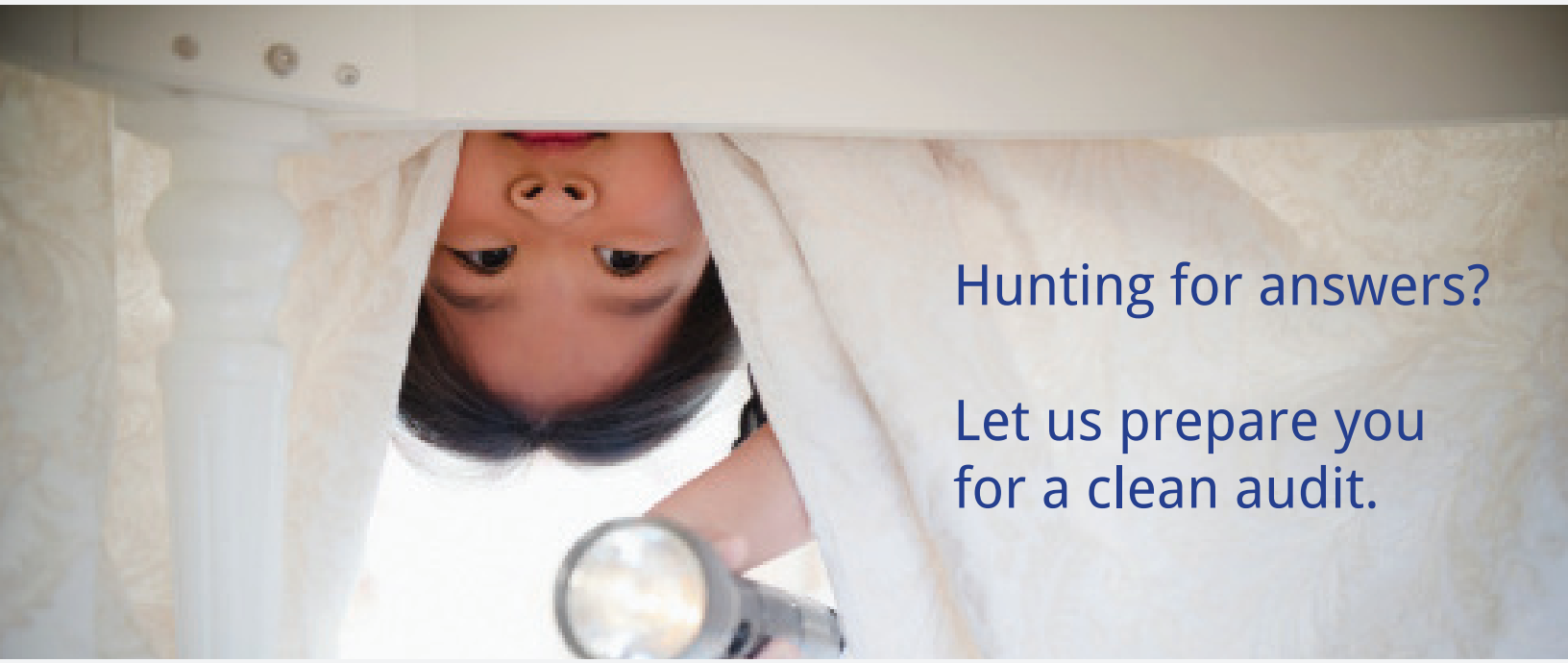
idem
translations, inc.



EXECUTIVE BRIEF

Tackling Translation Questions in a Regulatory Audit

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

Clients often tell us that, after a long day spent with a regulatory auditor, they get thrown a curveball:

"How do you control the quality of your translation supplier?"

Prepare yourself to knock this question out of the park. With a few key pieces of information, you can firmly establish the strength of your translation outsourcing and ward off any negative audit findings.

Your quality system likely has strict controls for suppliers. Both ISO 9001 and ISO 13485 share the same basic requirements for external service providers:

1. Define required criteria for supplier selection
2. Define controls for supplier evaluation/re-evaluation
3. Define requirements for verifying purchased services

Let's look at each of these elements on a broad scale (how does the translation provider meet your requirements?) and on a narrow scale (how do the individual translators working on your content meet your translation provider's requirements?).

In the eyes of your regulator, instructions for using your product are the most critical for translation. It could be your IFU (Instructions for Use), user manual, package insert, or prescribing information. This document is critical because an error in the instructions could increase the risk of patient harm. For this reason, product labeling (translations included) is typically considered to be an integral component of the product.

Broad View:
Your Process for Managing the Translation Supplier

Supplier Selection

Translation service providers who serve the life sciences industry provide a critical component of your medical product. Depending upon their degree of specialization in the medical industry and their operational maturity, their quality management system (QMS) may be certified to several different standards:

- ISO 9001: benchmark QMS requirements
- ISO 13485: QMS requirements for medical devices
- ISO 17100: the international standard for translation services (Note: ISO 17100 was released in May 2015. Prior to that date, translation providers were certified to the EN 15038:2006 standard; the transition is ongoing.)

