

Tips for Translation and Regulatory Compliance in the Pharmaceutical and Medical Device Industries

If you pick up a bottle of one of your prescription medicines you'll see various types of information on it - dosage and frequency of use, storage instructions, side effects, warnings, etc. – often in more than one language. The distribution of drugs and devices across borders has done away with translating packaging and labels as a luxury or value-add and, instead, made it a highly regulated, and more often than not, required process. Based on more than a decade of providing translation services to leading companies in the healthcare and life sciences industries, GLS offers the following tips for translation and regulatory compliance:

1. **Do not assume that you can use English-language labels in foreign countries.** In the European Union (EU) countries, for example, several directives, including the Clinical Trials Directive, Medical Device Directive (MDD) and In-vitro Diagnostics Directive (IVDD), have specific provisions that make translation of medical labels mandatory into the language or languages of the country in which the products are being tested, distributed, or sold. See the following directives which govern what labeling and instructions for use must accompany your product: Directive 98/79/EC of 27 October 1998 (IVDD) and Directive 93/42/EEC of 14 June 1993 (MDD).
2. **If you do not have the expertise within your company, hire an international regulatory consultant and work with a translation firm who has expertise in the specific in-country guidelines.** A consultant who is thoroughly familiar with the labeling and packaging regulations in foreign countries can review all regulatory compliance issues and provide expert guidance to your translators as they begin the translation process. For example, drug manufacturers and medical device companies who plan to test or market their products around the world must meet various in-country regulatory requirements. One of such regulatory requirements is proper translation, design, and content of all labeling and instructions for use. Specifically, the European Union has issued several directives regulating the CE mark, which is required prior to distributing medical and in-vitro diagnostic devices in the EU. Pharmaceutical companies looking to distribute in the U.S. must have certification that the foreign-language labeling is complete and accurate.
3. **Do not use a canned machine translation program.** Errors in translating medical labeling or instructions for use could lead to regulatory and/or product/civil liability. Therefore, it is especially important to work with professional translators who have medical and pharmaceutical translation experience, education, or both. Machine translation is not precise enough to accurately translate the highly technical terminology used in medical labels, and worse, could cause a misinterpretation of the actual meaning altogether.

4. **Consider developing medical labels for each geographic region with similar regulatory requirements.** More and more pharmaceutical and medical device companies develop region-specific labels or instructions instead of trying to fit all languages into one universal piece. For example, for the countries of NAFTA (United States, Canada, and Mexico), in which FDA-approved drugs can be marketed, the labels would include English, French, and Spanish languages.

5. **Assign a point person within your organization for the management of all translation projects.** As translation mistakes can delay product approvals and launches, managing translations becomes a critical component of the medical device and pharmaceutical global distribution process. By centralizing the translation process within your organization you will benefit from consistent quality of all translations, faster turnarounds, and reduced translation costs.

There is more to pharmaceutical and medical device packaging and label translation than replacing words with the native language. It is imperative to achieve a translation quality that moves beyond language, cultural, and regional differences, as well as meets all local and international regulatory guidelines. For more information about translation tips and tools in the pharmaceutical, medical device, clinical research, and healthcare industries, visit www.globallanguages.com.



About Global Language Solutions

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