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Optimizing Translation: In-Country Review in Life Sciences

PART 1

Eliminating ICR in the Translation Process

INTRODUCTION

In life sciences translation, the role and necessity of in-country review (ICR) are often debated. Is ICR necessary? After all, ICR is not a regulatory requirement but an optional industry best practice.

For example, the **European Medicines Agency (EMA)** and **Medical Devices Coordination Group (MDCG)** do not mandate it, nor does the US **Food and Drug Administration (FDA)**.

However, most 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.

Regulations like the Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) from the EU, and the New Drug Application (NDA) and Current Good Manufacturing Practice (CGMP) from the US require complete and accurate documentation of records, procedures, and reports, including their translations.

For compliance, Language Service Providers (LSPs) like Welocalize follow a translation process that aligns with **ISO 17100** and **ISO 13485** standards. Since ISO certifications align with translation quality standards, ICR becomes more of an elective procedure. Any additional quality assurance steps undertaken by the manufacturer, such as ICR, become superfluous for compliance purposes.

So, is it feasible to make ICR optional, depending on the manufacturer's preferences and content type? What essential elements must be in place for life sciences companies to uphold high translation quality standards without ICR? And how should this process be effectively documented and managed?

This paper (**Part 1** of **2**) developed specifically for medical device and pharmaceutical organizations, focuses on understanding the factors influencing translation quality and considering the possibility of eliminating ICR under ideal circumstances.

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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

ELIMINATING THE IN-COUNTRY REVIEW (ICR) PROCESS

Why Consider Getting Rid of ICR?

ICR is commonly seen as a bottleneck, which adds a lot of additional time to the process and, in some cases, costs. The result is often questionable, as reviewers may make unnecessary changes and introduce inconsistencies, especially in terminology. The lack of suitable resources and the fact that in-country reviewers often do ICR as a side job can turn the process into an endless back-and-forth.

Issues During the ICR Process

Most corrections made during the ICR process are related to terminology. Changes made by in-country reviewers are not always about replacing a wrong term with a right one. Often, terminology changes contradict approved and validated terminology. Additionally, many corrections are related to style and personal preferences rather than actual errors.

There is also a difference between non-critical and critical errors. Another area to consider is that reviewers are expected to have the necessary product knowledge and scientific background, which they may not have.

Solutions

Considering these issues, the following areas are crucial for developing the optimal process for eliminating ICR:

Terminology, Translation Memory (TM), and Other Translation Assets

Terminology management is a critical issue in ICR. Pharmaceutical terminology is highly specialized. Accurately translating chemical names, dosage instructions, and patient information is crucial for ensuring patient safety and avoiding medication errors. It is also essential to maintain consistency in pharmaceutical translations, especially for recurring terms in clinical trials and drug descriptions.

Medical device terminology is likewise technical, with specific details about components, functionalities, and specifications. Translating manuals, user guides, and safety information for medical devices demands precision to prevent misuse and harm.

These are some **best practices** to consider:

- Establish a well-structured **terminology management process**.
- Build a **solid terminology base** with validated and approved corporate and product terminology, including product names.
- Ensure the **translation memory (TM)** is **up-to-date** and **in sync** with the approved terminology base. The TM must be consistent in pharmaceutical translations, especially for recurring terms in clinical trials and drug descriptions.
- If the **TM** is **not in sync** with the approved terminology, it may be necessary to **clean up the translation memory**.
- Use the terminology base in the respective **TMS or CAT tool environment**, and all necessary terminology consistency checks must be done in the CAT tool or 3rd party QA tools using this terminology base.
- Apply **client and product-specific preferences** in the translation using style guides and translation guidelines that are validated and approved for all languages. These assets can also be used during the QA process after translation to verify the proper use of these preferences.

Qualifications and Training of Translators and Reviewers

Another aspect to consider for removing ICR is to define and match the qualification requirements for translators and reviewers.

What are the main qualifications, and how can they be addressed?

- **Native speakers:** While ISO 17100 does not mandate translators and reviewers to be native speakers of the target language, having such proficiency, along with educational certificates, professional qualifications, and relevant experiences, can significantly contribute to ensuring suitability for the task.
- **Background in pharmacology, medical, or related fields:** While not mandatory, a medical or pharmaceutical background equips translators and reviewers with in-depth knowledge of the subject matter.
- **Knowledge of corporate and product terminology:** A solid and structured terminology management system can meet this requirement along with the points we address below.
- **Knowledge of the market and audience:** This could be part of a style guide approved and validated by the specific country.
- **Product knowledge:** Translators and reviewers should attend training sessions focused on new products. This practice helps them to become more acquainted with the products they need to translate and review.
- **Scientific background and work experience with similar products:** Having qualified medical translators and revisors may not be enough, particularly for more specialized and complex areas. Look for translators with a scientific background, working experience in hospitals or laboratories, and a good understanding of medical devices and instruments.

A recommended best practice is to create a translator profile, jointly defining the required qualifications and work experience. Then, identify and approve suitable translators who fulfill the requirements. Ensure only approved translators and revisors work on the content by requesting their IDs with each deliverable.

EXAMPLE of Translator Profile

Language Combination: English (US) into LANGUAGE

Translator ID: xxx

Resources need to be qualified up to level 2 to be approved for the CLIENT account

Level	Qualification	Approved by / date	Comments
0	LSP-qualified translator based on ISO 17100:2015 requirements		To be filled in by LSP
1	Subject-matter / area of expertise: Biology, Medicine, Life Science, Pharmacology, Pharmaceuticals, Chemistry, Biochemistry, Molecular biology, Clinical diagnostics CAT tool:		To be filled in by LSP
2	Experience with CLIENT or similar client product category • Core Lab, e.g. hematology • Molecular diagnostics, e.g. oncology Experience with CLIENT or content/document types • Package inserts, IFUS, etc.		To be filled in by LSP

Is there no use for in-country subject matter experts, then? They can be involved at the start of the process, not the end. Local SMEs can provide valuable feedback on the source content, either by catching errors or suggesting improvements. They could support the review, validation, and approval of terminology instead of having them perform the ICR.

