

Meeting Global Guidelines in New Markets

INTRODUCTION

Companies operating in all sectors of the medical industry are well aware of the importance of accurately interpreting clinical trial results in order to obtain international regulatory approval for their drugs and medical devices. Since many of these trials and studies are conducted in foreign languages, it becomes crucial that the results are accurately translated back into English and any other required languages. MedDRA, or the Medical Dictionary for Regulatory Activities, is designed to be the global standard for medical terminology and product development processes for the global market. The U.S. FDA has implemented MedDRA to help define its Adverse Event Reporting System (AERS) while European authorities use MedDRA as a key part of their electronic database systems.

When the MedDRA database first debuted, it only provided multilingual terminology for six languages: English, German, Spanish, French, Portuguese, and Japanese. However, a leading pharmaceutical manufacturer wanted to extend its use of MedDRA to include Simplified Chinese. The company contracted CSOFT to supply the entire translation into Simplified Chinese and provide updates for the six other languages, as well.

CHALLENGE

Medical terminology is highly technical and requires substantial knowledge and subject-matter expertise for accurate interpretation and translation. To obtain precise definitions, each term often requires extensive research and analysis using a variety of medical studies for reference. For this project, the terminology was divided into five different MedDRA levels: SOC, HLGT, HLT, PT, and LLT.

The terms at the SOC, HLGT, HLT, and PT levels represent unique medical concepts or groupings and therefore must be uniquely translatable. No given translation could be used for more than one English phrase even if the phrases re-occurred at different levels. Most – if not all – of the LLTs also needed to be uniquely translatable.

CSOFT's team quickly learned that researching and translating terms was not nearly as time-consuming as ensuring that the complicated hierarchical relationships and interdependencies between all terms were correct, thorough, and consistent. Given the large number of terms (more than 100K), the term relationship checking quickly became the least controlled part of the process.

SOLUTION

Before officially kicking off production, we assembled a designated project team with qualified translators and reviewers, a client service and project manager (CS/PM), and an onsite project team leader (PTL) for this project. Team members used the planning phase to analyze and process all project requirements such as translation instructions, MedDRA background information, and other related references for preparation of project execution.

SPECIALIZED QUALIFICATIONS

Because of the unique requirements of this project, we assembled a team of translators who – beyond our usual minimum requirement of seven years of translation experience – also had professional experience in the medical field, quantifiable training, and relevant subject-matter expertise. Many of them were post-doctoral degree candidates at the Medical School of Beijing University and China Union Medical College (both highly respected institutions in China's medical industry), and other medical professionals. We also selected two senior members of the Chinese Pharmaceutical Association and State Drug Administration (SDA) for translation review, and publishers of major Chinese medical journals such as China Journal of Medicine and China Clinical Journal of Medicine.

In order to meet the client's quality requirements and aggressive deadline, the project team developed a detailed project workflow based on our standard L10N processes to maximize translation quality and efficiency. The following illustrates some of the important components made up this project's localization process:

File preparation

The project manager working with our L10N engineering team prepared a L10N Kit complete with translation tables, client translation instructions, internal life sciences guidelines, schedule outlines, and a list of medical reference materials. This L10N Kit ensured excellent communication and accurate transmission of project-related information to the translation team.

Initial Translation

Working with the localization kit and a list of medical references such as Dorland's Illustrated Medical Dictionary and the International Dictionary of Medicine and Biology, our medical translation team completed the initial translation within the required timeframe. Any translation issues (technical or linguistic questions) were quickly communicated to the project manager and then to the client via CSOFT's standard translation query reporting process.





Review & Editing

Once initial translation was complete, the localized terminology list was handed off to our internal subject-matter review team for proofreading and editing. The review team used the same set of translation instructions and reference materials to proofread the translated terms. All edits and changes were implemented by the initial translation team.

Expert Review

Select portions of the terminology translations were reviewed by outside experts from China's State Drug Administration. Since the MedDRA database demanded the highest quality translations, the Expert Review cycle ensured that our translations had the professional accuracy required by the State Drug Administration. All comments and edits were reviewed by the translation and review teams, as well as the project team leader.

Client Review

As with most projects, CSOFT regularly sent back portions of the translation for client review. In the case of MedDRA terminology translation, we also sent the complete translation for review by our client. With this three-step approach to translation, the client reviewers found no errors in the translated terminology. The project's translation memory was updated, thus ensuring the consistency and accuracy of the client's future translation projects.

Post-Translation Processing

All translated terms for this project had to be thoroughly checked for duplicates and conflicts across the five different MedDRA levels but, considering the number of terms involved (100K) and the complex relationship across the five levels, our team developed an alternative to the usual manual checking solution. Thanks to CSOFT's technical development experience, the project team was able to create a relational database in which the terms were sorted by level and compared automatically. Automating this process not only helped save time and money, but also eliminated potential human errors. Taking advantage of CSOFT's engineering capabilities, the team was able to quickly build a customized relational database to automate the task and the project was completed on time.

CONCLUSION

The MedDRA database was successfully launched in Simplified Chinese on time, under budget, and with the highest translation quality. The client was so impressed with the MedDRA translation and our technical solutions that they decided to use CSOFT's relational database as an independent online and fully searchable multilingual MedDRA search engine for all existing languages.

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