

The world's largest privately held medical device manufacturer had a cumbersome, costly, and time-consuming process for verifying labeling translations through overseas distributors. The company required a regulatory-compliant process to ensure necessary translation risk management and eliminate the need for full document review. Using the industry's only Notified Body-endorsed translation risk management method, Crimson Life Sciences designed a compliant process and authored a regulatory rationale for the elimination of full-document third-party review, which has resulted in increased accuracy, faster time-to-market, and significant cost savings.

The Client

Founded in 1963, Crimson's client is the world's largest privately held medical device manufacturer. The company is at the forefront of medical research and worldwide sales of products for specialty areas such as endovascular therapy, critical care medicine, general surgery, diagnostic and interventional procedures, bioengineered tissue replacement and regeneration, gastroenterology and endoscopy procedures, urology, and obstetrics and gynecology.

The Challenge

The importance of labeling (in general) and multilingual labeling (in particular) is highlighted by published regulatory guidance. Recent survey results indicate that the industry accuracy rate for translated labeling is dismal: four times lower (-400%) than the serious error rate associated with the current industry best practice. These low accuracy rates have drawn increased scrutiny in CE audits, leading Notified Bodies to declare translation an "important outsourced service." Translation providers are now subject to the stringent vendor risk management considerations of ISO 13485 and ISO 14971.

Like many other device and IVD companies, Crimson's client employed In-Country Review (also known as Distributor or Subsidiary Review) for verification of translated labeling and marketing materials. Although not a regulatory requirement, In-Country Review is a commonly used method for managing risk during the translation process. In this case, an uncontrolled process led to bloated costs and turnaround times. Total direct cost for In-Country Review of translated material (including time for project management, in-country review, verification of reviewer, comments, and implementation of reviewer comments) was estimated at \$360,000 per year. In addition, indirect costs included:

- Regulatory costs: Increased risks due to an uncontrolled process
- Time-to-market costs: In some cases, up to a three-month delay for a single IFU
- Opportunity costs: Sales staff spent valuable time reviewing, not selling
- Effectiveness costs: Lack of time and interest led to unreliable results

The Crimson Solution

Crimson is the first company to register to ISO 14971—the risk management standard for medical device manufacturers and their suppliers. Crimson's process, which controls translation risk at both the resource and process levels, is so effective that it is patent pending. For this case, Crimson consulted with the client to re-engineer and improve their labeling risk management by replacing the In-Country Review with a Notified Body-approved process, including:

- Creation, review, and approval of technical glossaries
- Notified Body-approved process for control of resource risks
- Notified Body-approved process for verification of semantic accuracy (BackEdit™)
- Patent-pending translation risk management process (including process redundancy and diversity)

Since implementation of the new labeling review system, the client's US headquarters has begun receiving positive feedback on translation quality, reviewer morale has improved, and translation turnaround times have been accelerated by over 50%. Additionally, based on the latest full-year data, Crimson's 14971-registered risk management system has reduced the client's translation costs by 20% while improving accuracy rates by 36%. Perhaps most importantly, elimination of full-document review saves the manufacturer \$360,000 per year—every year.

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