Translating Innovation: Medtech Made Local

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As the global nature of the medical device industry continues to grow, so do demands on companies to meet the needs of an ever-expanding number of localized markets. Effectively translating user documentation requires more than language and technology expertise – it also calls for deep knowledge of regulations, cultures and preferences the world over.

Global and regional harmonization is a key trend in the realm of medical device regulation, but when it comes to language, localization persists.

While English is the lingua franca of the medical device industry globally for doing business, conveying technical accuracy and precision in key documentation is a very different thing. Case in point: The European Union, where 28 member countries, along with some other aligned nations, basically coalesce under one regulatory framework to reach the broader market. But to actually launch your device in France, you most certainly should have labeling and instructions for use, among other documentation, in French, and the same goes for local languages in most of the rest of Europe. In many cases, national governments require it. (*See Box, "Parsing EU Language Requirements"*)

And in order to support safety, indications and proper use of a product must be conveyed accurately, precisely and in a manner that the end user can understand. This need has only increased as devices have become more complex – technologies are often at the center of high-risk, life-or-death interventions.

Meanwhile, the device industry is more global than ever. Today, for instance, 25% of U.S. medical devices are exported – increasingly to rapidly growing markets such as Asia and South America. With this, more governments worldwide are paying closer attention to devices and the potential risks, and setting up device-focused regulatory systems that put more documentation and testing demands on companies.

Parsing EU Language Requirements

But in the EU, the situation is somewhat fluid regarding what languages are allowed on device labels and manuals. For instance, under the current regulatory frameworks/directives for both IVDs and devices, it is up to the member state legislators to define the language of information provided by the manufacturer of medical devices.

The information provided by self-testing devices should be displayed in the official language(s) of the member state in which the device reaches the final user. For professional use devices, the picture is not so straightforward: if it's not regulated by the national law, or it is allowed by the national law, manufacturers can negotiate with the users to provide the software in English only.

And certain additional conditions can apply around the EU. For instance, Dutch legislation states that if an IVD medical device is exclusively used in a professional environment, it is possible to provide the instructions for use in English, if the user has an adequate knowledge of the English language.

In the face of these factors, the importance of language precision, the completeness of documents and the ability to communicate with different, local customer bases around the globe is at a high point for device companies. Cost-effective translation that is mindful of regulatory demands, local customs and sector-specific needs is more crucial than ever.

More Than A Technology Platform

Device companies with a large global presence that are contracting with an outside translation service provider are seeking technology-driven expertise in addition to regulatory knowledge to improve productivity and to allow the seamless processing of product documentation, including effective use of "translation memory" databases, suggests Waldemar Frank, VP of Global Solutions Management for the life-science focused translation company LUZ Inc., a member of the RWS Group.

> *"The user experience is important, and you also want to make sure you don't violate cultural norms that could potentially compromise the success of your product."*
> *– Waldemar Frank, VP*
> *Global Solutions Management, LUZ Inc.*

Particular requests from companies might be, "We want to move to XML, but not delay the release of our products. Do you have experience with style sheets? Can you ensure that we can put out our content in PDF and HTML or another format?" explains Frank, who not only has experience with these issues at LUZ, but also from his prior role running translation and publishing services at a large device company.

A device firm might seek help, for instance, in optimizing its language compliance for different regions. (*See Box, "European Language Compliance."*)

Typically, a translation service provider will enter the picture shortly before a device is set to enter the market, when user documentation, including user manuals, labels, release notes and other elements, must be translated – into, on average, 15-30 languages – for preliminary review and launch. That often means aggressive deadlines.

But the focus on technology, platforms, and process efficiency conceals an important translation challenge, and risk. The potential for details to go awry

in translation is non-trivial. And the consequences of errors in a such a regulated environment, and one that is so directly tied to patient health and safety, are high.

Having translation resources in place that are attuned to these risks can be crucial to avoiding missteps in the rush to launch.

Problems can result from something as simple as an address label. If the manufacturer's address is printed inaccurately in the process of translation and publishing, a regulator "would pull your product off the market because the address has to be accurate and current," Frank said.

He also points to risks that crop up during the translation review process often performed by companies.

"We translate the documentation and before the manufacturer finalizes it and releases it," Frank explains, "the client might say, 'we have a marketing manager or a sales manager or an engineer in Germany, and one in France. We want them to review your respective translations just to make sure that from a subject matter point of view – but also from a regional point of view – we like your translations.'"

