Language Scientific Explains IFU Translation Requirements for Medical Device Documentation

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Language Scientific has provided a practical overview of IFU translation requirements for medical device documentation, emphasizing how clear and accurate Instructions for Use support patient safety, regulatory readiness, and consistent device performance across global markets. The overview addresses a common reality in medical device development: translation is not a final packaging step, but part of the documentation system that regulators, clinicians, and end users rely on to interpret risk information and use devices correctly.

Instructions for Use are one of the most visible and most risk-sensitive elements of a medical device documentation set. IFUs typically carry essential information on intended use, indications, contraindications, warnings, precautions, step-by-step operating instructions, troubleshooting, maintenance, and storage. In many device categories, the IFU is the document most likely to be read outside a regulatory setting, and it is often referenced during training, onboarding, and post-market investigations. Translation quality directly affects whether the content remains usable and safe when distributed in multiple languages.

The overview emphasizes that IFU translation requirements vary by jurisdiction, device type, and distribution model, and that ?one translation approach? rarely fits all. In the European Union, language expectations are closely tied to where a device is made available and how it is supplied, with member states setting language rules for labeling and IFUs. Under the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), manufacturers are required to provide information necessary for safe use. These requirements intersect with national language obligations and the expectations of notified bodies reviewing technical documentation. In the United States, labeling requirements and related guidance influence how IFUs are prepared and maintained, with accuracy and consistency playing a crucial role in ensuring documentation is updated over time.

A key point highlighted is that translation has to preserve meaning, not just words. Medical devices rely on controlled terminology, standardized phrasing, and consistent hazard communication. If a warning is softened, a contraindication is mistranslated, or an instruction is interpreted in a way that changes sequence

or intent, a device can be used incorrectly even when the original source-language IFU was clear. Regulatory reviewers and quality teams pay attention to this risk, especially when translation changes safety statements, user responsibilities, or expected outcomes.

The guidance also draws attention to layout and formatting integrity, which is often underestimated. IFUs frequently include tables, symbols, step sequences, numbered instructions, cross-references, and units of measure that must remain consistent across languages. Small formatting breaks can create large comprehension problems, especially when a warning box becomes detached from the instruction it applies to, or when a table?s headings shift and values are misread. For devices distributed with multilingual packaging, space constraints and text expansion create additional complexity that needs to be managed early rather than during final production.

Another theme is change control. IFUs rarely remain static after launch. Design changes, risk management updates, new clinical evidence, corrective actions, or post-market surveillance findings may trigger updates. When the source IFU changes, translations must be updated in a controlled way so that language versions remain aligned. This requires clear version tracking, consistent terminology management, and a documented workflow that helps teams understand what changed, where it changed, and how those changes were reviewed.

The overview outlines practical elements that support consistent outcomes across languages. These include establishing a device-specific glossary and approved phrases for recurring safety content, maintaining style guidance for clarity and readability, and applying review steps that verify both technical accuracy and end-user comprehension. It also notes that review responsibility typically spans multiple roles, including regulatory affairs, quality assurance, clinical, engineering, and product teams. When review is handled without clear roles and timelines, the translation step becomes a bottleneck; when review is structured, translation becomes part of a predictable documentation cycle.

The role of technology is addressed in a grounded way. Translation tools can support consistency across large document sets and help maintain alignment across related materials such as labeling, IFUs, software prompts, and training documents. Technology can also help identify terminology drift and repeated segments that should remain consistent. However, the overview emphasizes that regulated documentation still requires expert human judgment to resolve ambiguity, interpret technical intent, and ensure the translated IFU is readable and usable for the intended audience.

Language selection and language variants are also covered. Many manufacturers plan for major markets early but face additional needs as distribution expands, including regional variants, local conventions, and market-specific review expectations. Planning for multilingual delivery involves more than listing languages; it requires understanding where devices will be distributed, which language obligations apply, and how

translation and formatting will be managed as documentation evolves.

Taken together, Language Scientific?s guidance frames IFU translation as a risk-managed documentation process. Accurate translation supports regulatory submission readiness, reduces confusion during use, and helps maintain consistency across global markets. For manufacturers, a disciplined approach to IFU translation can reduce rework, shorten review cycles, and make documentation updates easier to manage throughout the device's life cycle. For end users, clear and consistent translated instructions help ensure devices are used as intended, which is the practical goal behind every requirement.

About Language Scientific:

Language Scientific, Inc. is a US-based globalization company specializing in clinical, medical, scientific and technical language and linguistic validation services and solutions with a record of more than 25 years of excellence in over 215 languages. Language Scientific serves more than 1,500 clients in the pharmaceutical, clinical, and medical device industries, from Fortune 500 companies to small emerging companies. Our specialization, focus, innovation and customer-centered attitude have earned us the trust of many of the world?s leading life sciences companies. For more information, visit: https://www.languagescientific.com or email: info@languagescientific.com.

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