



**FOREIGNEXCHANGE
TRANSLATIONS, INC.**

124 Watertown Street, Suite 2B
Watertown, MA 02472
617.926.2791
888.454.0787 *toll-free*
617.926.2792 *fax*

www.fxtrans.com

NEWS RELEASE—For Immediate Release

CONTACT:

Rob Wagner
Marketing Manager
ForeignExchange Translations, Inc.
1.902.468.5553 x.14
rwagner@fxtrans.com

FOREIGN EXCHANGE HELPS VENTANA MEDICAL OBTAIN CE MARK

IVD manufacturer says life-sciences expertise drove ForeignExchange selection

Watertown, MA (August 12, 2004)—ForeignExchange Translations, the global leader in providing linguistic services to the life-sciences industry, today announced it has helped Arizona-based Ventana Medical Systems, Inc., obtain CE marking for more than 220 IVD instruments and reagents.

Ventana selected ForeignExchange to translate the instructions for use (IFUs) for 220 reagents and the user manuals for four instruments. In total, almost 900,000 words of English source text had to be translated into nine distinct target languages – French, German, Italian, Spanish, Portuguese, Greek, Dutch, Danish and Swedish.

As of December 2003, all in vitro diagnostic devices placed on the market in the European Union must bear the CE mark. Obtaining regulatory approval means adhering to a set of strict guidelines, including the individual linguistic requirements of each nation where the products are to be sold.

Ventana’s Vice-President of Regulatory Affairs, Cary Marcot, says, “Ventana needed an outsourcing partner with broad life-sciences expertise to handle this large and vitally important project.”

Ventana executives also wanted a vendor who could guide them through the complex, exacting and unfamiliar process of meeting the linguistic requirements of the EU’s IVD Directive. Budgetary constraints meant the project had to be done in the most cost-effective, yet timely fashion.

“We wouldn’t have gone with anyone who didn’t have that life-sciences experience,” Marcot says. “We have had such a wonderful experience. ForeignExchange has been an outstanding partner.”

In addition to being the most qualified, ForeignExchange was also low bidder among the translation vendors

competing for Ventana's business. President Andres Heuberger says the company's proprietary Multilingual Compliance Process enables ForeignExchange to offer the highest-quality translations and to routinely do so at a lower cost than other translation companies.

"We rigorously test and screen our linguists to make sure they have extensive experience with life-sciences texts," Heuberger said. "We use customized metrics to measure the quality of their work and give them continual feedback. That helps us maximize quality and minimize costly mistakes."

ForeignExchange also incorporates the latest translation-memory technology and leverages the results to lower the cost for its clients.

To ensure the massive Ventana project was completed on time and within budget, ForeignExchange assembled a specialized team and developed style guides, glossaries and translation memories. A creative solution was also devised and implemented to accelerate in-country reviews while minimizing the demands on Ventana's staffing resources.

"There are those who believe quality costs more," says Heuberger. "As far as we are concerned, doing things properly the first time saves our clients both time and money in the long run."

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ForeignExchange Translations, Inc., is redefining the delivery of foreign-language services to the medical device and pharmaceutical industries. ForeignExchange's solutions are based on its proprietary Multilingual Compliance Process, which combines expert linguists, best-of-breed technology, and measurable translation quality in a robust and scalable process that is deployed in up to 32 languages simultaneously. ForeignExchange provides Internet globalization, software localization, and technical translation solutions to clients such as Abbott (NYSE:ABT), Johnson & Johnson (NYSE:JNJ), GlaxoSmithKline (NYSE:GSK), Baxter (NYSE:BAX), and Guidant (NYSE:GDT). For more information, please visit www.fxtrans.com.

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