welocalize

Optimizing Translation: In-Country Review in Life Sciences

PART 2

Streamlining the ICR Process

INTRODUCTION

Before diving into Part 2, we strongly recommend taking a moment to explore **Part 1: Optimizing Translation Processes: In Country Review in Life Sciences, Eliminating ICR in the Translation Process** for a comprehensive foundation and to better understand the key concepts in this guide.

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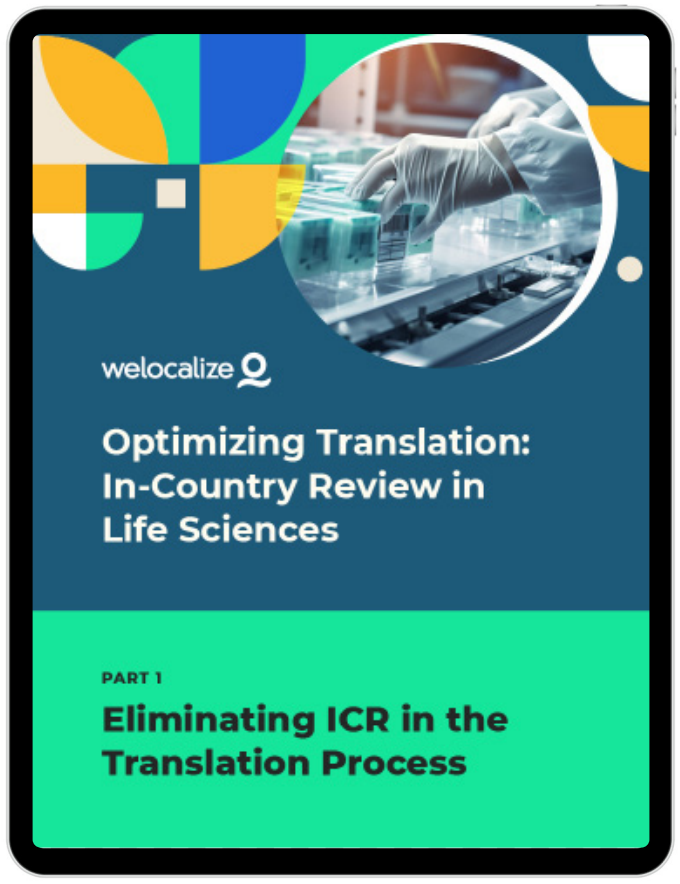


In **Part 1: Eliminating ICR in the Translation Process** we looked at some of the challenges of ICR for medical device and pharmaceutical organizations and the case for eliminating ICR.

But what if you don't want to eliminate ICR?

In this guide, we look at best practices for managing and streamlining ICR.

Did you know?

- ICR is not a regulatory requirement but an optional industry best practice.
- The **European Medicines Agency (EMA)** and **Medical Devices Coordination Group (MDCG)** do not mandate ICR, nor does the **US Food and Drug Administration (FDA).**
- Most global medical device and pharmaceutical manufacturers and local distributors require that their team conduct an ICR of translations as a final check for quality and accuracy.

This paper developed specifically for medical device and pharmaceutical organizations focuses on retaining and optimizing ICR.

WELOCALIZE LIFE SCIENCES

GLOBAL CONTENT SOLUTIONS

Enhance patient outcomes, support scientific research, empower medical representatives, and assist healthcare professionals through our specialized life sciences translation services. We provide precise, culturally sensitive multilingual content delivery, ensuring safety and accuracy across global audiences in the medical device and pharmaceutical industry.

Welocalize collaborates with **7 of the top 10** medical device companies, **5 of the top 10** global pharmaceutical companies, and **4 of the top 10** CROs.

525 **Language Combinations**

250,000 **In-Country Linguists**

7 ISO certifications, including **ISO 13485:2016** which is specific to medical device translation

We help clients connect worldwide, navigating the complex and unique nuances of global medical device and pharmaceutical projects, enabling the effective communication of multilingual content at scale. We help ensure patients all over the world are protected.

