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Purchasing Translation Services

By Kathrin Rueda

Timely, high-quality translations are essential for more and more clinical trials. When contracting for services like site monitoring, data management, and printing, in-house expertise is often available. In contrast, when contracting for translation services, most sponsors do not have native speakers of languages like Hindi, Mandarin Chinese, and Portuguese eager to review the accuracy of translations. A study sponsor may never find out about a problematic mistranslation. As a result, outsourcing translation services requires extra care in selecting the translation service provider (TSP).

Selecting a TSP

Translators range from part-timers with no formal training to certified and highly trained full-time translation professionals with deep expertise in specific types of documents. Informed consent forms, protocols, investigator's brochures, scientific publications, and other clinical research documents require a high standard of quality, so not just any translator will do.

Being proficient in a source and a target language is not enough to be a good translator. It takes subject-matter familiarity, document-type competence, overall level of education, extended residence in the target-language country, and years of translating experience. Good TSPs know which translators are best for which projects.

Good TSPs also have the systems in place to manage projects effectively. High-quality translation requires a surprisingly complex process that involves translating, revising, editing, reviewing and proofing. The process requires a team effort by both TSP and customer.

As mentioned above, outsourcing translation services requires extra care in selecting the TSP, so it is better to invest the time up-front to find a good TSP and establish a long-term relationship. A freelancer or small, specialized TSP may be a good choice if your translation requirements are limited in scope. On the other hand, a larger, full-service TSP can handle projects of various types and sizes with a consistent process.

Ask a potential TSP the following questions:

- How much of your work is in clinical research?
- Which languages do you handle? In which do you specialize?
- How long have you been in operation?
- What are your qualifications? How do you qualify your translators?
- What is your typical translation work flow (i.e., translation, review, revision, proofing)?
- What standards do you follow?
- How do you ensure high quality and timeliness?
- What software tools do you use?
- Who will manage my project?
- Can you provide me with sample translations? Will you translate a small sample for me?

- What additional services can you provide (e.g., layout/desk-top publishing, creation of glossaries or translation memories, certifications/notarizations)?
- Do you have the required software programs/tools for my project (e.g., InDesign for layout work)?
- How are files transferred to and from your facility (e.g., email, YouSendIt, uploads to a secured site)?
- What data security or confidentiality agreements do you provide?

Translation Quality

Translation firms employ a process of editing and review to ensure high-quality translations. Underlying these processes are standards, training programs, translator associations, professional certifications, and translation certification and notarization.

Standards

Translation is not an exact science. No two translators will translate a document exactly the same way. Word choice, grammatical construction, tone and linguistic style will vary. Technical terminology, regulatory requirements, ethical concepts, and readability are especially challenging for clinical research documents.

The following standards and international guidelines for translation services have done much to improve the overall quality of translations:

- ISO 9001 Quality Management System Requirements
- EN 15038 Translation Services – European Standard
- CAN/CGSB-131.10 Translations Services – National Standard of Canada
- ASTM F 2575 Standard Guide for Quality Assurance in Translation – USA

ISO 9001 is a quality management standard that can be applied to any type of business. The EN 15038 and CAN/CGSB-131.10 standards establish requirements for the translation industry. The ASTM F 2575 guide is of special interest to translation service clients because it provides a glossary, outlines the process steps in a typical translation workflow, and recommends questions to be asked when selecting a service provider and specifying project requirements.

Training Programs

Translator training is not as simple as getting a “translation” degree. While degree programs are offered at many universities (a list of some of these can be found at <http://www.lai.com/edures.html>), many of the best professional translators do not have a degree in translation. An excellent knowledge of the target language (the language being translated into) is more important than an actual translation degree. Perhaps more important is knowledge of the subject of the translation. Just as a non-lawyer should not be expected to draft a legal agreement, a translator with legal expertise should not translate a study protocol for open-heart surgery. The results could be disastrous. Also important is knowledge of the tools used in the translation process, such as translation memory tools or machine translation tools. Translator associations do an excellent job of providing up-to-date seminars on the latest advances in these technologies.

Translator Associations and Professional Certifications

The American Translators Association (ATA), founded in 1959, is the largest professional association of translators and interpreters in the U.S., with more than 11,000 members. ATA's primary goals include fostering and supporting the professional development of translators and interpreters and promoting the translation and interpreting professions.

ATA has established a certification program to enable individual translators to demonstrate that they meet professional standards. Translators who pass a written examination are certified by ATA in a specific language pair and direction (from or into English).

