Translating medical devices:
A rule-driven game

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Abstract

Translation for medical devices often presents a unique set of challenges arising from the products' complex natures and associated regulatory requirements. Beyond medical expertise, linguists – from translators and editors to bilingual quality assessors – may require strong software localisation skills and knowledge of intricate engineering topics. Supply chain audits related to medical devices can, in many cases, demand more extensive compliance measures for language service providers than those required by most other clients.

What is our playing field?

We use medical devices every day. From contact lenses to blood glucose monitors and X-ray machines to defibrillators – these devices are all around us, revolutionising how we manage our health and improving our quality of life. The global market for medical devices was projected to reach US$471.80 billion in 2023.[1]

The European Union's Medical Device Regulation 2017/745 (EU MDR)[2] defines medical devices as "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for… medical purposes." A comprehensive list of purposes follows.

Some teams in language services perceive the life sciences industry as a single entity. They group together pharmaceuticals, biotechnology, healthcare, and medical devices. However, it is crucial to recognise and differentiate between the various areas within this domain.

In the world of translation, our medical devices playing field includes software tools, packaging, user manuals, marketing materials, technical specifications, engineering drawings, labels, instructions for use, distributor information, legal matters, clinical trial-related texts, training materials (both e-learning and instructor lead), implementation information, websites, phone application content, and more. That means a broad authorship and readership and a wide variety of writing styles.

What are the rules?

Importing and distributing medical devices to countries around the world is subject to strict approval processes and compliance measures. Compliance is how medical device companies insulate their patients and business from risk. While internationally recognised systems are helpful in meeting many compliance needs for manufacturers, it is important to note that no single system is universally applicable. Due to varying regulatory requirements between countries, parties cannot rely on generic guidelines being suitable for a specific market. This contrasts with the situation for pharmaceuticals, where standard templates and the structured Common Technical Document[3] apply for major global markets and simplify the translation process.

The rules keep on changing

From market to market, change is the only constant. The past year or so has been dominated by changes resulting from EU MDR, and indeed, implementation delays. In the past, medical devices needed only to provide translations after a device earned the CE mark. This is changing in an effort to improve patient safety, and many documents required for the new approval process must now be translated into all 24 official EU languages prior to that approval process. This means that translation enters the product development process earlier, and translation partners may find it easier to involve themselves upstream. Specifics of language requirements for each country are now available.[4] That's the new EU regulation. But the EU is only one part of the large global market.

Good practices (GxP) guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[6] and the International Medical Device Regulators Forum (IMDRF)[7] documents are broadly applicable. ISO 14155: 2020 is the standard relating to Good Clinical Practice for medical devices. FDA requirements such as 21 CFR Parts 11 and 820 apply in the United States.[8] Add to the mix privacy-related regulations such as the US HIPAA and EU GDPR. Other smaller markets have their own regulations. The UK, post-Brexit, will implement its own device regulation but has delayed implementation and is extending acceptance of CE marks at this time.[9] Harmonisation efforts have had success but will not replace each locale's regulation.
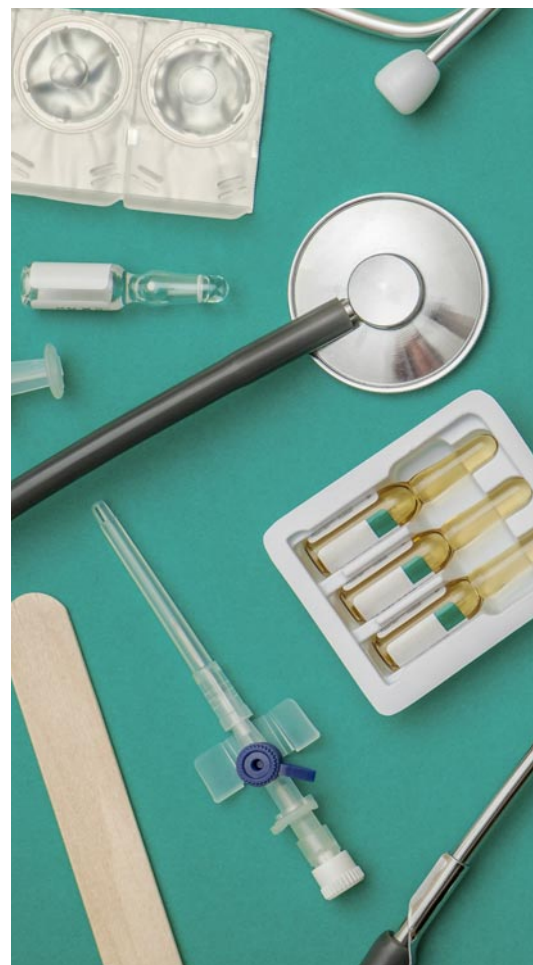
Regular referees

