



GUARDING THE GUARDS

Most companies outsource translation, but use internal resources to verify accuracy. But how do you know that your review process passes muster?

by Robert Sprung

The Roman satirist Juvenal wrote “quis custodet custodes ipsos”—who is to guard the guards themselves? This could well serve as the motto for the greatest challenge in multi-lingual labeling today: how do you ensure a robust process for verifying the accuracy of your foreign-language labeling text?

Most medical-device and pharmaceutical companies are outsourcing translation for the foreign text that goes on their labels. It is accepted wisdom that, however rigorous the processes the outsourced language vendor uses, the client must take responsibility for verifying accuracy of translation. Unfortunately, the process of affiliate review (the term we will use to describe a client’s internal processes for approving a translation) is fraught with quality and regulatory risks unless properly managed.

Below we outline some of the major pitfalls that lie in wait.

1. Are the right people reviewing the translation?

Are your reviewers employees or contractors? A contractor will typically not have the depth of knowledge of an employee, and

will also not have as vested an interest in guaranteeing accuracy. Employee status itself is no guarantee of accuracy. Many companies will have a sales representative or secretary review the text—a virtual guarantee that subtle technical errors in the translation will not be caught.

Under ISO and GMP, it is important to document training qualifications. Set a guideline for what it takes to review translation, and hold reviewers to this standard. Suggested baseline requirements: 1) fully bilingual in both the source and target languages (if a reviewer qualifies for Spanish, do not assume that they can also approve the Portuguese); 2) professional training and experience appropriate for reviewing technical documentation.

The Bottom Line:

Reviewers should ideally be employees, with direct product knowledge and experience with technical documentation. Keep a file on each reviewer, and document his/her qualifications for reviewing the translation. Keep this file up-to-date in case of an audit.

2. Are reviewers empowered and accountable?

Do reviewers take their task seriously and understand the potential implications of substandard performance—that a translation error on labeling text could potentially result in a recall?

If not, part of the problem might be in their job description. Many companies expect reviewers to look at translations on top of their regular duties, often with no additional compensation. Given that the text to review can be lengthy (an instructional insert could easily total 10,000 words), is it any wonder that a reviewer busy with his or her regular job will bristle at this new assignment? Or that he/she will be tempted to cut corners if a deadline looms for the review?

The Bottom Line:

Realistically determine the review commitment on an annual basis and ensure that reviewers have enough time to thoroughly review text—and are properly compensated for this additional duty.

3. Do you have a yardstick for review quality?

Your translation process should document exactly how reviewers look at text—what sort of errors should they correct, and what things they should leave untouched. A reasonable guideline is that the translation should be a complete and accurate representation of the source text. Note the word “complete”: reviewers should generally not be permitted to add or delete anything from the translation (if you are producing multilingual labeling that will be used in the US, most regulatory experts agree that the translation cannot deviate materially from the English source). Affiliate reviewers often add explanatory text for their local market, or delete text that they consider inappropriate.

Beware when affiliate-review personnel changes. A new reviewer will have different preferences, and might say that a translation is “wrong” that had been approved by a predecessor. Following this reviewer’s request might cost thousands of dollars in redoing previously approved documents.

The Bottom Line:

Have written procedures for the affiliate review, and use a project glossary of standard terms to ensure consistency and minimize the impact of changes in review personnel. Keep a paper or electronic trail that records each reviewer’s approval—this will be important when you are audited. Monitor the quality of reviewers and give them regular feedback.

4. What happens after the affiliate review?

Scrutinize how an affiliate’s requested changes are processed. First, they should ideally be reviewed by a separate native speaker to ensure that none of the problems listed above occur. Second, they should be incorporated into the final layout without additional errors (native-language proofreaders are a must). Finally, the affiliates or similarly qualified language professionals should carefully review printer’s proofs. In one egregious case, I encountered a Chinese label that was translated perfectly—but printed upside-down.

The Bottom Line:

Assume the worst and play devil’s advocate in critiquing the affiliate-review process. You’ll sleep better knowing that your translation approvals truly ensure quality.

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