

Do you feel trapped in an endless, in-country review cycle?
Escape!



EXECUTIVE BRIEF

Five Mistakes in In-Country Review: From Review to Validation

Founded in 1983, Idem Translations, Inc. is a full-service provider of translation and localization services. Idem specializes in certified translations for medical device, biomedical, and pharmaceutical companies, as well as other organizations and entities working in the life sciences sector, such as contract research organizations (CROs), healthcare research centers, and institutional review boards (IRBs). The company is a WBENC-certified woman-owned business and holds certifications to ISO 9001:2008, ISO 13485:2003, and EN 15038:2006

Does your team do in-country review? Does it make you want to tear your hair out? In-country review (ICR) adds significant value to the medical translation process, but is rife with pitfalls that can turn it into a battle of wits between your in-country expert and your translation service provider. Here are some tips to help you keep that from happening.

The Value of In-Country Review

For all their skill and expertise, translators rarely get the opportunity to handle the actual device whose instructions they are translating. They must select terms in their native language that seem most appropriate based on the information they have available to them. Imagine a device that contains some kind of latch as part of its mechanism. Your in-house team always calls this the “latch.” But a physician looking at your device might call it a “lock.” Or a “clasp.” How can your translator know which term to use?

It is a great idea to use an in-country reviewer to help establish and maintain this kind of device-specific terminology in translation. But you know what you don't need? For your in-country review process to increase your translation timelines, blow up your translation budget, or alienate your in-country team. Below are five of the biggest mistakes we see in processes for in-country review and how to fix them.

Five Mistakes to Avoid

1. Using ICR to compensate for incomplete validation of the source text

When reviewers are true product experts, they may understand how the device works better than your technical writing team. It is unsurprising, then, that they might want to improve instructions or device descriptions during the review process. To your translation provider, however, these “improvements” are actually deviations from the original source text that impact their ability to certify the final translation.

Fix it: include in-country reviewers as part of the validation process for English-language content before translation.

2. Asking reviewers to work without guidelines

You ask a colleague to proofread an e-mail. Do you want them to rewrite it or just highlight any major issues that impact how your message will be read? In-country review is no different. If you ask an in-country expert to review a translation but you don't give them specific guidelines, your reviewer may make minor improvements or preferential (but unnecessary) changes to demonstrate that they did their due diligence. Worse yet, they might rewrite the whole thing. Your translation provider will likely charge for the additional hours needed to verify and reformat the revised text.

Fix it: At a minimum, every reviewer should be told:

- What the purpose of their review is (identifying errors? ensuring preferred terms are used? validating quality?),
- How their review fits into the translation process,
- When they must return the review,
- What history they should know (e.g., an approved glossary of preferred terms), and
- What happens if change is a content deviation and cannot be certified against the source.

3. Using whoever is available to perform in-country review

You vetted your translation company carefully, right? And you surely have strict requirements for your engineers. What about your regulatory folks: they have to have all the right qualifications, no? Every function in your organization requires a particular skill set. If you use an untrained in-country employee or you use a different reviewer for each project, you're likely to create a "too many cooks in the kitchen" situation for your translations. And this will seriously impact your translation costs, translation timelines, and terminological consistency.

Fix it: Establish selection and training criteria for your in-country reviewers. Create consistency over time by building a glossary and holding reviewers responsible for adhering to terms that have already been approved by their colleagues.

4. Applying the same process to all content types

After years of collaboration, your supplier for thingamajig #12 has never let you down. When you receive a shipment of 20,000 thingamajigs, do you check each and every unit? Probably not. While manufacturers typically employ a range of verification processes for incoming materials, they often fail to think about translation in the same way. But a translated IFU is just another component part.

Fix it: Build a risk-based process for translation verification and validation. Consider the intended use of the translation (e.g., IFU versus marketing content) and the history of the provider (e.g., recent audit findings or clean record on nonconformances) and establish when a line-by-line review is required and when the translation only needs a spot-check.

5. Not telling your translation provider you're doing ICR

Any translation company worth their salt will be happy to collaborate with you on in-country review. They probably even have a set workflow that includes it. But you'll throw them for a loop if you perform a review on a document they think is final. Worst of all, you'll increase your translation timeline (and, depending on how generous they are, cost) because layout and quality control have to be re-done before the file can be recertified after the review.

Fix it: Tell your translation provider right at project launch that you'll be using an in-country reviewer. They'll be able to slide the review directly into their workflow and they might even be willing to work directly with the reviewer so you don't have to play middleman.

Adopting a Validation Mindset

At the end of the day, your translation provider is just like any other supplier. By keeping an open dialogue about expectations, a watchful eye over quality, and firm grip on the workflow, you can move away from a "review" mentality and toward a "validation" mindset. Not only will you save yourself some headaches, you might even save enough money to add another country to your product distribution!

Get Help

For more information about how we can take the risk out of translations for you and your team, please visit us online:



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