Leading industry experts use LDRA tools to help medical device developers achieve certification readiness

The Associated Press

SAN JOSE, Calif.--(BUSINESS WIRE)--Mar 26, 2012-- LDRA Certification Services (LCS), a division of LDRA, the leading provider of safety-critical software verification tools and software best practices for the past 40 years, is announcing a fully compliant IEC 62304 and ISO 14971 certification solution for medical device manufacturers. This offering brings together a team of certification industry experts fully accredited in medical standards along with certification-readiness tools tailored to meet the demands of IEC 62304 and its related ISO 14971 risk management standard.

The safety and effectiveness of software in a medical device relies on proof that the software fulfills the specifications for the software without causing unacceptable risks. The IEC 62304 standard requires compliance to ISO 14971, which details what is needed for the development and maintenance of risk and quality management systems for medical devices at a systems level. Building on the ISO 14971 foundation, IEC 62304 focuses on guidelines specific to software.

For medical device manufacturers implementing these new standards for the first time, there is considerable challenge in interpreting the guidelines of these complementary standards. Correct interpretation of the software and system objectives outlined by the standards is one of the areas where LCS adds its greatest value to the producers of medical device systems. The LCS comprehensive solution encompasses software, hardware and systems expertise.

The strength of the LCS solution is reinforced by a team of renowned industry experts with experience in hundreds of product certifications. Leading the LCS team is Todd R. White, an expert on automated quality and compliance management systems, whose expertise extends into medical electronic systems and standards, including IEC 62304. Mr. White is flanked by Dr. Holly Hildreth, a safety engineer with expertise in a wide range of international standards. Dr.

Hildreth's certification expertise in ISO 14971 and related safety and risk analysis disciplines includes complete safety analysis from system-level Preliminary Hazard List, Preliminary Hazard Analysis and Fault Tree Analysis (FTA) to software FTA/Failure Modes, Effects and Criticality Analysis (FMECA). These analyses of safety requirements, design, code and test are flowed back into system-level analysis. The LCS team's collective expertise in all phases of software, hardware and system development, including the pending IEC 62304 TUV(R) certification, assures IEC 62304 certification applicants predictable and cost-effective compliance.

"To avoid litigation or FDA crackdown, the medical industry is faced with a

seemingly insurmountable challenge-to adopt and apply best-practice standards to medical applications where the amount of legacy code and third-party software is substantial," noted Ian Hennell, LDRA's Operations Director. "Since studies indicate added functionality is the primary cause of errors, deployed code has been insufficiently tested. Guidance from industry expert auditors helps companies streamline their compliance efforts and achieve certification readiness as efficiently as possible." An FDA analysis of 3140 medical device recalls from 1992 to 1998 revealed 79% of the recalls related to software failures were caused by defects introduced after software upgrades. This extreme level of incidents related to service or maintenance of medical device systems has driven regulators to stipulate a software maintenance process considered to be as important as the software development process in IEC 62304. The most effective way to bridge the gap between development and maintenance processes is through a comprehensive lifecycle traceability and verification management system such as the LDRA tool suite as prescribed by LCS.

"As medical devices have become increasingly complex and Internet-connected, the leap to certification readiness becomes exponentially more challenging," confirmed Dr. Holly Hildreth, ISO 14971 auditor and LCS team member. "Not only do manufacturers need to validate their own software applications, but all third-party software must be rigorously tested within the medical device system to ensure that no unexpected events or failures are triggered, especially during the maintenance phase." The LCS team implements the certification process using the LDRA tool suite, a comprehensive software analysis and validation solution. The LDRA tool suite automates all stages of the verification process to achieve compliance readiness from requirements traceability to analysis, unit testing and validation. Using a broad range of qualifiable verification capabilities that support IEC 62304 certification objectives at all class levels, the LDRA tool suite manages and tracks lifecycle artifacts to achieve bidirectional traceability, as well as automated regression testing, through the development and maintenance phases.

The full capabilities of the LDRA IEC 62304 certifiable support package will be demonstrated at DESIGN West in San Jose, CA, March 27-29 in Booth 1337. Visit the booth to see how a software project can achieve certifiable readiness through requirements traceability from requirements creation through development and validation for the certification standard you need.

About LDRA For more than 35 years, LDRA has developed and driven the market for software that automates code analysis and software testing for safety-, mission-, security- and business-critical markets. Working with clients to achieve early error identification and full compliance with industry standards, LDRA traces requirements through static and dynamic analysis to unit testing and verification for a wide variety of hardware and software platforms. Boasting a worldwide presence, LDRA is headquartered in the UK with subsidiaries in the United States and an extensive distributor network. For more information on the LDRA tool suite, please visit: www.ldra.com.

Please send reader inquiries to: Mark James Email: mark.james@ldra.com Graphics and Word copy of release: You can tweet or share the release directly from the

LDRA Press Center on HCI's website. Graphics and other background materials are also available for download.

Caption for screenshot 1: Selecting the IEC 62304 standard to import into TBmanager@ Caption for screenshot 2: Managing the IEC 62304 objectives from within TBmanager@ CONTACT: Media Relations Hughes Communications, Inc.

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