Best Practices for International Electrical & Medical Device Labeling

Successful Supply Chain Labeling Addresses Diverse Regulatory & Translation Requirements

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Introduction

Electrical and medical device manufacturers face an array of challenges in delivering products to international markets. Complying with diverse and evolving regulatory requirements that vary by region, providing country-specific translations, and ensuring compliance and consistency throughout the global supply chain are critical to successful labeling, documentation and packaging processes.

In this paper, you will learn what international challenges manufacturers face and how they can best respond to them without affecting production and delivery. The best labeling practices for international markets includes plans for adapting to diverse and evolving regulatory requirements; meeting localization standards; optimizing translation processes; and managing label real estate challenges.

1. Electrical and Medical Device Labeling Challenges

For electrical and medical device manufacturers, the definition of “label” includes not only sticky labels at all levels of packaging, but also Instructions for Use (IFUs), technical data sheets and other documents, as well as, packaging. In the U.S. and many other countries, this definition even extends to promotional and advertising materials.¹

Labeling encompasses anything that describes the product, its capabilities and its intended use. This broad definition of labeling, and for countries where local language is also required, multiplies the challenges of international regulatory compliance. To further complicate matters, the regulatory landscape is continually evolving, particularly for international product delivery.

Organizations must comply with global country certifications and directives such as China CCC, EU Medical Devices Directive, US FDA, Japan PSE and other regional laws and directives with unique country-specific requirements. For example, there are at least 10 unique medical device codification systems in the EU alone. The variety of product identification standards in use today complicates harmonization efforts, with identification standards that include GS1, HIBCC, EAN and UPC.

GS1 and the other standards assist in tracking products through the global supply chain. For the medical devices industry, this can include contract manufacturers, private label and re-label partners, distribution points and point-of-use health care providers. While the Global Harmonization Task Force and similar groups pursue initiatives to synchronize standards for safety, quality, effectiveness, manufacturing and delivery, the reality for electrical and medical device manufacturers is a global marketplace with diverse regulatory and language requirements.

¹ The FDA definition of medical device labeling is available at: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm

Information about EU MDD and its labeling requirements are available at: ec.europa.eu/enterprise/medical_devices/legislation_en.htm
These requirements often have localized variances within regional authorities that must be applied and verified throughout corporate manufacturing, contract manufacturers, distribution facilities, component suppliers and distribution partners.

For example, in Mexico a manufacturer must comply not only with the NOM-008 symbology requirements referenced in the product safety standards, but each distributor must comply with the packaging/user manual/warranty instructions requirements referenced in the NOM-024 standard.

2. Anticipating Regulatory Change

Regulatory change is an ongoing challenge for electrical and medical device manufacturers, and it is particularly so for international marketers. Codification, symbologies, language and other requirements vary by region, and they very often include localized requirements.

While navigating this landscape is demanding, the greater test is assessing a manufacturer’s ability to accommodate new or changing requirements, often with just months to comply. In several recent examples, device manufacturers were given just a short window in which to comply with new regulations, at the potential cost of halting product delivery to that country.

In early 2008, Turkey announced a new requirement for an EAN-13 or HIBC barcode on all medical devices sold there. The regulation was effective January 1, 2009.

- In December 2009, the EU implemented Directive 2005/32/EC with regard to eco-design requirements for standby and off-mode electric power consumption of electrical and electronic household and office equipment. Effective dates have been set to meet the requirements with informational requirements to the user.
- In early 2009, Saudi Arabia customs announced the Country of Origin/“Made in …” labeling on all products and packaging shipped to the Kingdom.
- In February 2006, China implemented the Law on Management Method for Pollution Control of Electronic Information Products. This law had an effective date of March 1, 2007 and required manufacturers to comply with the requirements in addition to labeling and informational requirements.

Changes in regulations are constantly being made. The amendments to EU Medical Devices Directive (2007/4/EC), will require enhanced scrutiny to supplier compliance with an emphasis on the Legal Manufacturer having responsibility for the labeling compliance of contract manufacturers and distribution partners. The definition of medical device will also be expanded to include some stand-alone software applications. This introduces new challenges for IFU (Information for User) compliance, especially in managing translations and screen shots.

A second regulatory change impacting international medical device delivery is UDI (Unique Device Identification). UDI was introduced by the FDA with the Food and Drug Administration Amendments Act (FDAAA) of 2007, and calls for:

1. “… the label of a device to bear a unique identifier…”
2. “… the unique identifier to be able to identify the device through distribution and use …”
3. “… the unique identifier to include the lot or serial number if specified by FDA.”

A detailed description of the current status of the FDA UDI regulations can be found at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/default.htm
After completing UDI Readiness initiatives, medical device manufacturers report that the primary challenges with complying with UDI include: Capturing UDI data at time of production, tracking devices through distribution to point-of-use, and delivering this data electronically to the FDA. UDI data will include some combination of lot, serialization, expiry, manufactured date, company and product data.

Making changes to codifications or markings, creating new translations, and adding symbols to packaging materials often requires the creation of a project team, and the allocation of resources to examine static documents over multiple review cycles. In addition to being extremely costly and time consuming, it leaves the door open for a multitude of errors.

3. Conclusion

With risks to product safety, regulatory review and ultimately brand equity, organizations must ensure that labeling, documentation and packaging processes comply with the most up-to-date standards and regulations for each country. It is also incumbent upon these organizations to adopt practices that enable them to react quickly to process change requirements.

The problem is that requirements change often. The best success stories are from companies that have expended time and effort on researching the legal and technical requirements before the products go into development. Often, these organizations use partners to help them with this effort, and with this information, they are able to develop a detailed plan on testing, lead-time on certifications and cost.

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