Language Scientific Breaks Down Common Risks in Translations for Medical Device Companies

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Language Scientific has shared an overview of common risks in translations for medical device companies operating across regulated markets, with a focus on how small language and formatting issues can create outsized downstream impact. The review reflects patterns frequently seen in Instructions for Use (IFUs), labeling, clinical documentation, technical files, and quality system materials, where translation quality influences patient safety, usability, and regulatory readiness.

One of the most persistent risks involves terminology drift. Medical device documentation often spans multiple document sets that share core concepts, from intended use statements and warnings to performance claims and maintenance instructions. When key terms are translated inconsistently across IFUs, labels, training materials, and software screens, end users may receive mixed signals about proper device operation. Terminology drift is especially common when multiple vendors handle different content types, when legacy translations are reused without review, or when product teams iterate quickly without maintaining a controlled glossary. Even a subtle difference in how a contraindication, caution, or operating step is expressed can complicate review cycles and introduce preventable confusion.

Another frequent issue is the translation of risk-related language, including warnings, precautions, contraindications, and safety statements. These segments are not purely technical; they are safety-critical instructions meant to be understood quickly and applied correctly. Literal translations that preserve grammar but miss intent can increase the likelihood of misuse. Overly complex phrasing can also create difficulties, particularly in patient-facing materials where comprehension significantly impacts outcomes. Clarity, readability, and consistency are not cosmetic preferences in these contexts; they are part of risk control.

Formatting and layout integrity is a risk category that often receives too little attention until late in the process. IFUs and labels regularly include symbols, tables, callouts, step-by-step sequences, references to figures, and tightly constrained packaging layouts. If a translation for medical device companies expands text length without planning for layout, critical information can shift, wrap, truncate, or become visually separated from the element it describes. Problems can show up as misaligned tables, broken numbering, mismatched figure

references, or warnings that no longer appear adjacent to the relevant step. In regulated documentation, these issues can slow review, complicate approvals, and create practical usability concerns during real-world use.

Regulatory alignment is also a common source of friction, particularly when documentation is intended for multiple jurisdictions. Expectations can differ by market, and language requirements may vary depending on the country of distribution, the document type, and the use context. EU MDR and IVDR documentation requirements can differ from FDA labeling conventions, even when the underlying product information is similar. When translation planning fails to account for market-specific requirements, teams may face rework, extended review cycles, or delays in submission readiness. In these cases, translation becomes less of a final step and more of a compliance dependency.

Software localization introduces an additional set of risks, particularly for connected devices, software-driven workflows, and products with on-screen instructions. Text displayed on a device interface has constraints that do not exist in a Word document: fixed character limits, truncation behavior, line breaks, and context-sensitive phrasing. A translated string that looks accurate in isolation can become confusing in a UI where context changes based on workflow state. Misalignment between UI text and the IFU is also common, such as when an on-screen warning uses different phrasing than the printed documentation. Without in-context review and linguistic QA, errors can surface late, often during validation or readiness checks for release.

Version control and change management are recurring operational risks. Medical device documentation rarely stays static. Updates occur due to design changes, new clinical evidence, corrective actions, label updates, risk management revisions, or post-market findings. When translation updates are handled without structured change tracking, teams can unintentionally mix versions across languages, apply updates inconsistently, or miss a required revision in one market. Over time, this creates a fragmented multilingual documentation set that is difficult to audit and costly to reconcile.

Time pressure can magnify all of the above. Tight submission windows and product launch schedules often create urgency; however, speed without structure can lead to shortcuts that increase the long-term burden. Typical failure points under pressure include skipping terminology alignment, reducing review steps, failing to address source ambiguity early, or treating formatting as a last-minute task. The result is often longer review cycles, more internal escalations, and a greater risk of inconsistent language across a regulated documentation package.

Data handling and confidentiality are additional considerations for translation programs that include sensitive technical, clinical, or product information. Secure file transfer, access controls, traceability, and retention practices affect more than internal policy compliance; they shape how confidently cross-functional teams can share documentation externally, coordinate with multiple partners, and maintain continuity across long

programs.

The overview emphasizes that many translation risks are preventable with disciplined planning and clearer ownership across stakeholders. Practical controls include a maintained termbase and style guidance, structured review checkpoints, early identification of source ambiguities, in-context review for software content, and layout-aware workflows for IFUs and labeling. When these controls are integrated into the documentation lifecycle rather than treated as a last-mile step, translation programs tend to produce cleaner outputs and fewer late-stage surprises.

Language Scientific supports translation programs for medical device companies and in vitro diagnostics across regulated markets, with workflows designed around accuracy, clarity, and operational consistency. Work commonly spans IFUs, labeling, technical documentation, clinical content, and quality system materials, with a focus on maintaining formatting integrity and ensuring change control throughout the product lifecycle.

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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