Most readers will be familiar with ISO 9001, a generic quality management system standard that can apply to any organisation. ISO 13485:2016, "Medical Devices, Quality Management Systems, Requirements for Regulatory Purposes," has a stronger focus on medical device safety, traceability, and risk management. Many translation buyers will audit providers to the standards of ISO 13485 as they relate to service providers. We now also see reference made to ISO 14971.[10] "Medical devices, Application of Risk Management to Medical Devices," which goes even further to help companies systematically implement best practices that reduce risk.

Who is playing?

Who are the clients? Manufacturers, distributors, and other interested parties, of course. And who is translating? From small buyers using individual freelancers to translate one language pair to global giants with multimillion annual spends in programmes handled internally or through one or more large language service providers (LSPs), there's no one answer. What is common to all, though?

Subject matter experts

How well the team understands the device, how it is used, and the regulations for the target markets the manufacturer is selling in make all the difference. That begins with the linguists and extends to encompass the entire team.

Medical expert linguists are key players and ideally have a life sciences background. However, this may not be sufficient to fulfil manufacturers' needs for a successful translation programme. Add awareness of differences between devices, small molecules, and biologics, to strong knowledge in the specific domain at hand. Add experience with software localisation processes to clinical understanding. Engineering drawings and technical specifications can also call for significant expertise beyond the basics. These linguists are players who are highly knowledgeable domain experts.

Machine translation?

Some try to add AI as a player here. While this may be useful for particular functions, any medical device manufacturer incorporating AI without expert human defenders on the field is adopting an extremely high level of risk. Human expertise is required to oversee and regulate the use of AI in medical device manufacturing for safety and efficacy reasons.

Some governments are stepping in here, mandating a human component to enhance public safety. For instance, in 2022, the US Department of Health and Human Services proposed a Rule[11] stating that a qualified human translator must review machine translation if an entity uses machine translation for text that is critical to the "rights, benefits, or meaningful access of a limited English proficient individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal or technical language".

How do you score?

Let's not linger here on areas that apply generally to any translation and localisation project, such as suitability for the target audience in each locale or wise use of translation management systems and language assets. Those are basics. The work of translation providers for medical devices goes beyond that and is part of successful regulatory submissions.

Speed to market

Fluid processes can help with regulatory approval and speed to market. It helps if manufacturers' content management systems align with translation management systems so that systems integrate with the necessary regulators' databases and data flows smoothly.

Plain language

The ideal of using plain language to reach a target audience effectively is not unique to medical devices, but here, it is regulated, and the best providers will produce it every time. The EU MDR says that information given to the subject "shall be kept comprehensive, concise, clear, relevant, and understandable." The regulation also refers to the intended user: what is easily understandable for a healthcare provider and for a patient will of course often differ. Depending on how far the original content diverges from target audience expectations, this may require extensive rewriting, shortening or restructuring of the information. That means that linguists

must know what plain language is and is not in their target locale, which limits the talent pool.

Continuous improvement

Great translation providers help clients surpass a quality baseline and achieve continuous improvement. They point out inconsistencies. They are aware of the regulations and are translating with deep knowledge of the purpose of every document or software string. They help the client get to the next level.

Compliance

Providers could be audited to any of the quality management systems mentioned above, as far as they apply to service providers. Partnering with translation companies that have gone to the extent of becoming certified to a quality management system for medical devices, such as ISO 13485:2016, provides additional confidence for many manufacturers.

Who are the champions?

So who wins the matches on this playing field? Providers and manufacturers who form genuine partnerships are the true champions here. We talk about top-notch quality and effective processes for any translation, but few outside the life sciences sphere understand the extent to which these partners grow together to serve patients well with medical device and related stakeholders. That is perhaps why language service providers like the one I work for, Vistatec, have set apart their Life Sciences business units. They recognise that translating for this domain

requires special workflows, domain expertise, and linguistic talent with additional quality assurance measures.

It's inspiring to support the global medical device market. It's also a privilege to know that our work helps to improve patient care all around us – in any language, anywhere, on any device. May we enjoy that privilege through many iterations of changing regulations, covering global playing fields day in, day out.

Disclosures and conflicts of interest

The author declares no conflicts of interest. All opinions are hers alone.

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