Translation in the Medical Sector

Contents

Introduction

If your organisation is involved with medical translation of any sort, this guide will help you gain a deeper understanding of what's involved and how to avoid translation mistakes.

Specifically, this guide focusses on:

- Medical translation regulations
- Medical device translation regulations
- Pharmaceutical translation regulations
- Patient privacy and security
- The medical translation process
- Medical translation gone wrong

Medical translation regulations

Medical translation is serious business. Mistakes can be a matter of life or death. As such, medical translation is one of the most heavily regulated area of the translation industry.

Translation vendors and clients alike must navigate a complex labyrinth of rules at the local, national and international levels in order to stay compliant. Regulations govern what material must be translated, how data is transmitted and stored and the translation process itself.

Medical translation requirements can vary greatly depending on the product in question and the target markets. In most markets you need to have public-facing documents such as patient information sheets, marketing materials and forms for clinical trials translated into the local language. You may also need to translate into minority languages. Most of the time, material aimed at healthcare professionals must be translated, along with applications for patents and regulatory approval. ■

Medical device translation regulations

Medical devices are big business, amounting to €95 billion in sales in the European Union alone. To sell products internationally, medical device manufacturers must comply with requirements for all relevant target markets.

Each country has its own regulatory body and its own standards. In the European Union, sales of medical devices are governed by two main directives:

- 2017/745 The EU Regulation on Medical Devices; on general medical devices (MRD)
- 2017/746 The EU Regulation on In Vitro Diagnostic Medical Devices; on in vitro diagnostic medical devices (IVDD)

Translation requirements depend on the type of device and the target market. Materials that need to be translated could include but are not limited to marketing material, instructions for medical professionals and for patients and user interfaces for device software and firmware. Software interfaces may also need to be changed to accommodate local scripts.

Naturally, target languages for translation also depend on the desired market, the type of device being sold and the intended audience. In the EU, that might mean making marketing materials available in all of the 24 official and working languages of the member states. In other countries, expect to translate to the official language of your target market, and possibly into minority languages as well.

The type of device also matters. For example, currently the EU breaks medical devices down into four classes depending on the level of risk they pose to patients, with separate requirements for each category. Intended audience is another a factor to consider – in a few countries, such as Ireland, the United Kingdom, Cyprus, Luxembourg, Malta and Poland, you may be able to provide medical device labelling in English only if the device is intended for use by medical professionals. However, labelling a device “for professional use only” will not absolve the manufacturer of liability for injuries caused by inadequate translation.

It may seem like a minor oversight, but failing to provide appropriately translated materials can have serious consequences, including product seizures, denial of insurance coverage, and even criminal prosecution for medical device manufacturers.

Regulations governing **medical translation**, including for medical devices, are constantly changing, therefore it is vital to keep up to date with these changes as and when they occur. ■

Pharmaceutical translation regulations

Like medical devices, pharmaceutical products are strictly regulated in virtually every country; however, each country has its own rules. In the EU, your company must comply with guidelines set up by the European Medicines Agency (EMA) and its Committee for Human Medicinal Products (CHMP) as well as local regulations. In Japan, you need the approval of the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), both of which require application materials in Japanese. In China, documents must be translated to Standard Chinese before submission to the State Food and Drug Administration (SFDA).

The scope of pharmaceutical translation projects can include everything from Phase I clinical research trials to final marketing materials and everything in between: Phase II clinical trials and all the associated paperwork, licensing agreements; process, MSDS and manufacturing documentation, packaging and information for both patients and healthcare providers.

All of it must be properly translated into all required target languages. There is no room for error or ambiguity. Some regulatory agencies (such as the EMA) also have technical formatting requirements for translated documents, including details like font size and colours. ■

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Patient privacy and security

Medical translation projects often need additional data security safeguards in order to comply with laws protecting patient privacy. These laws can affect how materials to be translated may be transmitted and stored. ■

A guide to the medical translation process

For medical translation projects, there are two competing concerns: efficiency and quality.

