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REGULATORY LANGUAGE REQUIREMENTS AND THE EUROPEAN UNION

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Sustaining competitive advantage within the medical device industry involves a global product strategy that recognizes the European market's substantial global market share. Estimated at 30% of the global medical device market, the European community poses increasing regulatory challenges for medical device manufacturers. Regulations controlling the manufacturing, marketing and usage of medical devices in the EU are forcing manufacturers to incorporate language translation and localization into global development strategies as individual Member States demand product information in the language of the local user.

Medical device manufacturers involved in global product distribution are well aware of the December 2003, IVDD 98/70/EC directive requiring a CE Mark as a precursor to product acceptance in the EU Member States requiring local language representation. The IVDD Directive virtually eliminates the costly regulations imposed by individual member states. Manufacturers who comply with the Directive will be able to apply the CE mark to their products and market them freely within member states of the EU. Additional Member States are under consideration (table II) which may further complicate multiple language labeling and documentation with even more languages.

The IVDD (In Vitro Diagnostic Devices Directive) is one of three associated directives issued by the European Union, which together cover all forms of medical equipment with the intent to ensure that only safe and effective products are sold in the European market. The directives clearly outline regulations regarding manufacturing, importing, and marketing of such devices. The IVDD specifically involves in vitro (in an artificial environment outside the living organism) medical devices that examine human fluids or tissue samples to identify, diagnose, and monitor medical conditions. The IVDD 98/79/EC brings in vitro devices in line with other medical devices already regulated by the EU, the MDD (Medical Devices Directive) and the AIMDD (Active Implantable Medical Devices Directive).

The IVDD and it sibling directives apply progressive regulatory requirements to medical devices and their accessories depending on the classified risk they present to the user, defined in the directive as Class I through III. Unless the classified product is a low-risk Class I device that does not contain any sterile packaging or a measuring function, manufacturers require a third-party Notified Body to independently certify the device's compliance to the Directive's Essential Requirements (a.k.a. Annex I)-good faith is not enough. Additionally, in a new twist within the Directive, the authorized representative shown on the device label for Class I devices manufactured outside the EU may be required to produce the technical file, including copies of all translated materials. Any incorrect labeling or instructions for use may lead to regulatory criminal or product/civil liability in the EU.

Any medical device manufacturer wishing to market its products in the European Union is fully responsible for complying with the corresponding safety and administrative Essential Requirements and must display the CE mark of conformity as stated in Article 16 of the IVDD 98/79/EC. If that's not a red flag, consider the next regulatory deadline facing in vitro device manufacturers: By December 7, 2005, the European Union will not only require a CE mark to legally market a product, but will require a CE mark to legally put a medical device into service – requirement much more critical to the revenue of manufacturers and healthcare!

CE Mark: A passport to the European Union

An abbreviation of a French phase "Conformite Europeene," the CE mark indicates that the medical device manufacturer has conformed to all the obligations set forth by the Directive 98/79/EC of the European Parliament. Affixing this multinational standardized mark to a product will allow any global manufacturer a "passport" to freely distribute their products within the European Union without additional quality testing or approvals. Reflective of the 1946 Treaty of Rome, the CE mark is a conformity tool that is intended to further promote the establishment of a single market where the free movement of goods, persons, services and capital are ensured. Fundamentally, the CE mark and the medical device directives remove many regulatory hurdles while providing stronger regulations for smaller countries; however, it also creates critical language compliance issues that may prove to be costly for manufacturers. Regardless of the intended global harmonization, participating countries are preserving their national cultures and languages by requiring product information in their own local languages.

IVDD, MDD & AIM...more languages!

Depending on device classification, to legally display the CE mark, the IVDD, MDD, and AIMD all mandate that manufacturers provide all labeling, information for usage, documentation, and marketing materials in the official language(s) of the end-user's Member State, taking into account the training and knowledge of the potential users as stated in Article 4, Paragraph 4, IVDD 98/79/EC.

Documentation Translation Requirements: Conformity Assessment Procedures

Manufacturers are required to translate the documentation relating to the production, testing and quality processes in the official language(s) of the Member State in which the procedures are carried out as stated in Article 9, Paragraph 11 of the IVDD 98/79/EC. Depending on device classification, these documents must include a number of required disclosures dependent on the product classification.

Depending on marketing and distribution objectives, some products may require up to 22 languages, creating complicated multilingual product labeling and IFU challenges. There can be over 20 information pieces required for each product label of IFU, depending on the classification as detailed in Annex I, Part B, Section 8 of the Directive.

EU Member State Official Languages

Depending on the extent of the product's presence in the European Union, there are currently up to 22 languages required for the labeling, IFUs, documentation, and marketing materials in accordance with the IVDD and MDD necessary for CE mark as displayed in *TABLE I*.

