it has stood me in good stead as an interesting and flexible career.

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Abe Shevack's story

To retire or not to retire: that is the question.

My career in medical writing started relatively late. After working in basic research for many years in both academia and industry, I decided to change my career. I was introduced to medical writing in an unusual place. One evening, while exercising in the company gym, I overheard a conversation between two fellow employees. One of them was talking about being a medical writer. We spoke at length and afterward, I decided to apply for a position in the company and took a writing test. I was hired as a regulatory medical writer in the clinical development department. This started a career that has spanned more than 20 years where I have worked in a wide range of clinical indications. It was thrilling to have worked in so many areas and collaborating with all those interesting people. I have many wonderful memories such as the beer mug that I received from a German pharmaceutical company in appreciation for my helping with a submission.

Time flew by and I reached retirement age at Bayer in 2016. My colleagues organised a farewell party and laudatory words were spoken with toasts to my good health. Although I greatly appreciated this recognition, I still thought about having no plans for the future. Would I be happy just lazing on a hammock and catching up on my reading, watching movies that I missed, going to concerts, swimming at the local gym, and making entries in my long-neglected history of science blog? Or did I need something more?

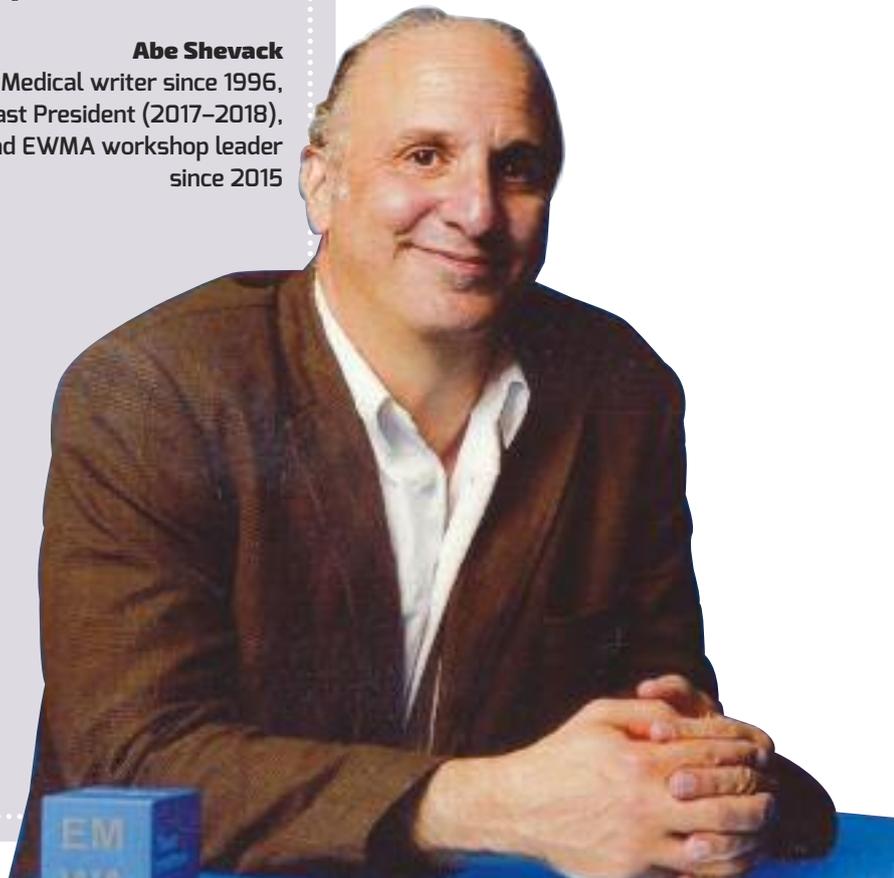
As it turns out, I have had no problem keeping busy due to my involvement with EMWA. I developed a workshop for the Brussels conference which I continue to enjoy presenting. And then to my surprise, I received a call later in 2016 from the EMWA executive committee (EC), asking if I would consider running for Vice-President (the prerequisite for becoming President in the following year). I felt very

honoured by their trust and after due consideration I agreed. The two years of my tenure on the EC flew by and kept me amazingly busy. The experience was both enjoyable and challenging and I have grown to appreciate how well EMWA functions with the help of so many talented and committed people.

At around this time, I started my own medical writing consultancy and am in the fortunate position of being able to select short-term projects that I find interesting.

Whether or not to retire is a question we will all need to answer someday. Some may say that they would like to enjoy their leisure time and do all those things they weren't able to do during their professional lives. Others may feel the need to keep busy, perhaps taking on fewer responsibilities but remaining open to new challenges, while having free time to follow one's own interests. I believe everyone wants to feel useful, but ultimately it is up to each of us to make this important transition as we see fit.

Abe Shevack
Medical writer since 1996,
EMWA Past President (2017–2018),
and EMWA workshop leader
since 2015



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