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## **PRESS RELEASE**

**Boston, MA and Northbrook, IL**

# **UL Issues World's First ISO 14971 Registration Certificate!**

**Crimson Life Sciences becomes the first ISO 14971 Registered Firm**

**August 22, 2007**

Underwriters Laboratories Inc. (UL), a world leader in product safety testing and certification and management system registrations, has issued the world's first ISO 14971 risk management system registration certificate to a leading provider of translation services for medical device labeling and documentation, Crimson Life Sciences, a division of TransPerfect Translations.

"Medical device labeling must convey to users critical safety information about the product while taking into account the language of both the user and the device documentation," said Steve McRoberts, Principal Engineer, Medical Regulatory & Proprietary Compliance, UL. "Crimson Life Sciences is to be applauded for attaining this first-ever ISO 14971 certification for a risk management system capable of mitigating safety issues inherent to translation of medical device literature – an issue of great importance to the medical community."

ISO 14971 has become an integral element for satisfying regulatory requirements in most major markets. ISO 14971 has been formally recognized by the U.S. Food and Drug Administration (FDA) and by Health Canada; the European Union has adopted it as a harmonized standard; Japan has designated it as a Japanese Industrial Standard; and Australia has made it their "de facto" standard for risk management.

### **Growing Importance of Risk Management**

The first-ever registration to ISO 14971 provides further evidence of the growing importance of risk management in the medical device industry. Additional evidence is provided by the latest edition of IEC 60601 (standard for electrical medical devices), which includes a normative reference to ISO 14971. Product-specific changes, such as the EU's recent up-classification of total hip and shoulder replacements, provide added proof. Observes Crimson President, Marc H. Miller, "Aging populations in the US, Europe, and Japan provide increased market opportunities for medical devices, but this growing 'installed base' also increases companies' exposure." So-called "Liability Visibility" is a key driver for the increased importance of risk management. Supplier risk is a particular concern that is specifically referenced in ISO 14971, ISO 13485, and GHTF guidance.

### **Registration Service Highlights Importance of Quality System Parity**

Given the growing importance of supplier risk management, Quality System (QS) Parity, equivalent levels of quality system certification between manufacturers and suppliers, has become an important prerequisite. In fact, research shows that 55% of "non-exempt" suppliers have voluntarily certified to ISO 13485:2003 over the past four years in order to demonstrate conformance (research summary by request from [mmiller@crimsonlanguage.com](mailto:mmiller@crimsonlanguage.com)). Key benefits of QS Parity for manufacturers include reduced audit burden, streamlined incoming inspection, and improved risk management. Now, UL's ISO 14971 registration service can provide manufacturers with important assurance that their supplier's risk management systems are in conformance with ISO 14971 – the next word in QS Parity.

### **ISO 14971 Co-Author Emphasizes Importance of Translated Labeling**

Crimson's registration audit was conducted by Dr. Harvey Rudolph, former Global Program Manager with UL, 25-year FDA veteran (Deputy Director Science and Technology; Chief of Medical Practices Section), Co-chair of the US Technical Advisory Group for Risk Management, and Distinguished Services Medal recipient (Public Health Service). The risk management importance of translated labeling was emphasized in an ISO 14971 gap analysis report by Dr. Rudolph:

*"Generating accurate translations for native language users helps to assure that devices are operated safely. This is especially true for those portions of the labeling that are themselves risk controls established by the manufacturer (information for safety)...[Crimson's] efforts to improve and perfect the translation of labeling should be an integral part of any client's risk management system."*

A translation risk management guidance document that incorporates feedback from Dr. Rudolph is available from Crimson – send requests to: [mmiller@crimsonlanguage.com](mailto:mmiller@crimsonlanguage.com).

### **Latest in a String of Firsts**

For Crimson, certification to ISO 14971 caps a long string of industry firsts. Crimson was the first company to certify a specialized medical device translation quality system to ISO 9001:2000 and is currently the only translation company certified to ISO 13485:2003. Crimson is also the only translation company whose risk management methods are Notified Body endorsed and patent pending.



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Says Miller, “Certification to ISO 14971 provides our clients with a fundamentally better service – we have already witnessed enhanced performance by establishing risk management internally as a proceduralized, common point of reference.”