With industry specialization and regulatory knowledge, our ISO-13485 certified translation process provides clients with the highest quality translations possible. We scale your translation process using the latest AI-enabled technology and ensure full compliance with all regulatory requirements.

Deliver better outcomes for all your audiences with a **30-minute discovery call** with one of our life sciences specialists.

GET STARTED

STREAMLINING THE IN-COUNTRY REVIEW (ICR) PROCESS

What if you don’t want to eliminate ICR? Many life sciences companies will likely maintain their ICR process due to quality and regulatory policies. In this case, it is imperative to make the ICR process smoother and more efficient.

Of course, the better the quality of the translations, the smoother the ICR will be. This means the best practices outlined in the previous section will be valid in this case.

In addition, there are other things you can consider adopting if you want to keep ICR.

Solution: Outsourcing

The biggest issue companies face today is the availability of suitable resources. This is because reviewers often have other jobs, such as product managers, application specialists, scientists, doctors, marketers, and salespeople. ICR is a time-consuming side job usually performed after hours. If you are using these people as reviewers, you should help them perform their jobs efficiently and smoothly without taking up too much of their time.

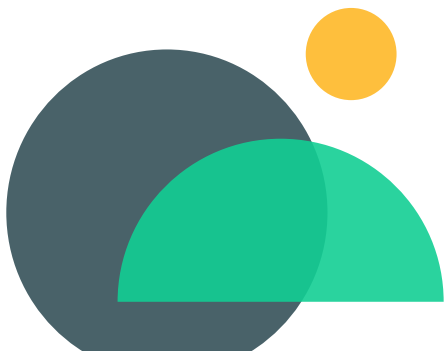
However, in cases where you cannot perform ICR with your internal resources due to increased volumes or lack of resources, such as in smaller countries, you can consider outsourcing ICR to an LSP like Welocalize. As we specialize in life sciences, we offer SME reviewers who match the qualifications of the internal reviewers of companies. Any missing knowledge, mainly on new products, can be covered through targeted training. Our reviewers are independent of the translators.

Solution: Training Guidelines, Dos and Don’ts

Unclear project scope and insufficient knowledge of new products can be addressed through proper training. Creating a specific training guide and conducting training sessions will ensure reviewers have the necessary information. What specific topics should the reviewers be trained on?

Training Guidelines

- New products, new technologies, etc.
- Tools and review environment:
  - If you use PDF: how to annotate PDFs the right way for better implementation of corrections
  - If you use a review system or a TMS/CAT tool: how to use the system or the tool correctly for review
  - If you have another way of doing ICR (XLS, bilingual Word file, etc.): how to work in this environment
- The review process and the overall localization concept of TMs and terminology databases. These include the importance of sticking to agreed timelines and the impact of unnecessary changes on the quality and consistency of the translated content.
- Corporate terminology and the importance of staying consistent with the validated and approved terminology. When it is necessary to change an approved term with a more accurate one, reviewers should learn to submit a change request instead of simply changing the term so as not to affect legacy content, TMs, and term bases.
- Translation guidelines and style guides to prevent potential deviations. Reviewers must consider the specific requirements of the company and those of the local markets and audiences, using the established style guides and translation guidelines.



Dos and Don’ts

Reviewers must be trained on what to correct to avoid unnecessary communication.

What to DO:

- Check for completeness
- Check for scientific correctness
- Check if appropriate for target market and audience
- Check for company-approved terminology
- Focus on in-scope content
- Return on agreed date according to the review schedule
- Be precise
- Provide feedback on source content

What NOT to do:

- Do not introduce inconsistencies
- Do not make unnecessary stylistic or preferential changes
- Do not deviate from the meaning of the source content, and do not add or delete content
- Do not deviate from regulatory requirements
- Do not introduce linguistic errors
- Do not change approved corporate terminology

Suitable Process and Review Environment

There are two ways to perform ICR:

- Annotated PDFs
- Systemized or system-supported ways

While the annotated PDF solution is still the default way of doing ICR, the systemized way is gaining more ground.

