Medical Writing in
CHINESE

Language-specific considerations for Chinese regulatory medical writers

Working as a medical writer in China (specifically, as a regulatory medical writer), we are expected to support regulatory submissions. Examples of these submissions include: clinical trial applications (CTA), investigational new drug (IND) applications, new drug applications (NDA), and biologics license applications (BLA). These are addressed to various major authorities (e.g., the US FDA and the EMA), while we must also priortise submissions for the China National Medical Products Administration (NMPA), where Chinese is the official language. As a result, Chinese medical writers face a unique set of challenges because we must be capable of producing regulatory documents in both Chinese and English with equal proficiency.

For global submissions, Chinese medical writers typically write regulatory documents directly in English, just as writers in other regions do. However, for regulatory submissions in China, the process can be more complex. When the project team includes non-Chinese members, writers often draft in English and then translate the final document to Chinese. Alternatively, writers may discuss study results and align content strategy in English, then draft documents in Chinese with China local teams directly.

As non-native English speakers, Chinese medical writers encounter several language-related challenges. Grammar and syntax pose typical difficulties. For instance, determining when to use articles like “the” can be challenging for junior writers, as Chinese lacks this grammatical feature. Similarly, errors in tense usage frequently occur due to the absence of specific tense distinctions in Chinese, in which time is often implied by context rather than explicitly stated through verb forms.

In terms of content and expression, there's a risk of directly translating Chinese language logic or fixed expressions that do not exist in English, which can lead to inaccuracies or ambiguities. For example, a statement in Chinese Clinical Study Reports is: “在治疗组A (treatment group A) 中 (in) 变量X (variable X) 的 (of) 下降 (decrease) 具有 (has) 统计学 (statistical) 意义 (meaning) 和 (and) 临床 (clinical) 意义 (meaning)”. A Chinese writer might translate the sentence from native language directly to English as "In treatment group A, decrease of variable X has statistical meaning and clinical meaning”. However, a better English expression would be: "In the treatment group A, the decrease in variable X was considered both statistically significant and clinically meaningful".

To enhance language skills, Chinese medical writers often use ongoing projects as opportunities for practice. We request support from native English speakers who act as document quality reviewers, using their insights to refine our language use. Additionally, medical writers also utilise technology tools such as Microsoft Word Editor, PerfectIT, or AI tools for language checks, leveraging these resources to improve the accuracy and fluency of writing.

Supporting simultaneous submissions for China’s NMPA alongside other major regulatory authorities presents additional challenges (i.e., China submissions for global trials where China joins at the same or later points in time). Chinese medical writers frequently serve as a bridge between local China teams and global project teams, facilitating clear and efficient bilingual communication. Additionally, writers must ensure consistency between Chinese and global submissions and guide the team to make informed decisions about the primary language for authoring China’s NMPA documents based on project specifics. If English is the primary language for authoring, writers should consider the language differences between Chinese and English, prepare the documents concisely for better translation efficiency, manage translation processes and timelines, and assist regulatory affairs teams in ensuring accurate Chinese translations and language consistency across documents.

In addition to improving English language skills, Chinese medical writers play an important role in harmonising regulatory submissions between China and other regions by continuously enhancing bilingual proficiency and cross-cultural communication skills.

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