Clients want a fast turnaround for as little money as possible, but the life-or-death nature of medical translation makes even minor errors unacceptable. How can we design a medical translation process that minimizes time and cost to the client, yet still meets regulatory standards and ensures accuracy?

Balancing these goals takes careful consideration and planning during each stage of the medical translation project. No computer program can ensure your message comes across clearly and accurately as well as a skilled human translator can, but using technology appropriately at each stage can streamline the process.

Preparation

Preparation lays the groundwork for the project. Efficiency begins here; mistakes made in this part of the process can be expensive and time-consuming to correct later. Both supplier and client have roles to play.

Scope

The first step is to define the scope of the project, including what needs to be translated, the desired target languages and any applicable regulatory requirements. These factors influence how the translation work flow will be structured.

Localisation

Next, depending on what is being translated, the product may need to be localised to support all target languages. Many languages include diacritics (like accents, tildes and umlauts), and fields for addresses and phone numbers may need to be altered to accept different formats.

Source Documents

Clients can help streamline this process by providing documents in an editable format, such as files produced using a word processing program. The harder it is to edit the original document, the more time it will to take to get it ready to translate. If your team is producing content that will need to be translated, also direct them to keep image captions editable instead of embedding text inside the images.

Glossary of Terms

An important part of the preparation process is the creation of a glossary of key terms to be used in the translated document. This ensures consistency in the final product and helps reduce editing costs caused by inconsistent terminology. For accuracy's sake, the glossary must be validated by a native-speaking expert in the appropriate medical field before it can be used.

Translation can start

Once the product is ready for translation and the glossary has been validated, the translation team can get to work. The exact steps in the translation process depend on a number of factors, including what is being translated and applicable regulatory requirements. Initial forward translation may be done by one translator working alone or by two translators working separately, with the two versions “reconciled” to make a “best of” translation. Larger projects often require additional translators.

Translation memories improve speed and accuracy

Translation memory software can make this process more efficient right from the start, as frequently used words and phrases are translated in context with the project. These translations can then be reused, improving efficiency as more phrases are added to the memory bank.

> “The use of translation memories cuts down on the amount of work required and helps ensure a consistent finished product”

Quality control for medical translation

After the initial forward translation, the translation vendor will undertake a number of editing and quality control procedures to ensure the original message comes through as clearly as possible in the target language. Depending on the project, these may include:

- Editorial review for accuracy and consistency.
- Back translation and reconciliation.
- In-country review by a validator who is both an expert in the field and a native speaker of the target language.
- Patient questionnaires and product testing in the target language.

Some quality control procedures carry a hefty price tag. For example, consider back translation, in which a document is translated back from the target language into the source language to check for discrepancies. This adds a significant amount of extra work and expense. Some in the translation industry consider it a useful quality control measure, while others believe the benefits are not clear enough to justify the additional cost. Regardless, for many medical translation projects this is a necessary step, as it often required by IRBs for clinical trials and by various regulatory boards for items like marketing materials and packaging.

How technology can streamline the process

Technology can streamline the medical translation process in a number of different ways. First, as discussed above, the use of translation memories cuts down on the amount of work required and helps ensure a consistent finished product. It should go without saying that the original translation used to create the memory must be correct. Garbage in, garbage out and if your organisation is not working with a top-quality translation company you could waste a good deal of money tracking down and fixing the same translation mistake over and over again.

Second, technology can improve ease of communication between the vendor and the client, which is absolutely critical to improving efficiency. At K International, our clients have access to our own bespoke in-house translation project management software, **Tracklingua**.

Tracklingua is custom-built for translation projects and can be easily customised to integrate with existing client software programs, systems and work flows. With Tracklingua, we offer improved efficiency and accuracy right from the start of every single project. Requesting a translation is as easy as uploading a file, forums and messaging make it easy to communicate with the team of experts assigned to your project, and our “Library” feature makes it easy for everyone involved to find relevant documents like manuals and terminology glossaries.