As the EU continues to grow and the trading barriers dissolve, prospective Member States are actively transitioning regulations to meet the CE mark criteria, requiring new languages. A midday regulatory shadow to the EU, European Free Trade Association (EFTA) countries of Iceland, Liechtenstein and Norway are aggressively enforcing the CE mark, shown in *TABLE III*. Although not a member of the EFTA, Switzerland is also enforcing medical device CE mark.

Global Harmonization and International Quality Standards

In 1998, the United States and the European Union introduced the New Transatlantic Agreement (NTA) to improve economic cooperation between the two economic powers. In this landmark accord resides the Mutual Recognition Agreement (MRA) that acknowledges the regulatory standards of the respective economic bodies-an area of transition that affects the medical device industry. The European Union medical device directives refer to ISO 9001 as the series of quality management standards and the US refers to

Table I

Official Language(s) of European Union Member States

Member State	Official Language(s)
Austria	German
Belgium	Dutch, French & German
Cyprus	Greek
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxemborg	French, German & Luxembourgish
Malta	English & Maltese
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Slovakia	Slovak
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
United Kingdom	English

Table II

Official Language(s) of Member States Applying For European Union Membership

Member State	Official Language(s)
Bulgaria	Bulgarian
Croatia	Croatian
Romania	Romanian
Turkey	Turkish

Table III

Official Language(s) of EFTA Member States

Member State	Official Language(s)
Iceland	Icelandic
Liechtenstein	German
Norway	Norwegian
Switzerland	German, French & & Italian

(Switzerland is not a EFTA member but requires translation)

FDA's Quality System Requirements and all corresponding good manufacturing (GMP) practices regulations. Benefiting medical and pharmaceutical companies, both quality systems have made considerable efforts to synchronize their requirements further increasing the common ground between quality systems in North America and Europe.

GMP (Good Manufacturing Practices)

In December 1978, the FDA Good Manufacturing Practices (GMP) Regulation became effective, establishing Quality System Requirements for products regulated under the FDA, including medical devices. In 1990, the Safe Medical Devices Act (SMDA) expanded the GMP to include design, manufacturing, packaging, labeling, storage, installation and servicing of all finished medical devices.

Exporting American Medical Devices

Any medical device in the US market may not be legally exported anywhere in the world without prior FDA notification or approval; however, for a device to be legally distributed in the US, the FDA requires:

- Registration of both the medical device and manufacturing site
- Authorization for commercial distribution through either a 510(k) pre-market notification or a Pre-market Approval (PMA) application depending upon the classification of the device
- Compliance with FDA labeling requirements
- Manufacturing compliance with the FDA's Good Manufacturing Practices (GMP)

While the FDA does not place any restrictions on the export of these devices, certain countries require an Export Certificate that the manufacturer and its devices are indeed in compliance with FDA regulations. Medical devices that do not have a 510(k), PMA, or are solely manufactured for export may by approved for exportation by the FDA through Section 801(e)(1) of the FFDCA; however, the manufacturer may experience regulatory difficulties depending on the individual country's requirements of an FDA Export Certificate, which, as stated above, require a 510 (k) or a PMA.

Sorting through the regulations to achieve global product delivery

The question facing medical device manufacturers in the current global market is how to meet all language requirements in the most cost-effective, regulatory compliant manner. Managing regulations and translations are among the most critical aspects of developing and marketing products for the life sciences industries. Any mistake, no matter how minor, can delay product approvals, launches, or cause widespread public relations disasters. Therefore, developing translation and localization processes has become a competitive advantage for global manufacturers of medical devices.

Working closely with a translation and localization vendor who specializes in medical language services and is ISO registered is an important step in conquering the ever-changing international regulatory process. The choice of the translation provider is extremely important to ensure that translations are accurate, consistent and technically correct, as well as harmonious with the manufacturers' processes.

Medical language service providers should, at the very least, provide documented processes that involve native-speaking linguists that have expertise in both translation and the medical industry. To deliver consistency, quality and reduced costs, the language service provider should also implement terminology management tools and computer-assisted translation solutions in concert with the team of human translators.

In the process of developing documented multinational quality processes and programs, selecting an ISO 9001 certified language service provider is critical. It is important to recognize the difference between vendors who are actually certified and those who only present themselves as ISO "compliant." The difference is as significant as a medical device manufacturer "promising" the European Union compliance to the respective directives and not physically displaying a CE mark. In the eyes of government regulatory agencies, an ISO certified language service vendor is equivalent to having an in-house translation and localization department with approved processes that may be audited at any time.

Conclusion

Complex and ever-changing international regulations controlling the marketing and usage of medical devices are forcing manufacturers to incorporate language translation and localization into global development strategies. The European Union members currently require that all product information be in the official language of the local users and the diversity of this economic area is only growing to include more regulations and official languages. A simultaneous global release of medical devices involving up to 12 languages in Europe alone makes this issue as critical as the intended purpose of the medical device.

Medical device manufacturers can cost-effectively market their products globally while satisfying international regulatory requirements by partnering with a qualified language service provider in the very early stages of product development. The right language partner can turn what may now appear as a chaos of regulatory requirements into a successful international product release.