Crimson Life Sciences Offers Cost-Saving Technology Solution for Chinese Regulation 276

The Associated Press

BOSTON & SAN FRANCISCO--(BUSINESS WIRE)--Nov 5, 2012--Crimson Life Sciences, a division of TransPerfect and the only ISO 13485 and ISO 14971 certified translation provider, has introduced an advanced XML labeling solution to help manufacturers cope with the effects of changing regulatory requirements such as French Decree No 2012-743 of May 9, 2012 and China's medical device Regulation Number 276 (unofficial translation and analysis available upon request from info@crimsonlanguage.com). The regulatory changes, prompted in part by healthcare scandals such as the PIP breast implant recall, require device companies to make substantial content updates. Crimson's XML-based publishing solution enables manufacturers to automate labeling updates, eliminate formatting costs, and realize savings up to 40% over traditional methods.

Changing Regulations Drive Labeling Costs A raft of new and revised medical device regulations, including France's Decree No 2012-743 of May 9, 2012 and China's updated Regulation Number 276, will create significant compliance challenges for many manufacturers in 2013. That's the prediction of Marc Miller, President of Crimson Life Sciences: "Labeling mistakes are the number one cause of product recalls and these new regulations will affect tens of thousands of IFUs and marketing pieces industry-wide." In fact, recent research from Crimson indicates that the "Total Cost of Content" for device makers, including updates imposed by changing regulations, amounts to $1 billion per year (research memo available upon request from info@crimsonlanguage.com). According to Miller, "Most manufacturers operate with a document-based system for their labeling and marketing materials – working in applications like Word, InDesign, or Illustrator. In order to make updates, each individual document must be opened and modified. For large manufacturers with hundreds or even thousands of products, each small change can take weeks or even months to implement and comes with enormous cost and error risk." A Cure for the $1 Billion Industry Headache As labeling updates become more frequent due to changing regulatory requirements and corporate rebranding, manufacturers are exploring new ways to achieve cost and time savings. Crimson's solution is based on industry-standard DITA XML publishing strategies and proven, mature technologies to help manufacturers safely reduce labeling costs by as much as 40%. Explains Miller, "Not only does XML publishing make sense for manufacturers who want to reduce the cost of labeling, it also opens up a whole range of opportunities for content reuse in other channels, such as the web and tablet-based multimedia apps." Through the development of a custom "Information Model," Crimson works with manufacturers to convert their content to XML format for storage and automated retrieval in the same Component Content Management system used by device makers industry-wide (and developed by sister company, Astoria Software). Publishing is then automated through the use of document templates. Any content changes made by the user are automatically

propagated to all documents where the designated change occurs. Says Miller, “Thanks to the many cost-cutting efforts underway in the device industry, XML publishing based on the DITA standard is quickly becoming the labeling strategy of choice for global, multi-product manufacturers. We are pleased that we could develop this solution in partnership with Astoria Software—the recognized leader in DITA-based XML publishing systems.” About Crimson Life Sciences Crimson Life Sciences is a division of TransPerfect Translations International, Inc. and is the only translation practice exclusively devoted to the medical device industry. Crimson is the world’s first translation firm certified to both ISO 13485 and ISO 9001 and the only translation firm certified to ISO 14971. Crimson’s ISO 14971-certified risk management system is the basis for the world’s only translation risk management patent (U. S. Patent No. 8,140,322 B2). TransPerfect, certified to ISO 9001 and EN 15038, is the world’s largest privately held language services provider with more than 80 offices worldwide. For more information, visit www.crimsonlanguage.com.

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