



INTRODUCING:

The Only ISO 13485:2003 Controlled Process for Multilingual Software Validation

The Easiest Way for You to Satisfy ISO 13485:2003 and IEC 60601 Risk Management and Multilingual Software Validation Requirements

The Opportunity

Software lies at the heart of a new wave of “smart” medical devices. According to the IEEE Computer Society, *“Advances in health information systems and healthcare technology offer a tremendous opportunity for improving the quality of care while reducing costs.”*

As with any area that exhibits potential for dramatic improvement and cost reduction, profitability opportunities are also substantial. In fact, industry sources estimate growth rates in one emerging device technology (wireless) at nearly 300% over the next five years—from \$3.7 billion to over \$10 billion (source: FDANews).

The Challenge

Rapid market growth presents challenges for companies selling into important EU and Asian markets. The newest revisions of ISO 13485:2003 and IEC 60601 contain specific requirements for risk management and software validation. Localized (translated) versions of your device software also require documented validation.

The Crimson Solution

Crimson Life Sciences is the only translation company in the world to hold an official endorsement to ISO 14971:2000. The company’s Service Realization procedure contains the world’s only ISO 13485:2003 controlled validation process for multilingual software. Crimson’s documented validation process is based on current industry Best Practices combined with patent-pending risk management methodologies. Together, you receive:

- A compliant, documented procedure for multilingual software validation that’s suitable for inclusion in your Risk Management/Technical file
- A translation/localization process that satisfies current ISO 13485:2003, IEC 60601, and ISO 14971:2000 risk management requirements
- The world’s only ISO 13485:2003 controlled multilingual software validation process
- The world’s only Notified Body-approved translation risk management process
- The world’s only Notified Body-approved process to eliminate distributor review

Call Crimson now and take the guesswork out of your multilingual software validation. Our credentials, processes, and experience can help reduce your overall “cost of compliance” for multilingual software and labeling.

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