Anatomy of a Multilingual IFU

A project lifecycle, from content creation to final print.

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Ready to commercialize your product abroad? With regulatory approvals in the works, it's time to plan the next step in your product distribution cycle. For many medical devices and biotech products, this means creating a multilingual IFU that ships directly with your product around the globe.

This executive brief walks you through the decision-making steps necessary to plan and execute an in-box multilingual IFU, from drafting the content to sealing the box. A bit of advance planning will go a long way to ensuring that your product launch is stress-free.

Step #1: Content

Clearly, you need to draft your English IFU content as the first step on the road to a multilingual IFU. When possible, it is worth spending a little extra effort on the IFU content to ensure it is crystal-clear before the verbiage is locked down. This linguistic clarity will save you time (and money) in the future. Here are several easy things that you can do that pay off future dividends in terms of managing a multilingual IFU:

1. **use international measurements**
   Outside the US, metric units of measurement (mm, cm, m, ml) and temperatures in Celsius are far more common than feet, inches, and degrees Fahrenheit. If you only include the typical US measurements, your translators will need to ask how you wish to convert the numbers for use abroad. By including the international measurements (either alone or in tandem with the US measurements), you can perform those conversions up front and avoid questions during the translation process.
2. **create a glossary of key terms**
   It's easy for unintended synonyms to creep into technical documentation, even in short IFUs. While your internal team will read right past them, they may cause doubt in your translators: Are these referring to the same thing? Or did the authors of the IFU intentionally use different terms to make a distinction? Keep your terminology in a one-to-one relationship by drafting a short glossary of key terms so that a sleeve is a sleeve (and not occasionally a sheath).
3. **get a read-through**
   Ask a physician who is unfamiliar with your product to read the IFU and highlight any ambiguities they spot. If a medical expert is not 100% sure what the author intended by a particular instruction, it is highly likely that your translators will have the same question.

All of the steps above will reduce the number of questions your translators must ask, which streamlines the translation process and increases the overall quality of your IFU.

Step #2: Graphics

Does your IFU contain an illustration of your product? If so, do you have the original image file (e.g. Photoshop, Illustrator, AutoCAD) or do you only have a .jpg? When you compile many languages into a single IFU, real estate becomes a precious commodity. As a result, the size of text and images is often reduced when compared to the single-language version of the same document. To ensure that all images (including any callouts describing parts of the image) are crystal clear, your team will need access to the high-resolution graphic where the text is editable. Track down those image files early and, if they cannot be found, plan to have them recreated.

Step #3: Package

A multilingual IFU will be a key component in your shipping box, so the size and shape of this box will play a pivotal role in the planning for the printed IFU. Make sure to select a box with adequate real estate for your IFU, either inside or as an external adhesive. This is particularly important if the actual device is very small and the number of languages in your IFU extensive; in such cases, the folded IFU may be the largest item in your box.

Step #4: Languages

It's likely that your multilingual IFU will grow over time to encompass more languages than you include on the first print run. In order to streamline the process for your first multilingual endeavor, however, you will want to decide early which target markets will be included, primarily because the number of languages you try to include in a single document determines the size of the paper on which you print it. Lock in those target markets and confirm with Regulatory Affairs which languages will be mandatory for the first release. If your team decides to change the number of languages too close to release, you may be forced to reformat the entire multilingual IFU (and possibly source additional, last-minute translations), which you clearly would like to avoid.

Step #5: Specs/Design

Here is where things begin to come together. Having established the English content, the number of languages, and the space available in your packaging, your printer can select a flat paper size that is large enough to accommodate all the text and that is also optimized to fold down into a shape that will fit in your box. Ask your printer to create a mockup by drafting an InDesign layout that uses placeholder content for the future translations. It is important to note, however, that most languages take up more "real estate" than English when conveying the same idea, so your printer should leave a 30% buffer on each placeholder version of the duplicate English to be certain that the translated content will fit in the space allotted.

This is also the time to determine how you want to handle the visual parts of the IFU that aren't simply textual instructions. Here are some questions to consider:

Document Title

- ✓ Will you have just one panel that contains the document title in all languages? Or will each language begin with its own document title?
- ✓ Will the title be the same size in all languages? Or will the English title be more dominant and a smaller font used for the translated titles?

Device Illustration

- ✓ Will the illustration appear just once or will it be repeated in every language?
- ✓ Will any explanatory text (callouts) be part of the image or keyed (A/B/C) to appear in a table below?

Symbols Table

- ✓ Will each language get its own symbols table? Or just one table for the whole document?

Manufacturer/EC Rep Address

- ✓ Will you include the contact information with each translated language? Or only once at the end?
- ✓ Will the address be translated or left in English?

Part Number and Release Date

- ✓ Where in the document do you want the part number and release date to appear?

Language Order and Naming Convention

- ✓ In which order should the languages be placed?
- ✓ Will they be titled by their English names (French, German, Italian), their translated names (Français, Deutsch, Italiano), or by their ISO 639-2 code (FR, DE, IT)?

Step #6: Package Validation

After your printer has created the mock-up and your team is happy with the overall layout, size, and fold dimensions, ask for a few hand-folded samples to use for your packaging validation. The last thing you need is for your new format to fail packaging validation at the eleventh hour, so validate early.

Step #7: English Approval

Now that your English content has been relocated to a new format, you also need to ensure that it will slide comfortably into your document control system. Perform any necessary verification processes on the content before you send it off to the translators.

Step #8: Translation

Time to translate! Your translation provider will need a kit that includes:

- ✓ The InDesign file your printer created for you that contains your verified and approved English content.
- ✓ Any associated graphics that have been embedded in the InDesign file.
- ✓ Any special fonts you use.
- ✓ A PDF of the approved English content, which can be used as a baseline for quality control and certification.
- ✓ The languages you require and the order in which they should appear.

Your translation provider should return to you an updated InDesign (and matching, print-ready PDF) that contains your English content, now replicated in all the requested languages.

Step #9: Printing

Since your printer created the initial specifications for the InDesign, such as paper size and margins, they should be able to print directly from the certified PDF provided by your translation provider. For more detail on creating a seamless process between translations and printing, check out these fast facts.

Step #10: Give Yourself a Pat on the Back

You did it! Of course, by the time you get the first multilingual IFU out the door, your strategy team has probably decided to expand into Scandinavia, so it's time to repeat the process with a larger paper size and some additional languages... You can pull off the new version in no time!

The steps to creating your first multilingual IFU are simple. But the order is crucial. As you begin the journey, work early to identify reliable partners from whom to source your packaging, printing, and translation. By thoroughly planning each step of the process, you will sail smoothly into the next stage of your product's international distribution strategy with a professional IFU that fits right in your box.

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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