



Getting More for Less: The Alchemy of Risk Management

First ISO 14971-Registered Risk Management System Yields a 36% Accuracy Improvement and a 20% Cost Reduction

Introduction

In July of 2007, Crimson Life Sciences (the specialized medical device division of TransPerfect Translations) became the first company to register to ISO 14971—the risk management standard for medical device manufacturers and their suppliers. Now, with over a year of post-production data analyzed, the true value of a formal risk management system is clear: Crimson's process yielded a 36% improvement in accuracy as well as a new benchmark for "labeling translation GMP." In addition, by applying risk management principles to the translation process, Crimson has cut clients' translation expenses by 20%.

Background

Due to an industry-wide focus on risk management and concern for patient safety, medical device labeling translation has come under increased scrutiny. In fact, an emerging body of research as well as several recent signal events have prompted further examination of manufacturers' translation risk management procedures:

- A study by the Dutch Healthcare Inspectorate observed a 50% failure rate in the risk management function of Class III device labeling. Follow-up a year later showed little improvement.
- A German newspaper, Der Tagesspiegel, reported that between May 2006 and March 2007, 47 patients received knee implants without the necessary bone cement and were forced to undergo revision surgery. The hospital noted a lack of appropriate German-language instructions.
- Results from a two-year labeling audit survey¹ spanning 21 languages and over a million translated words, determined that the average "serious error rate"² in translated device labeling (errors that may result in patient harm) was four times higher than the serious error rate produced under current industry best practice.

In fact, Notified Bodies now include assessment of labeling translation processes and procedures as a standard part of their CE registration audits.

The Challenge

Labeling translation is a professional service that requires effective controls at both the resource and process levels. US device manufacturers often lack the qualified resources to perform thorough audits of translation suppliers or inspection of their translated labeling. Even in the most favorable economic climate, manufacturers may be tempted to base supplier selection largely on price—economic hard times only serve to increase this hazard. Meanwhile, translation providers may be tempted to omit specified processes ("process fraud") or utilize low-cost, unqualified resources in an effort to cut prices while maintaining margins.

Together, these hazards expose manufacturers to the substantial risk of inadequate labeling translation, including CE audit nonconformances, delayed product release, and even product recall. Most importantly, inadequate labeling translation increases the risk of patient harm. The recent benchmarking memo, "A Current Assessment of Translated Medical Device Labeling Risk" indicates that there are approximately three serious translation errors in an average 4,000-word Class II/III device IFU. Many specific examples far exceed the average.

The Alchemy of Risk Management

Thanks to the implementation of an ISO 14971-registered risk management system, Crimson clients benefit from labeling translation accuracy that is 75% higher than the industry average—and linguistic costs that have been reduced by 20%.

¹ A Current Assessment of Translated Medical Device Labeling Risk" – a benchmarking memo published by Crimson Life Sciences

² A serious error (SE), as defined by the SAE J2450 standard and Notified Body-approved medical device adaptation, is any translation error that may result in patient harm.

Getting More for Less: The Alchemy of Risk Management

First ISO 14971-Registered Risk Management System Yields a 36% Improvement in Accuracy and a 20% Cost Reduction

However, a formal risk management system, compliant with the requirements of ISO 14971, provides a means for resolving the often conflicting goals of accuracy and cost-savings. As the world's first ISO 14971-certified company, Crimson has gained valuable experience that enables it to achieve the seemingly impossible—lowering clients' overall translation costs while improving accuracy.

The Crimson Solution

In response to these concerns, Crimson contacted Underwriters Laboratories (UL) and its Global Medical Device Program Manager, Dr. Harvey Rudolph. Dr. Rudolph, a 25-year FDA veteran and one of the original authors of ISO 14971, was responsible for guiding the development of UL's first-of-its-kind ISO 14971 registration service.

During the course of 2006, Dr. Rudolph and UL conducted a comprehensive gap analysis that helped Crimson recognize shortcomings in its system. The result, after a year of sustained effort, was an innovative approach to labeling translation, compliant with the requirements of ISO 14971. In fact, Crimson's risk management system proved so effective, it became the basis for the world's first translation risk management patent (pending).

But the full measure of the system's value has become evident only after compiling 12 months of audit data for Crimson's 2008 Management Review: Between 2006 (the last full year without a formal risk management system) and 2008 (the first full year with a formal system), Crimson successfully maintained its client satisfaction goal of over 95% while increasing company revenue by over 50%. More importantly for clients and patients, Crimson's already impressive accuracy rate (50% better than the industry average) was further improved by a substantial 36%. In other words, thanks to the introduction and implementation of a formal risk management system, Crimson's translation accuracy rate is now 75% higher than the industry average.

Further, by employing the risk management principles of ISO 14971, Crimson has been able to strategically apply linguistic QA for maximum effect with minimum cost. The result for clients has been a dramatic improvement in quality combined with an average 20% decrease in translation expense.

Failures of labeling translation comprise post-market information that the original device manufacturer needs to assess as part of its risk management process...Crimson must play a role in their clients' risk management process, and their efforts to improve and perfect the translation of labeling should be an integral part of any [manufacturer's] risk management system.

- Dr. Harvey Rudolph,
co-author of ISO 14971

**Crimson's experience proves the alchemy of risk management:
You can get more for less.**

Crimson Life Sciences

Boston: T +1 617.731.6920 | F +1 617.731.5244
San Francisco: T +1 415.563.8663 | F +1 877.824.8500
info@crimsonlanguage.com | www.crimsonlanguage.com

