

Congratulations!

Regulatory Affairs professionals are key to getting new medical products and pharmaceuticals approved and in the hands of patients who would benefit from them. You are also often instrumental in managing translations for your company.

Your new credential is a major achievement and we want to amplify your future success with a solid foundation in how translations are made.

In the pages that follow, we give you an overview of how standard translation procedures and your internal processes will intersect to create accurate translations from your original English. Here's what we talk about:

Part 1: Building a Package Insert

Part 2: How Translation Works

Part 3: Running In-Country Validation

Part 4: Other Stuff

Enjoy!

Part 1: Building a Package Insert

Ultimately, the cost and quality of translations are dependent upon the quality of the English source document. A key way to save time and money (and spare yourself many a headache!) is to ensure that your team’s source documentation process is well-defined and well-managed. This is particularly vital when it comes to documents that will ship with your product, such as IFUs and user manuals.

Format

Last things first: how will the final document be printed? Start with your plan for the end product and work backward:

How will the document be printed: 8.5" × 11", booklet, or foldout?	Will the document be single-language or multilingual?	What software tool will you use?
<p>Unless you plan to use the office Inkjet, talk to your professional print supplier to confirm your options and what they will need from your translation provider. Once you have decided on the format, your printer should be able to provide basic specifications, such as: paper size, margins, folds (columns), maximum number of pages, etc. From day one, get your translation provider and your printer on the same page.</p>	<p>Single-language files make the translation format simple and straightforward, but they inevitably complicate packaging because you have to ensure that the right language gets into the right box. If you decide to go multilingual, make sure that there is sufficient space for all the translations in your chosen format. This is because the amount of space needed for the translations will be different than the English. Slavic and Germanic languages, for example, tend to require more space than English, but Chinese requires less. In order to err on the side of caution, multiply the English length by 30% for each new language added; this will ensure you have enough space to accommodate your future translations.</p>	<p>Many companies use Microsoft Word as a starting point for document creation. However, it is not a long-term solution for multilingual documentation because Microsoft Word is a word processor, not a desktop publishing tool. As a document grows in complexity and length, it can become unstable. Word’s performance also degrades when many graphics are added to a file. Although Microsoft Word may work for your team now, keep a close eye on how your documents evolve and plan the move to a more stable application when you go into a multilingual format or add a large number of graphics. And don’t worry if you don’t have the in-house expertise to move to another format—your translation provider can handle that for you.</p>

We have also compiled a top ten list of translation stumbling blocks in source content creation that you might find helpful. You can find it [here](#).

Style and Consistency

Everyone who deals with your package insert – your regulators, your translators, and certainly your end users – will appreciate clear, simple English. By using clear language and writing the English with translation in mind, you can significantly reduce the number of questions and concerns that your translators will raise as they move your content into another language. You also reduce the risk of any mistranslation caused by ambiguous English.

When drafting English content, consider the following guidelines:

- Strip your document of excess verbiage.
- Never sacrifice clarity.

- Avoid idiomatic expressions as these rarely translate well into another language.
- Use the active voice.
- Limit the use of acronyms.
- Replace text with illustrations wherever possible to improve understandability and reduce the number of words that need translation.
- Curb your creativity. Your translation provider will recycle previously translated content to offer consistency and cost savings, so write consistently and re-use content when it makes sense to do so.

In addition to the above, you might also consider maintaining a style guide to ensure long-term consistency of the English. This can include things such as the proper format for the product name, and how and when trademark symbols should be used.

File Management

Most documents actually have several component parts, including the base document and any embedded graphics. If these graphics contain translatable text, your translators will need to translate this text separately from the base document. This means the graphic will need to be modified before it is embedded in the final document, which increases costs.

When you imagine all the minor modifications that will be needed, both to the graphics and to the base document over time, you have quite a few files to manage! Some advice:

1. If graphics with embedded text will not be re-used across different documents, separate the graphic from the text by building the text directly into the base document (for instance, using text boxes or text frames).
2. On the other hand, when you do plan to re-use the same text-laden graphic across different documents, create a consistent file naming convention. In this way, whenever you request a new translation that uses the graphic, you can point your provider directly to the previous project that already contained the translated version.
3. In general, maintain clear file naming conventions for all files and require your translation provider to do the same. Avoid sending files for translation with unofficial names (such as "Additional text for IFU.docx") as it impedes long-term traceability. When you say "we're adding one new paragraph to LBL0072," you want that to be as clear to your translators as it is to your internal team.
4. Remember that a PDF is not the same as a live document. In order to provide you with consistent cost-savings, your translation provider will always need the "native" format (e.g., .docx, .indd, etc.).

Part 2: How Translation Works

Translation agencies who serve clients in the life sciences industry have very strict processes, which are often designed to meet the requirements of ISO 9001, ISO 13485, and ISO 17100. The basic elements of these processes are highly similar across translation agencies, and understanding them will help you communicate clearly with your vendor (and, of course, save money in the process). Here is an overview of how translation works:

Step 1: Preparing the document for translation

The translation industry uses special software (called 'CAT,' for Computer-Assisted Translation) to optimize the translation workflow. There are several CAT tools on the market and each operates in a similar fashion: the source document is broken down into translatable chunks, called "segments." A sentence is a segment. So is a heading. Basically, any text separated by a period, semicolon, colon, or hard return is considered a separate "segment." During translation, a human translator compares each segment to your translation history, which is housed in a database called a Translation Memory, or "TM" for short. Translating each segment within the context of your TM has two benefits:

- It enables the translator to consistently use the terminology that was used before.
- It helps reduce translation costs when you re-use text.