Problems can arise, though, when an in-country reviewer adds or revises the content. If the updated content deviates just enough from the original language version, "that's off-label use," Frank stresses. "A translation supplier who doesn't understand the concept or regulatory impact of off-label use will never be able to tell the client, 'Your reviewer introduced new content that make some claims that you could potentially get flagged for,'" he said.

"These are things that translation suppliers who are really good need to know and understand."

Evolving Regulatory Landscape

Knowledge of regulatory details is even more crucial during a period of significant change. That certainly describes the current global context for medical devices.

The European Union, for instance, is transitioning from its current system of "directives" governing oversight of medical devices and diagnostics to new Medical Device and IVD Regulations. The new rules, which will fully kick in over the next three to five years, will mean more clinical data demands, more oversight from notified bodies for many products and, overall, more scrutiny on devices and the documentation that supports them.

Ensuring that each product is accurately and appropriately represented

under the new rules in each of the 24 official EU member-state languages will be a challenge that an engaged translation service can help with.

Regulatory evolution in the region has already been something that companies have needed to be wary of from a translation perspective. For instance, as software tools have more often been designated under the EU system as "medical devices," this has triggered the need to meet EU country requirements to translate software and its documentation to local requirements, according to Frank.

The issue is even more pronounced in developing markets, particularly in Asia and South America, that are in some cases building oversight systems specifically targeting medical devices for the first time. This comes as more device companies are introducing a broader spectrum of products, including more clinically complex devices, into these markets.

Overall, the result is more pressure on the precision of language and getting things right for each region in which a device is sold, Frank says.

"Because of the complexity and the diversity of the markets as they're maturing, the requirement to not only be precise, but also provide a more customized document for a particular region ... is increasing," Frank said. "That requires both clients and translation companies to pay greater attention to detail and make sure that the right terminology is used in the right region."

Of Language And Culture

New device regulations in developing markets will hopefully provide more predictable and transparent rules of the road for companies, in terms of entering markets, data collection and producing product documentation. In addition, governments are working together to try to align requirements across borders – for instance, 10 countries are currently working to adopt uniform requirements under the ASEAN (Association of Southeast Asian Nations) Medical Device Directive as early as 2019. Countries in the region, such as Vietnam, are concurrently developing their own national systems.

But even as government-established rules become clearer and more harmonized, companies must be cognizant of regional preferences and cultural norms when rolling out translations for a product launch.

Translation and localization considerations "can be quite regional," Franks says. "You need to understand what dialect is acceptable in a particular region. That's one thing. The second thing you need to understand is cultural differences."

Frank, as an example, points to the Chinese market. "A lot of people come to us and say, I need to have this translated into Mandarin," he explains. "Well, the first thing that we tell clients is Mandarin is a spoken dialect; it's

not a written dialect. The predominant written scripts are traditional and simplified Chinese. So mainland China uses simplified Chinese script, whereas Taiwan and Hong Kong use traditional."

Language choice can also depend on your specific customer base within a country. In Belgium, for instance, there is the potential to use Flemish (Belgian Dutch) or French. Clients often ask whether a Dutch translation is necessary, and the answer depends on the circumstances, Frank says.

"Sometimes, it's really a decision that needs to be worked out with a client. Because, let's say, if it's a French-speaking hospital in Belgium, then they might prefer their documentation in French and not in Dutch," he explains.

There are also considerations in different countries about appropriate use of symbols, conventions in usage of measurement, and other idiosyncrasies, matters that go well beyond simply translating language.

"The user experience is important, and you also want to make sure you don't violate cultural norms that could potentially compromise the success of your product," Frank said.

"It's easy to recruit or to hire a translation service provider, but if they don't have the expertise and experience to look out for you on your behalf, to flag the things that potentially could become an issue down the road, then, obviously, you're working with the wrong supplier."

European Language Compliance

At first glance, language compliance appears to be a basic straight-forward requirement that should not come as a surprise to medical device manufacturers. Too often, however, language compliance and its planning become a last-minute activity as companies prepare for the market entry of new products. Moreover, when regulatory changes affect economic markets such as the European Union (EU) and European Economic Area (EEA), different regional language requirements and maintaining compliance still apply despite a generally standardized regulatory framework.

With a population of more than 510 million people and 28 current member states, the EU represents one of the largest economic markets in the world. In general, Europe is among the largest markets for health products and related healthcare services. In addition, an increasingly aging population reflects the typical demographic trend observed for many industrialized nations.

This trend and the size of the EU market provide conditions and opportunities that will only continue to boost the demand for healthcare services and products. Currently, the EU recognizes 24 official languages used by its 28 member states. Furthermore, the Medical Device Directives (MDDs) and a changing regulatory landscape continue to add to the complexity of language compliance across member states.