It is important to understand whether your translation provider is certified to any of these standards and which standards you require of them.

Know Before the Audit

- ✓ To which standards is my translation provider certified?
- ✓ If not certified, is my translation provider at least compliant with ISO 17100 (the international standard for translation services)? How do they demonstrate compliance?
- ✓ Does my translation/labeling procedure require that the provider hold any specific certifications or meet any other requirements?

Supplier Evaluation/Re-Evaluation

Once you've selected a supplier, it's important to establish an ongoing process to confirm that they continue to meet your requirements over the long term. You expect them to maintain their external certifications and the rigor of their quality system, so you will need a recording mechanism to confirm that they haven't made any dramatic changes. It is also helpful to look at their nonconformance record and how they have responded to any supplier corrective actions.

Know Before the Audit

- ✓ How does my SOP handle supplier re-evaluation (surveys, on-site audits, etc.)?
- ✓ When was the last time my translation provider was re-evaluated? What were the results?

Post-Delivery Verification

Companies differ in how they verify completed translations. Here at Idem, there are three tiers of verification we typically see from our medical clientele:

1. Filing of a Certificate of Accuracy (no additional review)
2. In-house, non-linguistic review (such as counting bullet points, verifying numbers, etc.)
3. In-country review cycle (read our executive brief on ICR)

While some people believe more is always better, remember that the heavier the verification layer, the longer the translation timeline and the higher the final cost. As a result, savvy companies mix-and-match these options, increasing review for new translation suppliers and decreasing review for suppliers with a clean performance history.

Know Before the Audit

- ✓ What is my post-delivery process?
- ✓ If I don't do additional review after the translation provider delivers, how do I justify my reliance on the Certificate of Accuracy?

Translation Standards

ISO 17100
international standard for translation services, released by the international standards organization in May 2015

EN 15038
European standard for translation services, ultimately adopted by the ISO as 17100

ASTM F2575
guideline for translation services that was originally developed as an American standard (no certification available)

CAN CGSB 131.10
Canadian standard for translation services

Narrow View:
The Translation Supplier's Internal Process

Translator Selection

When you select a translation supplier, you are likely working with an agency that handles translation into more than one language. This agency, in turn, selects individual translators to translate your content. The international translation standard, ISO 17100, requires that providers use translators who have the competence and qualifications needed to perform accurate translations. Most translation providers comply by establishing minimum requirements for individual translators, specifically: educational level achieved, relevant work experience, and agency testing scores.

Know Before the Audit

- ✓ What educational background and work experience does my translation provider require of its individual translators?
- ✓ What testing do translators undergo before they can work with my translation provider? (For example, are they tested on general material or is testing specific to medical, pharmaceutical, legal, or marketing content?)

Translator Evaluation/Re-Evaluation

Know Before the Audit

- ✓ How does my translation provider re-evaluate individual translators?
- ✓ How does my translation provider confirm that the re-evaluation status of the translators who work on my documents is up-to-date?

Although various organizations do provide certifications to individual translators, these certifications differ from country to country. As a result, translation providers rarely rely exclusively on third party certifications to re-evaluate their network of translators. Instead, they build a homegrown system to ensure translators are always doing their best work. Here at Idem, we have a complex, risk-based, re-evaluation process that is firmly integrated with our CAPA (Corrective & Preventive Action) system. It uses industry metrics that were designed to gauge translation quality on an individual document (such as the LISA model, SAE J2450, or TAUS DQF).

Some auditors may speak another language and spot a "mistake" in your translated materials during the audit. Don't panic! Remind the auditor of the requirements used by your translation provider to vet individual translators and open a direct dialogue with your provider. In most cases, your provider will be able to demonstrate that both the established translation and the auditor's version are equivalent ways of saying the same thing.

Process Controls

One translator isn't enough to ensure consistent quality. As a result, most translation agencies adopted a "translation + editing" approach before it became an integral element in the ISO 17100 translation standard. It's important to understand just how many levels of checks and balances exist in your translation provider's process and how their process prevents errors. When you can demonstrate that your provider's process is robust, you can better justify to your regulator why you circumscribe the re-evaluation and verification processes you use to manage your translation provider.

Know Before the Audit

- ✓ What is my translation provider's process?
- ✓ Is there independent editing of each translation? If so, what qualifications must the editor have?
- ✓ Is there independent quality control?

The Bottom Line

Hold your translation provider to the same exacting standards as the rest of your vendors. When your regulator drops by for an audit, you'll have the information and records you need to demonstrate that your translations are trustworthy.

Get Help

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

WEBSITE
www.idemtranslations.com

TWITTER
twitter.com/IdemTransInc

LINKEDIN
www.linkedin.com/company/idem-translations-inc.