It involves using a TMS/CAT environment or a specialized review system that is connected and/or fully compatible with the CAT environment the translators are working in.

There are also some hybrid and system-supported solutions to export from the TMS/CAT-specific files (e.g. bilingual RTF from SDL Studio using track changes) for external review.

Main Challenges of the Review Process

- Terminology disconnection, which refers to the lack of integration between the terminology and the environment the reviewer works in. Although they may have access to Excel lists and online term bases, it is unlikely that reviewers will refer to them for every instance of a term.
- Delay in the process in general.
- Delays in the feedback loop can turn into a never-ending story due to unclear authority, unnecessary changes, and source deviations
- Delays with incorporation of changes and issues with incorrect and inconsistent incorporation.
- Approved legacy content disregarded by the reviewer.
- Requests for changes to legacy material, including both translations and source content, can cause further delays.
- Reviewer training and knowledge are often insufficient, and turnover among reviewers necessitates frequent retraining.
- Delays in content creation reduce the time for translation and ICR analysis.

Best Practices

Here are some suggestions for the review process:

- System or tool connected or compatible with the tool environment the translators are working in, which reduces the file import and export, file conversion back and forth, and intermediate PDF creation (could be a time extensive process when XML/CMS is in place).
- System or tool that works online and offline.
- System or tool that allows display of content in layout and in-context mode.
- System or tool connected with the approved corporate terminology, similar to how the translators work in the CAT environment, where approved terms from the term base are highlighted in the sentences under review. This way, the reviewer can see directly which terms are approved, and all people involved in the process (translators, LSP PMs performing QA, reviewers) will work with the same terminology base.
- System or tool that automatically updates the project files but also the TMs system or tool that allows clear traceability of all changes, all in one system, meeting all regulatory documentation requirements in regard to audits.
- System or tool that supports automatic sign-off.
- System or tool that supports the entire feedback loop (reviewer-client-LSP-translator) within the same system.
- System or tool that supports the easy collection of meaningful KPIs.
- Delays in content creation reduce the time for translation and ICR analysis.

KPIs for ICR

Having meaningful KPIs for the ICR process can help inform you about the performance of the translators, reviewers, authors, and the overall localization process. They can also help you decide whether ICR could be totally removed, at least for some languages.

These are some KPIs used for ICR:

- Number of corrections (this may be subjective in case most of the corrections are preferential or contradict the approved corporate terminology the translators followed)
- Category of corrections (terminology, spelling, grammar, mistranslation, etc.) may follow the SAE J2450 or TAUS DQF metric
- Severity of corrections
- Number of real errors vs. preferential changes
- Reviewer output, how much is getting reviewed in what amount of time
- Number of corrections not implemented
- Number of corrections that have been incorrectly implemented
- Number of corrections related to the source content (source error or readability and translatability issue)

While collecting KPIs during the review process to make informed decisions is important, this can add an extra layer and cause further delays.

However, if this data can improve the review process by making it smoother, more efficient, and faster in the mid-term, or even eliminate it altogether, then it is worth defining the necessary KPIs and assigning roles and responsibilities in the process.

Given the shortage of capacity and bottleneck of reviewers, it is likely the LSP's responsibility to categorize the reviewers' corrections and gather meaningful KPIs.

A suitable review system or tool will also be able to collect certain KPIs, such as reviewer output, automatically.

CONCLUSION

Many life sciences companies will likely maintain their ICR process due to quality and regulatory policies. We hope this guide has given you some actionable best practices, to help make your ICR process smoother and more efficient.

Robust quality procedures, the training of translators and reviewers, and an effective process and review environment all contribute to high-quality translation and help to ensure the health and safety of patients and other key stakeholders.

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WORK WITH WELOCALIZE

Drive better outcomes for patients, scientists, medical reps and healthcare professionals. Our specialist life sciences translation and IP services help you deliver safe, accurate multilingual content to audiences all over the world.

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