Quality Process with Integrated QA Steps

In the pharmaceutical industry, it is not only the translation of drug-related information that is critical. Clinical trial documents, regulatory submissions, and packaging labels must also have accurate translations.

As such, the quality workflow should include QA checks at various levels, such as technical QA checks, **linguistic QA checks**, and, if necessary, QA checks on formatting. Pharmaceutical-specific checks must include compliance with drug regulatory authorities' guidelines and patient safety considerations.

Given the high stakes of the life sciences industry, QA checks must be as comprehensive as possible. Consider customizing your current QA check by incorporating hazard lists, which can catch critical errors. A hazard list is a useful tool to help identify and mitigate potential risks.

An example of such a hazard list is below:

English	Target	Opposite meaning	Comments
<	<		
>	>		
≤	≤		
above	au-dessus	HAZARD PAIR TERM: Please make sure this has not been translated as "below"	
activated	activé	HAZARD PAIR TERM: Please make sure this has not been translated as "deactivated"	
advance	avancer	HAZARD PAIR TERM: Please make sure this has not been translated as "withdraw"	
aerobic	aérobie	HAZARD PAIR TERM: Please make sure this has not been translated as "anaerobic"	
after	après	HAZARD PAIR TERM: Please make sure this has not been translated as "before"	
always	toujours	HAZARD PAIR TERM: Please make sure this has not been translated as "never"	
anaerobic	anaérobie	HAZARD PAIR TERM: Please make sure this has not been translated as "aerobic"	
anterior	antérieur	HAZARD PAIR TERM: Please make sure this has not been translated as "posterior"	
antibody	anticorps	HAZARD PAIR TERM: Please make sure this has not been translated as "antigen"	
antigen	antigène	HAZARD PAIR TERM: Please make sure this has not been translated as "antibody"	

LSPs should also use innovative technologies, such as artificial intelligence (AI) and machine learning (ML) for quality control. Welocalize has been at the forefront of AI/ML and now Generative AI (GenAI) for translation and QA.

These steps mentioned above are needed to remove ICR. Once the quality level without ICR is met, we can remove the ICR process step by step for certain or all languages. To be cautious, we can implement a QA assessment plan with periodic sample assessments of the translations using industry quality metrics such as SAE J2450 or TAUS DQF.

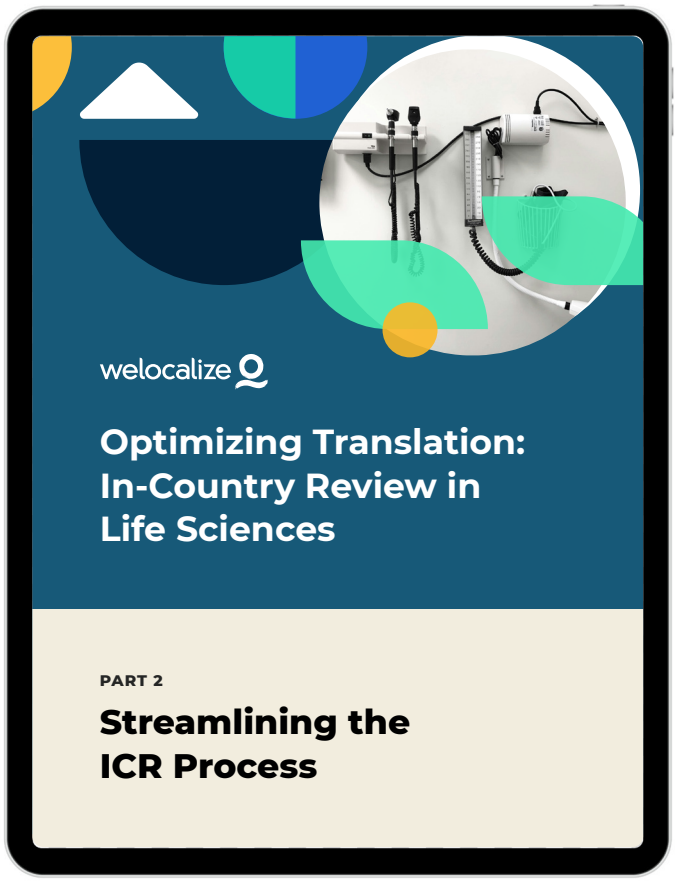
Conclusion

Translation accuracy is essential in every sector but is especially critical for the medical device and pharmaceutical industries, as errors could endanger patients and lead to serious legal and financial consequences for manufacturers.

Whether eliminating or optimizing the ICR process, these essential elements will help ensure translation quality in all your content. Moreover, they help drive positive outcomes and ensure the health and safety of patients and other key stakeholders.

NEXT ON YOUR JOURNEY

What if you've decided to retain ICR instead of eliminating it?



In the next guide in this Welocalize series, 'Optimizing Translation: In-Country Review in Life Sciences, Part 2: Streamlining the ICR Process,' we delve into the strategies for streamlining and optimizing the ICR process. Discover the best practices to maximize the effectiveness of your translation review.

Ready to dive in? **DOWNLOAD PART 2 NOW** and learn more about **Streamlining the ICR Process**

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