LDRA Tool Suite Selected by Esprit Lean to Prove IEC 62304 Medical Compliance

The Associated Press

WIRRAL, U.K.--(BUSINESS WIRE)--Aug 30, 2012--LDRA, the leading provider of automated software verification, source code analysis and test tools, has been selected by Esprit Lean to prove compliance of medical technology being developed to assist in cancer treatment. Esprit Lean chose the LDRA tool suite to provide the static analysis and standards verification needed to achieve compliance to IEC 62304.

Esprit Lean, a France-based company focused on developing custom electronic and software systems for satellites, automotive, medical and industrial control applications, wanted a verification tool that not only implemented coding rule compliance, but also enabled the team to boost productivity, adopt standardized style and code comments, and eliminate errors at the programming level. The LDRA tool suite was chosen to prove compliance to the IEC 62304 medical standard and implement the stringent quality techniques and practices Esprit Lean wanted to adopt.

Improves Development Process “Knowledge of a standard isn’t enough when software complexity is high and people’s health and safety will be affected,” stated Ian Hennell, LDRA Operations Director. “A tool that enforces and automates the IEC 62304 medical standard mitigates risk and provides medical developers and their customers extra security and confidence that the software developed has met standards requirements and is error free.” The Esprit Lean team began development by configuring the LDRA tool suite to meet company programming standards as well as those of IEC 62304. The LDRA IEC 62304 template streamlined configuration, detailing the steps for process workflow and standards compliance. LDRA’s graphically displayed analysis made it easy to identify sub-functions and quickly perform a thorough analysis, helping the team work iteratively toward compliance.

With process documentation an inherent part of the LDRA tool suite, all aspects of Esprit Lean’s development were fully documented. LDRA documentation provided a tangible proof-of-process, improving team communication and helping document specific details when members of the team moved on to other projects.

Since the FDA found defects introduced after software upgrades in 79 percent of 3140 medical device recalls between 1992 and 1998, medical device regulators stipulated in IEC 62304 that the software maintenance process be considered as important as the software development process. Esprit Lean harnessed the LDRA tool suite to enforce common process, methodology and coding practice. Armed with LDRA technology, the company established a consistent process workflow in which errors were quickly identified and addressed, and software designed using an

easily maintainable architecture.

“We now have a sales quality argument that we can present for new contracts,” confirmed Frédéric Rabouin, embedded software developer at Esprit Lean. “The LDRA tool suite ensures that our products are compliant and that security is worth a premium for customers. They can rest assured that any code we provide has been rigorously reviewed, achieves standards compliance and will be easier to maintain, reuse and add functionality to.” LDRA offers both certification services and standard-specific tool support for companies needing to adhere to IEC 62304. Enhanced certifiable support competencies will be demonstrated at Design East in Boston on September 18 and 19 in Booth 415. Visitors to the booth can see how a software project can achieve certifiable readiness through a streamlined, standard-specific verification process. Look for more details in LDRA’s September news.

About LDRA For more than 40 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 [1].

Please send reader inquiries to: Mark James Email: mark.james@ldra.com [2] Graphics and Word copy of release: You can tweet or share the release directly from the LDRA Press Center on HughesCom’s website. Graphics and other background materials are also available for download.

Caption for graphic: Synchro Module: Radiation therapy system for cancer treatment
CONTACT: Hughes Communications, Inc.

Janice Hughes, +1 705-549-8952 Media Relations Mobile: +1 705-774-8686 janice@hughescom.net [3] or LDRA Mark James, +44 (0)151 649 9300 Marketing Manager mark.james@ldra.com [2] KEYWORD: UNITED STATES NORTH AMERICA CALIFORNIA INDUSTRY KEYWORD: TECHNOLOGY SOFTWARE RETAIL FASHION SOURCE: LDRA Copyright Business Wire 2012 PUB: 08/30/2012 09:00 AM/DISC: 08/30/2012 09:00 AM http://www.businesswire.com/news/home/20120830005066/ [4]

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