Additionally, Tracklingua integrates with translation memory software memoQ to maximize the potential of computer-assisted translation. ■

In medical translation, improving efficiency while ensuring accuracy comes down to the following:

- Use an effective quality assurance process to ensure an accurate end product. A mark of quality-controlled processes is the ISO 9001:2008 certification.
- Use translation memories to reduce unnecessary repeat translations. By integrating translation memories and translation management software, cost and efficiency savings can be made.
- Choose a vendor with a top-notch project management process.
- Use a trusted translation company who will get your project right the first time. Look at the company’s client list, what type of organisations trust them?
- Choose a vendor who can reduce indirect costs by integrating with your company's work flow.

Translation for clinical trials

Over the past decade, clinical trials for new drugs, treatments and medical devices have increasingly been conducted in countries overseas. Emerging markets offer attractive benefits to sponsors, including significant cost reductions, easier recruitment and faster study completion. Top countries for outsourcing clinical research include India, China and Russia.

The need for quality medical translation grows, as more clinical trials are conducted in emerging nations. Clinical research accounts for a significant percentage of the cost of bringing a new drug to market, but poor-quality translation during the trial period can incur even more significant costs. Put simply, the wrong translation provider can compromise an entire study.

Regulation of translation for clinical trials

There are a number of considerations when it comes to providing translation services for clinical research. First of all, proper translation is a regulatory issue. To generate usable data, clinical research protocols must comply with rules and regulations from a variety of sources, which could include the European Union, the FDA, local governments, the World Health Organization, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and local institutional review boards (IRBs). To ensure that the trial data is accurate and that the material presented to patients meets ethical standards, these entities have different rules that direct how study material is translated.

Also, 2014 was a turning point, as new medical regulations to protect patients were enacted around the world, including the European Union and top research destinations like India and China.

Aside from these rules, quality translation into the right languages is an ethical imperative. No matter what language they speak, patients have the right to provide informed consent when they participate in clinical research. Informed consent forms must be translated and translated correctly, in a manner that the target audience can easily understand. ICH guidelines require that "the information that is given to the subject or the representative shall be in language understandable to the subject or the representative." Even minor changes in meaning can cause confusion, as can using terminology that's too technical in patient-facing materials.

Even before the study begins, translation has a role to play in your recruitment programs. A good translation company will ensure that your brand voice and message is reflected in all translated marketing materials, in a way that resonates with your target audience.

Careful translation is also essential when the time comes to evaluate the results of a trial. Often, study data has to be translated from one or more source languages into the sponsor's target language. It is crucial that your translation company follows best practices for quality assurance when performing this task. Incorrect study conclusions on safety and effectiveness can have a significant human cost once a new drug or device comes to market.

While English remains the most popular language for publishing clinical research, translating the final draft of the study can make it easier for scientists around the world to read the results and build on previous research.

Choosing A Translation Company for Clinical Research

Are you looking for a company to help with translation during a clinical trial? Choose wisely! Translation mistakes that would be merely embarrassing in other fields can have devastating consequences in a clinical research setting. Having to redo research is a huge waste of time, money and resources, not to mention the potential loss of trust for your brand.

> “The ISO 27001 security standards for data protection are an indication of robust security processes”

How do you choose the right company? To start, look for a company that is accredited to international quality control standards. The ISO 9001:2008 certification is recognition of a company meeting or exceeding ISOQAR standards of quality control procedures. Companies with this certification get regularly audited to ensure that all their processes are compliant with regulations.

Many of the documents that need to be translated during clinical trials are confidential, including patient records which are often strictly protected by law. Look for a company with robust procedures for protecting sensitive data. The ISO 27001 security standards for data protection are an indication of robust security processes.

Companies offering translation for clinical trials should be able to help you navigate the tangle of regulations governing clinical trials in different countries, at least the regulations having to do with translation. Often specific quality control procedures are required, such as having multiple translators translate the same document or using back translation to check that the intended meaning has been conveyed.

