March 21, 2010: Another Y2K for Technical Writers?

New complications for companies that design, manufacture, or re-package medical devices. A hidden incentive exists in the complexity as well...

Attention technical writers, regulatory specialists, and localization coordinators! If your company designs, manufactures, or re-packages medical devices with any type of software intelligence or user interface— listen up. Come March 21, 2010, your job complexity will get better and worse, thanks to changes in Medical Device Directive (MDD) standard 2007/47/EC.

Currently recognized as "voluntary", MDD 2007/47/EC becomes mandatory law in March of next year. Because the Federal Food and Drug Administration (FDA) recognizes MDD standards as guidance for US law, anyone with a domestic or international customer base is impacted by this new standard. Changes in two key areas are relevant to individuals managing medical device/medical product documentation (user manuals and instructions for use [IFUs]), labeling, and product packaging.

When MDD 2007/47/EC becomes mandatory, required translation volumes could effectively double.

Particularly for companies with small writing departments, the impact of MDD 2007/47/EC could potentially cause a rippling bottle neck effect as more than twice the volume of documentation (now for software and hardware and in more languages) must be reviewed, validated, and approved.

First Some Good News: Acceptance of eLabeling – The Incentive

While a growing trend in the labeling world is to provide IFUs in both print format (usually shipped with the product) and in electronic format (either on the company website or on a CD also shipped with the product), the current mandate is for companies to provide printed documentation in the appropriate language with each device. Particularly for Class III devices—devices usually requiring pre-market approval and extra scrutiny by the FDA and the European Notified Bodies (ISO and EC)— documentation size can ultimately impact the size of product packaging, increase shipping weight, and in some cases impact the ability of the product to pass sterilization testing.

eLabeling will not only save companies the cost of printing manuals in large batches (larger batches decreases unit price), cost associated with scrap will dramatically decrease (not to mention, Mother Nature will be much happier). Many companies have been eagerly anticipating the acceptance of eLabeling as law. Supply chain management can now print on demand, and users can also print entire manuals (or sections of manuals) as needed. Translation is still needed, but printing is not. With this change, the documentation world will not change as fundamentally as it will in the next key area: software.

Software Becomes Classified as an Active Medical Device

Significantly more complicated than eLabeling is the change to the scope of what is considered an "active medical device". New to the list is software—either as a stand-alone product or integral to the functionality of the device. Further, software validation will also become an essential requirement. To address the potential impact to technical writers, regulatory specialists, and localization coordinators (engineers and product managers, for that matter), the remainder of this white paper discusses software documentation as it relates to content management and the translation process.

Fundamental Change to Traditional Software Documentation

Most medical device/medical products have a user interface that is documented in the form of user manual, IFU, regulatory submission, or other quick reference guide. Traditionally, documentation of software code/software strings all fall under the scope of the engineering department, and unless this information is relevant to the end user (perhaps in a table, example, or screen capture) it is typically not considered part of product labeling or the regulatory submission. However, when medical devices are sold to customers in different languages, the software code/ software strings are translated and incorporated back into the software program. This process of extraction and insertion is usually managed by the engineering department in conjunction with the translation department, translation agency, and/or the localization coordinator. Often English/ European English is completed first, and the other languages follow.

Companies without effective change management systems will be at increased risk for recall and customs or regulatory holds.

If a company does not have a standard operating procedure (SOP) or quality management system (QMS) that provides a check-and-balance between what is on the screen and what is in the manual, the potential for risk (unfortunately, potentially impacting human lives in an adverse way) increases. Because of this risk, many companies have already been adhering to MDD 2007/47/EC. However, the need to separate the intelligence (software) from the device introduces a new level of complexity in the way companies track, document, and manage their software development process (and perhaps eventually making point releases and update patches a distribution methodology of the past).

Change Management: Preparing for March

With the change to software as a "product," the processes companies currently use for documentation will likely be revised throughout the greater medical device industry. The practice of concurrently developing end user documentation with software development will face new scrutiny—ultimately impacting engineering schedules and project management.

With the world closely watching the first few submissions under the new law, it is likely software products will face the same levels of scrutiny as high-level product submissions. In the documentation world, questions similar to the following are already being asked:

- Will product labeling support both the software and the hardware as a regulatory requirement?
- How will the software engineers work with technical writers, translators, and regulatory professionals in an effort to complete testing, validation, and pass code to the hardware teams?
- Will the software documentation act as a labeling subset for the high-level product submission?

Regardless of a company's strategy for submitting, marketing, and ultimately distributing software products, what is documented for the end user will not change. Software code will still need to be translated and the user interface will still need to be explained to the end user. With that said, there has never been a better time for implementing a content management system. eLabeling will give companies the freedom to disseminate information electronically—a sophisticated methodology for parsing and assembling that content can both eliminate risk and increase the bottom line.

Working Locally to Distribute Globally

A sound practice for companies outsourcing translation is to select a translation vendor with the following criteria:

- **Extensive regulatory experience.** Look for extensive knowledge not only in the governing laws and governing bodies, but in the practices of companies tracking to submission deadlines, audits, and the threat of warning letters.
- **ISO registration and notified body certification.** Make sure your translation vendor is ISO 9001:2001 certified. Review their registration documents, including their QAM (Quality Assurance Manual).
- **A focus on total cost containment not per/word cost.** Companies utilizing advanced translation memory can help contain translation costs through re-use and elimination of scope creep. Ask for case studies on how content management and advanced translation memory has enabled better project management and lowered costs across complex projects and between fiscal years.

Embracing Change

As the world learned with Y2K nearly 10 years ago, months of planning and formulating disaster recovery strategies helped avoid a potentially catastrophic shut down of the world's electronic infrastructure. Planning (albeit on a much smaller scale) for the worst with 2007/47/EC could help get medical devices/ medical products to market faster (domestically and internationally) and continue to save and improve the quality of our lives.

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