The medical writing landscape in China

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Abstract
The Chinese medical regulatory writing and medical science writing landscapes are changing rapidly. Changes in regulatory reforms continue as China further strives to align its pharmaceutical industry with the world, which necessitates collaborative writers who are capable of keeping up with both changes in regulations and innovative medicine. Medical science writing is dependent on the adaptation of the material to suit Chinese media platforms. Despite the vast differences in regulatory writing and medical science writing, the essential skills are similar – understanding data and knowing one's audience.

Introduction
Medical writing exists on a broad spectrum ranging from regulatory medical writing to medical science writing.[1] Therein, the corresponding drivers of trends in medical writing span from regulatory changes to new discoveries and cultural changes. Extensive reforms in regulations since China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as a new Regulatory Member have inevitably changed the clinical development landscape countrywide, and of course, everything related to document preparation for the regulatory medical writer.[2,3] Contrastingly, medical science writing – the dissemination of scientific and medical information to the general public – is largely determined by the language and medium through which communication occurs and these revolve around culture and trends. This article explores the recent trends in medical regulatory writing and medical science writing, as well as the essential skills to becoming a successful medical writer in China.

Medical regulatory writing trends in China
Brief history of medical regulatory writing
Regulatory medical writing is a relatively new profession that has emerged and taken off in China. According to Dr Ning Zheng (2018, personal interview with N. Zheng; unreferenced), Medical Writing Associate Director at *dMed Biopharmaceuticals* (a contract research organisation in China), China has been "repeating the history seen in Europe and the US, where clinical research physicians (CRPs) also prepared documents and medical writing was not a distinct profession". It was considered strange that you needed someone to help you develop a document and it was also "difficult to persuade management as to why you needed a special writer". Although it is true that CRPs can write, medical writers may express the idea more clearly. Amidst the work that many CRPs have (medical monitoring and communicating with principal investigators), they may not necessarily have sharpened and honed their writing skills. "As medical writers, we write every day, hence we have more experience, but we still need input from physicians because they have the therapeutic expertise". Indeed, the medical regulatory writing profession has grown in China in recent times as more and more companies see the value in outsourcing work to medical writers or even having an in-house team.

Dr Nan Wang, Head of Global Medical Writing at *Bayer HealthCare (China/Finland)*

(2018, personal interview with N. Wang; unreferenced), added that as "regulatory requirements became tighter and with research and development on the rise in China" there came a "bidirectional need" for efficient clinical development: global pharma companies needed to start adhering to the more stringent regulations, meanwhile local companies wanted to go global. As such, "a strong market need for medical writers" has arisen; however, not only was there a "limited" supply of writers, everyone was also rather "inexperienced". This is how the scattered regulatory medical writers of China came together in 2014 and formed a medical writing community. The group is active on *WeChat* and has become a platform for knowledge exchange. They also represent Chinese medical writers and help bridge Chinese medical writers with the world. At the time of writing, the community contains an avid group of 400-500 members.

Recent regulatory changes

Rapid changes in Chinese drug regulations call for changes in document development for a medical writer. In early 2018, the National Medicinal Products Administration (NMPA) implemented five secondary ICH guidelines (Notice No. 10 2018): M4, E2A, E2D, M1 and E2B (R3).[4] E2A, E2D, and E2B (R3) define standards for safety reporting. For medical writing, the implementation of M4 is a big step because it calls for the use of Common Technical Document (CTD) modules for the submission of documents. This year, the NMPA has started to ask for public comments on electronic CTD implementation.[5] All these guidelines call for more efficient document handling and transferability in documents across regions worldwide.

A major change in the procedures for investigational new drug (IND) applications /new drug applications (NDA) (Notice No. 50 2018) also came in 2018.[6] This was followed by procedures on setting up a pre-IND meeting (Notice No. 74 2018).[7] Briefly, the optimised IND and NDA approval times are now 60 and 150 working days, respectively. This allows companies to consider involving the Chinese market early on during pivotal developmental stages. Further, a single IND approval is valid from Phase I through to III. To further close the gap, the Centre for Drug Evaluation released a List of Urgently Needed Overseas Drugs – drugs already approved in Japan, the EU, or the USA – to allow direct market application for said drugs as long as ethnic insensitivity can be demonstrated.[8,9] These changes directly affect the overall timelines for document development with which medical writers are normally used to in China; the average waiting time for an IND application was 14 months between 2013-2015.[10]

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Joining the ICH has led to a more stringent regulatory environment, while opening doors for truly innovative new drug development and opportunities. Being able to comply with the ICH guidelines, while keeping up with the fast-changing landscape and retaining document quality, has become more important than ever.

Essential skills for the medical regulatory writer

Ning revealed that the title Medical Writer can be "misleading" because writing is a must – you need good grammar and the ability to express logically; however, other skills include "attention to detail" and the ability to "keep calm under stress" (2018, personal interview with N. Zheng; unreferenced). More importantly, project management plays a bigger part and is the more challenging aspect to medical writing. Some examples Ning mentioned include how to "manage reviewers especially when they do not follow your timeline", how to "engage your project team" to complete tasks, how to rise above "cultural challenges" when working in international teams, and how to "manage stakeholders who are often of higher seniority than you". These all boil down to effective communication and coordination.

Nan agrees and further explains that medical writing is a "cross-discipline job where you need to communicate effectively with others, while controlling, managing, and finding risks to complete a project" (2018, personal interview with N. Wang; unreferenced). Being a fast learner to grasp the crux of a project while not being the subject matter expert is very important. As Nan

recalled, "being able to design or contribute to the design of a protocol may not be that important for a writer; instead, the ability to 'borrow' another person's knowledge to complete a project is more important. To me, this was a difficult thing to do in the beginning". She reasoned that when you write a document, the document is not the limit. "Frequently, it encompasses an entire therapeutic area and learning is infinite. So, what is actually more important is the ability to use the right resources effectively in the limited time to complete a project".

