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Though structured product labeling (SPL) promises many long term benefits, drug makers are facing numerous hurdles as they scramble to comply with FDA's deadline of late 2005 for complete electronic processing of all drug related content.

Last February, the FDA issued a draft guidance on the XML-based SPL last February, and upon final approval, SPL will replace the current format in use, portable document format or PDF, and will be used for the process, review and archive of product information.

"Though managing product information - shepherding huge volumes of content through multiple internal and external hurdles for drugs on the path from the research lab to the marketplace - is an ongoing challenge for pharmaceuticals, the question for drug makers is whether they will treat the conversion of product-labeling documents to an open-source digital format as a blessing or a curse," says Dan Dube, director of business analysis for Innodata Isogen, a Hackensack, N.J.-based provider of content supply chain solutions for the information industry based in Hackensack, N.J.

SPL, he says, is forcing big pharma to figure out that it can drastically reduce the cost of content supply chains by implementing XML-based content management systems. Dube also points out that XML or extensible markup language, the open-source code the FDA mandated for SPL, has a long track record of success in other industries for supporting single-source publishing systems.

"Faced with increasing requirements to put more information on packages and share it with pharmacists and doctors, more and more drug companies are doing a full XML-based overhaul of their system," explains Dube, adding that there are also hurdles to overcome.

Dube identifies three pitfalls that organizations face while deploying new content management and publishing systems: Inefficient processes, organizational boundaries and technology limitations.

"Drug makers need to be sure that their new XML system allows them to utilize highly skilled staff and subject matter experts in the areas they are most adept in; that their departments are not duplicating effort across departments; and they don't get bogged down by proprietary systems as they make it difficult to migrate content, metadata, links and automated workflows into a new system," says Dube.

Ann Rockely, president of The Rockley Group (Markham, Ontario), lists accelerated FDA reviews, better communication with consumers and better sharing of clinical data as the key values that SPL offers.

"The use of XML offers additional benefits such as separation of content from presentation, easy identification of content, reusability, XML not being a proprietary language and ability to internationalize the standard easily," Rockley says.

However, she also adds that SPL doesn't support global labeling practices mainly due for two reasons. One, SPL is an FDA standard, while PIM, a consortium initiative between the EMEA (Europe's regulatory body) and EFPIA (a European pharmaceutical industry group) has its own standard. Japan , Rockley adds, is looking to have one of its own.

“Thus, we need to take the SPL structure and map it to PIM and other structures when needed. Second, there is lack of structure in the narrative and we need to extend SPL to create semantically rich narrative content,” Rockely says.

Dube says that while companies are feeling the pressure to do comply with SPL requirements, at the same time, many are postponing the pain as much as possible.

“Companies are underestimating the commitment it takes and are still thinking it is alright to do all the initial work in PDF or other formats, and then convert it to XML at the end just prior to FDA submission,” he adds.

Companies still are facing obstacles in totally converting to the SPL system because of cost and time factors. Training is needed to understand XML, a completely new and different system that focuses essentially on the content and not on the format.

Dube also lists other traps such as depending on a “standards-based” system that manages content in proprietary ways, using tools for something they weren't designed for and patchwork integration of systems. “Separately, each of these traps can severely impair an organization's efforts to build an efficient content supply chain,” warns Dube. “Collectively, they make it all but impossible. Organizations that adopt a careful, strategic approach to SPL compliance, one that embraces XML and its potential while avoiding these pitfalls, will clearly seize a clear competitive advantage and drive significant improvements throughout their organization.”