Depending on location, clinical trials may require translation for a number of different languages, including minority languages, to meet the needs of all stakeholders. Look for a provider who has a network of translators all around the world with the necessary industry experience so that they can ensure technical terminology is conveyed accurately. ■

Medical translation gone wrong: 7 devastating medical translation errors

"First do no harm" is a difficult promise to keep when language barriers interfere with communication between doctors and patients.

Medical translation and interpreting can break down those barriers. However, quality is of the utmost importance when lives hang in the balance. These examples of medical translation errors show why it's important to use highly skilled and specially trained medical translators and interpreters.

Is this the most expensive medical translation error? Willie Ramirez and the $71 million word

Willie Ramirez was only 18 and out with friends when he suddenly developed a splitting headache. By the time he got to his girlfriend's house, he was barely conscious. They rushed him to the hospital, but he woke up paralyzed. He will never walk again. A brain bleed left him a quadriplegic for life.

But it didn't have to be that way. The haemorrhage should have been treatable, but the Ramirez family did not have access to a Spanish interpreter. So, when they told the emergency room doctors that they believed Willie was "intoxicado," he was treated for a drug overdose. As **Health Affairs** explains, "intoxicado" is not the same as "intoxicated."

Among Cubans, “intoxicado” is kind of an all-encompassing word that means there’s something wrong with you because of something you ate or drank. I ate something and now I have hives or an allergic reaction to the food or I’m nauseous.

Doctors only discovered the haemorrhage after days of improper treatment. By then, it was too late. The hospital, which should have provided a professional interpreter, is liable for a settlement of approximately 71 million dollars to pay for Willie's care for the rest of his life.

> “Knee replacement surgery is a painful procedure that takes months of recovery. Over the course of a year, 47 people had to undergo that ordeal twice for no reason”

Teresa Tarry received an unnecessary double mastectomy

British mother Teresa Tarry lost her breasts to an unneeded double mastectomy in Spain eight years ago, after a translation error led her doctors to believe she had a family history of breast cancer.

She claims doctors believed that both Teresa's mother and sister had suffered from breast cancer after a translation error ended up on her medical records. Then she struggled in speaking to the doctors.

In reality, she has no family history of cancer, so it was unnecessary to remove her breasts.

The worst part? The lump she initially sought help for wasn't even cancerous! After losing her job and living what she describes as "an eight-year living hell," she is now suing the hospital for €600,000 in compensation.

Medical translation errors cause botched knee replacement surgeries

Medical translation errors don't have to be fatal to have serious consequences. For example, in Germany in 2006-2007, a translation error resulted in 47 failed knee replacement surgeries. **The Journal of Specialised Translation** describes the case:

"Two different types of that knee prosthesis are available — for use with or without cement. The source language label on the package of the prosthesis included the information that the femoral component was "non-modular cemented," which was incorrectly translated as "non-cemented" or "without cement."

Knee replacement surgery is a painful procedure that takes months of recovery. Over the course of a year, 47 people had to undergo that ordeal twice for no reason.

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George Vs. Biggs – Informed consent requires patient understanding

In 2015, Sandra George, an elderly Macedonian speaker with limited English skills, sought help for a tumour on her vestibular nerve. In her first consultation, she used a friend instead of an accredited interpreter. She left that consultation with the understanding that her tumour was malignant. But it wasn't. And despite the fact that future consultations included certified Macedonian interpreters, she continued to believe it was cancerous.

One of the surgeons accidentally severed Ms. George's facial nerve during the surgery, resulting in palsy on one side of her face. Imagine her displeasure when she learned that the tumour was never malignant in the first place!

This case shows the importance of having a **qualified interpreter** present for all patient consultations. Sometimes it is difficult to correct misunderstandings once they have already happened. Better to get it right the first time!

Francisco Torres and the case of the missing kidney

In 2010, California's Riverside Parkview Community Hospital Medical Center operated on a Spanish-speaking man named Francisco Torres. The operation was supposed to remove Mr. Torres' diseased kidney.