In the same way, the Canadian Translators, Terminologists and Interpreters Council (CTTIC), established in 1970, brings together the organizations responsible for certifying professional translators, terminologists and interpreters in Canada's provinces and territories. It coordinates the actions of its member organizations and promotes cooperation among them to ensure uniformity in professional standards. It also conducts relations with national and international bodies representing language specialists. Through its member organizations, CTTIC seeks to promote professional certification as a guarantee of quality and competence, thereby contributing to the advancement of the profession and the protection of the public.

Similar national organizations exist around the world.

Translation Certification and Notarization

Many translators certify their translation in a document stating that the translation has been performed by them and is a complete and accurate translation of the source document. If they have been tested and certified by their national, state or provincial translators association, they may also stamp this document with the official seal of the association. The certification document is then attached to the translation.

Many translation agencies also offer a notarization service whereby a notary public stamps and signs the certification letter indicating that he or she has witnessed the translator's signature on the letter. In some states, these notarizations can be performed electronically by combining the translation and the notarization into a single document that is then digitally signed. Other states, such as Massachusetts, do not permit digital notarization and all notarizations must be on paper.

Project Specifications

An educated customer is the best customer and most likely to be satisfied with the final product. All too often, time and money are wasted and buyers of translation services end up dissatisfied because crucial information was not passed along to those working on the project. The ASTM guide states: "Quality in translation cannot be defined on the premise that there is only one correct, high-quality translation for any given source text. Quality is defined as the degree to which the characteristics of a translation fulfill the requirements of the agreed-upon specifications." In other words, the TSP needs to know exactly what you, the customer, wants before it can deliver exactly that.

You can judge a TSP by the questions it asks about your project. A good TSP will help you define your requirements so there are no unpleasant surprises down the road. However, unless you, the client, have some knowledge about translations and the translation industry, you may find yourself ill-prepared to formulate adequate specifications for your translation project.

A good TSP will ask numerous questions, most of which will fall into three categories: the nature of the source material, the target text specifications, and the process and administrative aspects of the project. It is best to create a project specification document with at least preliminary answers to these questions in advance. The document will be very useful in communicating with TSPs. It will also help you narrow down the list of TSPs to contact for the project.

The TSP should ask the following questions about the source text:

- What is the language of the source text (including dialect or locale)?
- What are purpose and subject matter of the source text?
- What is the format of the source text (electronic or paper)?
- What is the origin of the source text (when authored, by whom)?
- What word processing or layout program was used to create the source text?
- On what computer platform was the source text created (e.g., Windows, Mac, Linux)?

- Was the source text created following a style guide or template? If so, are the style guide and template available for the translations?
- Does the source text include any graphics or special text elements that need translation (e.g., callouts, side bars, insets)?
- Is the source text a revision of a previously translated text? If so, are previous translations available for reference?
- Does a glossary or electronic translation memory exist (e.g., within a translation program like Trados)?
- Is any other reference material available that could guide the translator in word choice and linguistic style (e.g., product brochures, training videos, web content)?

The TSP should ask the following questions about the target text:

- Into what language(s) will the text be translated (including dialect or locale)?
- What is the purpose of the translation (i.e., for publication, to satisfy a legal requirement, for internal use only)?
- Who is the target audience (e.g., clinical investigator, site monitor, study subject) of the translation?
- Is the translation a straight translation or an adaptation (e.g., a summary)?
- Does the translation require layout/desktop publishing work (e.g., to create print-ready copy for publication)?
- What is the deliverables media (type of electronic file, paper, CD)?
- Are there any special instructions (e.g., technical terms, names or locales to stay in the source language)?

The TSP should ask the following questions about the process and administrative aspects of the project:

- What are the project's start and due dates, and how fixed or flexible are they?
- Who will be the customer contact for the project?
- Who else will be on the customer's translation team and what will their roles be?
- What is the preferred means of communication (e.g., email, phone, fax)?
- Are changes to the project anticipated (i.e., is the source text is still undergoing revisions or ethical review)?
- Will customer personnel review translated documents? If so, who will perform the reviews?
- Are back translations necessary?
- What are the budget constraints or expectations?
- What are the needs for data protection and confidentiality?
- Do translators have to be U.S.-nationals (i.e., for sensitive government files)?
- Are additional services required (e.g., creation of a glossary, translation memory, notarization or certification)?

Conclusion

Finding a good TSP for clinical trial documents requires time and effort. Fortunately, the translation industry includes numerous qualified TSPs with suitable experience. Industry standards have raised the quality of translations and management processes to consistently deliver high-quality translations on schedule. In addition, the ASTM F 2575 Standard Guide for Quality Assurance in Translation – USA provides a good, basic education for both TSPs and customers.

Although the translation industry produces text that cannot be tested like a chemical solution, customers in need of translation services should be able to find a good TSP that meets their needs.

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