If you want more information on how TMs work, read [our related brief](#).

Don't confuse CAT tools with MT (machine translation). Human translators use CAT tools to cross-reference previous translations and client-specific terminology; MT technology relies upon previously translated corpora, linguistic rules, and machine-based learning to automate translation.

Step 2: Translation, Edit, Proofreading

Professional linguists assigned to your project work within the CAT tool interface. The first linguist (the Translator) performs a draft translation of the document. The second (the Editor) compares the source document to the translated version and suggests any necessary corrections. Lastly, the document is proofread to see how it stands on its own; this is done either by a member of the Translator/Editor pair or by a third linguist.

Step 3: Outputting the translation in the native format

CAT tools play nicely with most standard word processors and desktop publishing applications. Once translation is complete, these tools "push" each translated segment back into the original format to create a one-to-one correspondence with the original source document. Because different languages take up different amounts of space, some clean-up is required to ensure that the final document looks nice. For instance, page breaks may need to be adjusted or long words may need to be manually hyphenated.

Step 4: Quality control

There are two kinds of quality control in the translation world: mechanical and linguistic. Mechanical is more standard; it involves an independent professional who compares the source and the target, both in their final layout, to verify completeness and to identify any non-linguistic formatting issues. For instance, if the product name is missing its trademark symbol in one location, this could be flagged by a mechanical quality control.

Linguistic quality control is used when a final linguistic review will be especially beneficial. For example, if a team is translating a very small graphic, the text may need to be further shortened or abbreviated for a professional appearance.

Step 5: Post-delivery activities

After translation is complete, your project manager updates your translation assets to ensure they are ready for the next translation project. This includes updating the TM database with the final translated text, as well as updating any glossaries.

A key consideration to keeping translation projects on track, especially for large multilingual projects, is ensuring that the source content is as perfect as it can be before you get to Step 2. For the sake of illustration, imagine that you are translating into the 23 official languages for the European Medicines Agency centralized procedure. Your translation provider will be coordinating the work of at least 46 individual professionals. If you make even a tiny change to the source, it has to go back through all those people.

Part 3: Running In-Country Validation

Your translation SOP may require in-country review or you may decide that it is prudent to have a local stakeholder verify your translations before product launch. As you establish a process for this review, you may want to consider:

Purpose

Get your whole team on the same page about why you're doing an in-country review. For technical documentation, you probably want this to be a final "green light" that the translations are accurate before they are released, rather than an opportunity to make stylistic tweaks. For other types of content, such as marketing brochures, you might want your reviewers to focus as much on style as on content.

When to Review

It is tempting to wait until the translation is complete and formatted to perform a review. However, this requires your translation provider to use their desktop publishing resources twice: once to format the file before the review, then again to implement any changes suggested by your in-country team. Most CAT tools have a built-in option to export the unformatted text for a side-by-side review before the translation even heads to final formatting, which can shorten review timelines and reduce costs.

Reviewer Selection

Who within your organization is qualified to perform this review? At a minimum, they need to be a native speaker of the target language, have full English proficiency, and possess detailed knowledge of your product. In addition, you should maintain some continuity of reviewers over time. 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. This will seriously impact your translation costs, translation timelines, and terminological consistency.

Reviewer Guidelines

When 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, causing the meaning to deviate from your original English. Your translation provider will likely charge for the additional hours needed to verify and reformat the revised text.

At a minimum, every reviewer should be told:

- The purpose of their review (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)
- How to notify you if they think the actual content needs to be changed (e.g., they identify a source error or need to make a substantive change for the local market) so this doesn't get lost in the shuffle

Looping in Your Translation Provider

Always, always, always let your translation provider see the suggested changes from your in-country reviewers. In most cases, they will do their own verification, then update the translation at no additional cost. By circling back around to your provider, you:

- Ensure that the final document is certified in its entirety.
- Provide an opportunity for professional linguists to catch any minor typo made by your in-country reviewers or any deviations from the English of which you need to be aware.
- Communicate preferred terminology to your translation provider so they can update your translation memory and glossary accordingly.
- Guarantee that your provider has the final version, which simplifies future updates.

Part 4: Other Stuff

Of course, there is more to translation than just package inserts. For instance, you may have regulatory correspondence that you need translated into English. These projects are more straightforward...as long as you have a legible document for the translators to use!

Or perhaps your company has never translated before and you are hunting for a supplier for the first time. How do you pick one and how do you control the quality of their work? We had our own quality guru, Idem's Management Representative, draft a brief on how to tackle translation questions during a regulatory audit. It focuses heavily on supplier control and may provide you with some inspiration on how you want to integrate a translation supplier into your own quality management system. Grab a copy of it [here](#).

About Idem Translations

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, healthcare research centers, and institutional review boards. The company is a WBENC-certified woman-owned business and holds certifications to ISO 9001:2015, ISO 13485:2016, and ISO 17100:2015.

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