Science writing in China

Brief history of science writing

Science writing (also known as popular science in China) is the dissemination of scientific content to the general public. Science writing dates back to the late 1940s and was initiated by The Ministry of Culture, which stagnated during the Cultural Reform between the 1960s and 1970s.[11] After the 1970s, the Chinese government encouraged science associations to disseminate scientific findings to the general public so that they can benefit from it through lifestyle changes. With the advent of technology and as China started to open up, science writing took off since information was no longer propagated only by the government and professional associations. Over time, the public's engagement has risen[12] – in the age of information, publishers, science communication agencies, and even the public have joined in.

Science writing, particularly with regard to medical content (medical science writing), in China is much like science writing in other parts of the world. Mingyue Jia, a medical writer at *Guokr* (a science writing agency in China) (2018, personal interview with M. Jia; unreferenced), commented that the purpose of science writing is "to provide the public with general health-related and medical knowledge", such as common diseases, remedies, how to overcome certain diseases, how to communicate with the doctor, and shed light on doctors' perspectives. "It is a platform for communication". Articles are varied and range from general information to cutting-edge research. Mingyue mentioned that many of the articles they worked on are sourced from overseas; these can be both journal publications as well as articles written by other science writing agencies. The key to science writing is the fine balance between "accuracy and attraction". For Mingyue, analogies, adapting for cultural differences, and relevance are key to drawing their readers' attention; this is the fun and artistic side of medical journalism. "Just laying out the hard facts and jargon will bore the reader". She mentioned that one of the biggest differences in science writing between China and the US is that the US has a longer history and a more solid foundation. This can be attributed to the fact that high impact science journals are in English making it easier for science writers to "rewrite" the original source into an article that can be understood by a lay audience. In China, original materials in English have to be translated and cultural differences, habits, and relevance have to be considered. These are all key to public outreach, which, in modern times, revolve around social media.

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Platforms for dissemination in China

In recent times, China has shifted from website-based dissemination to mobile-app based dissemination, thereby affecting lifestyle and habits. Contrastingly, most Western societies are used to accessing information via websites. The conundrum is that many businesses in China do not own or maintain a website; instead, they maintain businesses on mobile platforms (such as *WeChat*), and the contents of the mobile platform are only accessible on the phone and not through websites. Imagine a version of *Facebook* or *Twitter* where the posts you post and read are only available while using the cellphone app. Mobile-based platforms are the default in China. You may find booking an appointment at a hospital difficult because the hospital may not necessarily have a website or that the website may be outdated. However, if you search for them using *WeChat*, the hospital may have a *WeChat* mini-programme through which you may find updated information, book an appointment, and find relevant reviews on different doctors.

Not only does success in getting information lie in navigating the different methods of social media use but so does success in informing. A study showed that retweets on *Weibo* (a Chinese social media platform) were higher than retweets on *Twitter* by several orders of magnitude; therein, pictures, videos, and links accounted for a large percentage of the tweets.[13] This is because trends in China are largely set by the public retweeting content while trends on *Twitter* are often attributed to news sources or information from organisations that people follow. So, if you want to run a successful campaign in China, you need to consider the difference in practice.

While most of the world uses social media platforms such as *Facebook, Twitter, YouTube,* etc., China uses its own versions of social media platforms as a result of nationwide regulation of the internet (i.e. *The Great Firewall of China*). The most common are *Weixin* (or *WeChat*), *Sina Weibo*, and *Tencent QQ*. If we look at the figures, to quote Gary Liu (CEO of the *South China Morning Post*) from his *Ted Talk,*[14] "By the end of 2017, the Chinese internet population had reached 772 million users. That's larger than the populations of the United States, Russia, of Germany, of the United Kingdom, of France and Canada combined. Ninety-eight percent of them are active on mobile. Ninety-two percent of them use messaging apps. There are now 650 million digital news consumers, 580 million digital video consumers, and the country's largest e-commerce platform, *Taobao*, now boasts 580 million monthly active users. It's about 80 percent larger than Amazon". This is a huge untapped market for non-Chinese companies! Beside the language barrier, which can be easily overcome by translators and interpreters, another challenge lies in navigating the Chinese internet, and this is crux to success in the Chinese market.

Essential skills for medical science writing

For those interested in medical science writing, Mingyue mentioned that "good writing skills" are a must (2018, personal interview with M. Jia; unreferenced). Considering that some of the articles are published in English journals, good English skills are also a prerequisite. Although a medical background (for medical-related content) is preferable, those without a medical background must be able to grasp the concepts easily and possess good reasoning skills. Most of Mingyue's colleagues have either a Bachelor's or Master's degree. Since medical science writing targets a wider audience, the ability to engage and connect the dots through wordsmithing, storytelling, and creative metaphors are essential. Finally, depending on the purpose, being able to use and navigate Chinese social media platforms is a bonus.

Conclusion

The medical writing landscape is changing rapidly in China. For regulatory writing, being able to keep up with the rapid changes in local regulations while working with the team to develop documents are essential. Luckily, a very active group of Chinese regulatory writers are there to support each other. For medical science writing, the government has passed the popularisation of science ball onto publishers and the public. Being a compelling storyteller and engaging the audience on relevant platforms to pass on jargon-heavy and difficult concepts easily are critical. The common essential skill is to deliver the message most efficiently to very different target readers – health authorities for regulatory writing and the public for medical science writing – even though the data behind could be the same.

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The opinions expressed in this article are the author's own and not necessarily shared by her employer or EMWA.

Conflicts of interest

The author is employed by dMed Biopharmaceuticals but the views and opinions in this article are entirely her own.

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