At the direction of hospital staff, Mr. Torres signed a consent form indicating which kidney was to be removed. But the document was in English. And since he was never provided a copy in Spanish or access to an interpreter, he had no way of knowing that the hospital staff planned to remove the wrong kidney. After the hospital caught the mistake, they removed the diseased kidney, too. Unfortunately, that still left Mr. Torres with no kidneys.

According to NBC, the Health Department cited the hospital "for errors leading up to the surgery, including failing to follow safety protocol and failing to communicate accurately with the Spanish-speaking patient."

> “The minor daughter was acting as the interpreter for her parents and she was interpreting complex medical terminology about her own life threatening conditions”

The Tran Case

When it comes to medical interpreting and translation, the case of the Tran family is an especially tragic cautionary tale. In this case, the patient, a girl of only nine years, was asked to interpret for herself until she collapsed as a result of a reaction to one of her prescriptions. At that point, her 16-year-old brother took over and attempted to translate for his Vietnamese-speaking parents. Unfortunately, by the time the doctors figured out what was going on, she was already dead, and it was too late.

Generally speaking, it's a bad idea to have family members interpreting for patients. What's even worse? Relying on a child in distress to translate the information her parents need to make decisions about her care.

Additionally, when the girl was initially discharged from the hospital after being dosed with the drug that would kill her, none of the discharge instructions were translated into Vietnamese.

The girl's family sued and was awarded damages to the tune of $200,000. **As an expert witness at the trial stated:**

"Conducting the communications without a professional medical interpreter failed to meet the standards of care applicable for the physician and the facility. The effect is [that] she did not receive the care she should have. The parents were not able to adequately understand and address her medical needs. In my opinion, the failure of the doctor and the facility to provide a professional medical interpreter was a substantial factor in causing [patient]’s death."

The Lin case – another heart-breaking example of a child patient interpreter

In the Lin case, the patient, a 17-year-old girl originally from Taiwan but living in California, developed a brain abscess after being hit in the head with a tennis racquet. In the emergency room, she acted as interpreter for her parents until she went into respiratory arrest. As Pacific Interpreters noted, "Not only was the minor daughter acting as the interpreter for her parents, she was also interpreting complex medical terminology, and the life-threatening conditions she was communicating were her own."

< Medical translation gone wrong: 7 devastating medical translation errors

Since she did not receive timely treatment for the abscess, she died. There is no way to tell whether or not better communication would have improved the outcome. But I cannot imagine that the doctor, the patient, and her family were communicating effectively under those circumstances.

Chinese Pharma – (mis)translating labels

In 2017, the Chinese drug manufacturer Guangdong Zhanjiang Jimin Pharmaceutical C received a warning from the US Food and Drug Administration (FDA). They received the warning as labels on one of their products, Piyanping Anti-Itch Lotion, showed to contain the ingredient hydrocortisone, when in fact the active pharmaceutical ingredient that was dexamethasone acetate. The company stated that the mislabelling was caused due to a translation error and they believed that both ingredients were the same.As a result, the drug was recalled from the US.

There have been new translation directives issued by the China Food and Drug Administration (CFDA) which encompass requirements for registering medical devices in the Chinese Market.

Avoid medical translation errors with qualified translators and interpreters

The bottom line? Professional medical translation and interpreting services save lives and improve quality of care. Controlling healthcare costs is on everyone's minds these days, but translation and interpreting are not places to cut corners. ■

At K International, we have over 30 years' worth of experience in medical translation, working with clients including medical device manufacturers, pharmaceutical groups, the NHS and the British Army. Our medical translation experts can translate your content to or from any language in professional use today.

We are ISO 9001:2008 certified, with independently audited quality control procedures that ensure superior translation services. Our data handling procedures are ISO 27001 compliant, so you can feel confident entrusting us with sensitive data.

Additionally, with our extensive medical translation background, we are adept at navigating the tangle of medical translation regulations for our clients.

Got a project coming up?

Get in touch...
Tel: **+44 (0)1908 557900** or email **info@k-international.com**

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Operating since 1986, we provide targeted solutions for some of the largest global corporations and governments.

+44 (0) 1908 557900
www.k-international.com