Kai Simonsen, VP of Production & Quality Systems, and chief architect of the company’s risk management system, agrees, “Integrating risk management principles into our system has created tremendous value for us and our clients. Not only has it enabled us to further improve process and resource effectiveness for high-risk applications, such as Class III or List A IVD labeling, it has also helped make risk-based processes accessible for a broader range of service needs, including lower and medium risk device labeling, software localization, and other documentation needs.”

Based on the company’s audited risk management processes, Crimson has developed a portfolio of innovative labeling and labeling translation services:

- Notified Body-endorsed process for elimination of full document distributor/overseas review
- ISO 14971-controlled process for outsourced labeling updates
- Notified Body-endorsed process for audit/review of legacy labeling translations

**About Crimson Life Sciences**

Crimson Life Sciences, founded in 1992, provides “Expertise in Translation for the Medical Technology Industries.” Crimson is the only translation organization in the world certified to ISO 9001:2000 and ISO 13485:2003 (by KEMA) and registered to ISO 14971:2000 (by UL). Crimson’s work has been recognized as MDD-compliant by an EU Notified Body. Crimson clients include industry leaders such as Cook, Stryker, Chiron, Bio-Rad and Arrow International.

In 2005, Crimson merged with TransPerfect Translations (world’s third largest language service provider), to form the industry’s premier translation practice for Class II and Class III devices and List A and List B IVDs. Clients enjoy access to the expanded process and technology resources of the entire TransPerfect family of companies, including software localization specialist, Translations.com. More information is available on the Crimson website: [www.crimsonlanguage.com](http://www.crimsonlanguage.com).

Crimson’s original founder, Marc H. Miller, continues to provide management guidance as division President. Miller received a BA in languages and literature from Harvard University and an MBA from the Scottish Business School in Stirling Scotland. While working as a Senior Research Fellow with the international strategy consulting firm of SIAR, he authored strategic assessments for European and US medical technology firms.

Key process development guidance is provided by Kai Simonsen, Crimson’s VP of Production & Quality Systems. Co-author of the industry’s first risk management patent, Simonsen has been responsible for the development and implementation of Crimson’s specialized production and quality systems since 2002. A native of Flensburg, Germany, he completed his undergraduate studies in English, Education, and Physics, and has held various positions in the translation and localization field since 1997.

Crimson’s specialized approach to medical technology translation has been featured in industry publications such as *Medical Device & Diagnostics Industry*, *Medical Products Outsourcing*, *Orthopedic Design & Technology*, and AAMI’s *BI&T Journal*.

**About UL**

Underwriters Laboratories is an independent, not-for-profit product safety certification organization that has been writing Standards for Safety, testing products and involved in conformity assessment for well over a century. UL evaluates more than 19,000 types of products, components, materials and systems annually with 21 billion UL Marks appearing on 71,000 manufacturers’ products in the global marketplace each year. UL has also issued nearly 9,000 registrations to management system standards and has performed over 12,000 assessments in 62 countries. UL’s worldwide family of companies and network of service providers includes 66 laboratory, testing and certification facilities serving customers with business operations on six continents. Visit <http://www.ul.com/hitech/iso14971>.

**Further Information**

<p>Marc H. Miller President Crimson Life Sciences 167 Corey Rd Ste 100 Boston, MA USA 02135 617-731-6920 phone <a href="mailto:mmiller@crimsonlanguage.com">mmiller@crimsonlanguage.com</a></p>	<p>Kai Simonsen VP of Production &amp; Quality Systems Crimson Life Sciences 2181 Fillmore Street San Francisco, CA 94118 415-563-8663 phone <a href="mailto:ksimonsen@crimsonlanguage.com">ksimonsen@crimsonlanguage.com</a></p>	<p>Tara Kambeitz Global Marketing Manager, Medical Business Unit Underwriters Laboratories +1-877-ULHELPS (1-877-854-3577) ext. 55610 Mob +1-360-269-6238 <a href="mailto:Tara.L.Kambeitz@us.ul.com">Tara.L.Kambeitz@us.ul.com</a> <a href="http://www.ul.com/medical">www.ul.com/medical</a></p>
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