



CASE STUDY: Eliminate the Burden of Distributor Review

One client
saves \$360,000
every year and has
cut labeling
turnaround times
by over 50%.

CE Labeling Case Study for the
Medical Device Industry

BACKGROUND

Crimson's client, the world's largest privately-held maker of medical devices, is a leading designer, manufacturer, and global distributor of medical device technology for diagnostic and therapeutic procedures.

The importance of labeling (in general) and multilingual labeling (in particular) is highlighted by published guidance from the Global Harmonization Task Force (GHTF). This guidance (SG3/N15 R8) specifies effective labeling as the minimum that must be done within "a fixed hierarchy of risk control measures" to help mitigate product risk. In other words, accurate labeling and instructions are not only a requirement, but also an essential tool in mitigating residual risks associated with your product. The regulatory structures of the EU and Asia make this equally true in overseas as well as domestic markets (see Note, below, for further labeling language guidance).

Due to this important risk management role, labeling activities such as translation are subject to risk management consideration. Translation, in particular, is a critical service because of its importance for satisfying the essential requirements of the MDD and the IVDD. In fact, published Notified Body guidance declares that translation is an "important outsourced service" and that translation providers are subject to the stringent vendor risk management considerations of ISO 13485:2003 and ISO 14971:2000.

THE CHALLENGE

Like many other device and IVD companies, Crimson's client employed In-Country Review (a.k.a. Distributor Review or Subsidiary Review) for verification of translated labeling and marketing materials.

Although not a regulatory requirement, In-Country Review (by subsidiaries or distributors) is a commonly used method for translation risk management. In this case, an uncontrolled process led to bloated costs and turnaround times.

Note: See "publications" at www.medical.crimsonlanguage.com for a complete list of EU and Asian language labeling requirements.

Continued on back

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THE COSTS

Direct Costs

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): **\$360,000 per year**.

Indirect Costs

- Regulatory anxiety (due to uncontrolled process)
- Time-to-market costs (in some cases, up to three-month delay for a single IFU)
- Opportunity costs (sales staff reviewing, not selling)
- Effectiveness costs (lack of time and interest may cause unreliable review results)

THE CRIMSON SOLUTION

Crimson worked 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)

Crimson has the only translation quality system that is officially endorsed to ISO 14971:2000. Crimson's process controls translation risk at both the resource and process levels and is so effective that it is patent pending.

Since implementation of the new system, the client's US headquarters has begun receiving positive feedback on translation quality, reviewer morale has improved, and translation turnaround times have been reduced by over 50%. Perhaps most importantly, elimination of full document review saves \$360,000 per year – every year.

Crimson's patent-pending translation risk management approach and a Notified Body-approved strategy provided the means to slash \$360,000 in review costs and decrease translation turnarounds by 50%. Since re-engineering their multilingual labeling process, the world's largest privately-held medical device manufacturer receives positive in-country feedback and has been freed from the unnecessary burden of full document review.