

GHTF guidance addresses risk-management topics

Marc H. Miller

On May 20, 2005, the Global Harmonization Task Force (GHTF) issued guidance SG3/N15R8, based on ISO 13485:2003 and ISO 14971:2000, which addresses risk-management issues (available at www.ghtf.org/sg3/inventorysg3/sg3n15r82005.pdf). What are its implications for translation vendors serving the medical-device industry?

The GHTF guidance confirms a growing awareness within the device and *in-vitro* diagnostic (IVD) industry that risk management is a requirement for all areas that affect a company's quality management system. This requirement was first introduced in the device-specific quality standard, ISO 13485:2003. In it, risk management and the current risk-management standard (ISO 14971:2000) are directly referenced.

The role of the GHTF

The GHTF, a voluntary group representing medical-device regulatory authorities and trade associations, develops and publishes harmonized guidance documents on basic regulatory practices to educate the medical-device sector. The documents provide non-binding guidance to regulatory authorities.

Ed Kimmelman, a principal author of ISO 13485, says that many device companies are struggling with effective implementation of risk management within their quality systems, largely because of an expanded definition of compliance. Kimmelman notes that areas such as competence of personnel, nature and depth of acceptance activities, handling of nonconformances, and complaints and corrective action/preventive action (CAPA) are all outside of product realization – the traditional boundary of risk-management activities.

Similarly, product labeling – including instructions for use – manuals and other instructional material, is directly affected by risk management. The accuracy of labeling information – in both its source and translated versions – is essential.

Marc H. Miller is president of the Crimson Life Sciences division and vice president of quality systems for TransPerfect Translations.



Labeling translation and responsibility

Most medical technology companies produce their own English-language labeling and documentation. Here, risk management is implicit since the company that develops the product is the clear choice to author the labeling. Still, product labeling receives close scrutiny from regulators and auditors even after a thorough vetting within the company.

When producing translated documentation, companies face a new risk – how to ensure that their translated labeling is accurate and fulfills the same risk-management function as the original. Panelists at the 2004 Regulatory Affairs Professionals Society conference noted that inaccurate translation might jeopardize conformance to ISO 14971:2000 in overseas markets.

According to the GHTF guidance, “processes required by the quality management system and performed by suppliers to the manufacturer are the responsibility of the manufacturer. Risk-management activities relating to any process within the quality management system are ultimately the responsibility of the manufacturer.”

So, labeling is a risk-management tool, and the manufacturer is responsible for ensuring that it is accurate.

With responsibility assigned to the manufacturer, the importance of due diligence in the vendor selection process is clear, and evaluation criteria are clearly required for translation vendors.

Labeling translation risk defined

The first step in defining appropriate criteria for translation vendors is to understand the risks associated with the activity.

Labeling translation involves two basic risks: *resource risk* and *process risk*. Resource risk is mitigated through screening, testing and audit. Screening involves predetermined criteria such as an advanced degree in the subject area or minimum years of professional experience in the subject area. Testing and audit are best carried out using controlled materials and with the help of an objective standard. Crimson employs a Notified-Body approved

version of the SAE J2450 translation quality metric modified for use in a medical context.

Process risk is managed using classic techniques such as redundancy and diversity. For instance, traditional translation risk management relies on a single redundant review – translation and edit. This basic process is, however, inadequate for the requirements of medical translation. A provisional patent filed by Crimson specifies three separate, redundant reviews in addition to translation/edit to ensure effective risk management.

Along with redundant review, risk management can be improved through process diversity – for instance, through a linguistic optimization step and a quality control step. This process has received Notified-Body approval as a safe and effective substitute for in-country review (also called distributor or subsidiary review).

Criteria for choosing a vendor

Established vendor selection criteria (based on resource and process risks) are essential. These criteria should include:

Registered quality system. Third-party certification helps to ensure compliance with generic (ISO 9001:2000) or medical-specific (ISO 13485:2003) quality system requirements.

Resource screening, testing, audit. What is the vendor's process for ensuring that resources are qualified? Can the vendor provide evidence of testing and qualification? Monitoring and

(when appropriate) dismissal? Does the vendor use an objective standard such as SAE J2450?

Control of process risk. Does the vendor employ process redundancy and diversity? How does the vendor address the “native speaker dilemma” – that is, verify semantic accuracy?

Process documentation. Can the vendor provide in-process documentation as evidence that all specified steps were carried out as required?

Client feedback, references and/or endorsements. Can the vendor provide references from medical clients, Notified Bodies or other regulators to demonstrate the effectiveness of its process? What is its process for gathering client feedback? Results?

Conclusion

GHTF guidance directs companies to exercise risk management in their important outsourced processes. One of the most commonly outsourced activities – translation – may have critical implications for risk-management strategy (through labeling) in overseas markets. Based on this, notified-body guidance specifies appropriate risk management when selecting a translation vendor.

Criteria for selection, evaluation and re-evaluation of labeling translation suppliers should take into account the known risks associated with the translation activity. **M**