Innovative Research Solutions with Industry

Medical Devices

CLIENT:
BioBusiness

AREA:
Software

Process assessment and improvement of medical device software

DUNDALK
INSTITUTE OF TECHNOLOGY

ICTI
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A key aim of the medical device software industry is to design and develop safe software in a regulatory compliant manner. The objective is to produce effective medical device software which minimizes risk and meets the mission critical requirements of the healthcare industry.

Today software plays a key role in the diagnosis, treatment and care of patients. This has resulted in a substantial increase in the functionality and overall complexity of medical device software. These developments have been coupled with the necessity to meet the regulatory requirements of the location where the medical device is to be marketed. As a result there is now industry led demand for the implementation of highly effective and efficient medical device software development processes. To facilitate this, there is a need for the development and implementation of a domain specific medical device software process assessment and improvement model.

In 2008, Dr Fergal McCaffery identified the need for a software process assessment and improvement model for the medical device domain. His initial focus was on the development of two capability assessment models: one for Configuration Management and the other for Risk Management. These both addressed specific industry requirements and were successfully implemented. With the help and cooperation of Dundalk Institute of Technology (DkIT) the Regulated Software Research Centre (RSRC) was established. Work is commencing on the development of the full domain specific

Dr Fergal McCaffery

software process assessment and improvement model Medi SPICE. In addition innovative research in a number of related areas also commenced.

Three lightweight process assessment methods for the medical device software industry have been developed and implemented both nationally and internationally. Development of Medi SPICE is ongoing and an industrial trial of 11 Medi SPICE processes has been performed. Dr McCaffery is a member the IEC 62304 international standards development team and the RSRC is currently developing a technical report based on Medi SPICE for assessing compliance against IEC 62034. ·>

•> Other research undertaken by the RSRC includes development of: software process roadmaps; effective traceability processes for Medical Device software; a model for assessing medical IT networks against IEC 80001-1; Medical Device Security Assurance Cases; and medical device products.

External funding was secured to support these activities including: SFI Stokes Lectureship, Principal Investigator and Lero CSET2 funding; Enterprise Ireland Innovation Voucher, Commercialisation Fund and Innovation Partnership support; IMDA Skillsnet funding; HEA ICT Skills Programme resources; and EU FP7 support via the Artemis CHARTER project. Many of these projects directly leveraged industry support.

The RSRC is internationally recognized as a leader in medical device software development research. Collaborators include world class experts in the areas of medical device software development, software process improvement and international medical device standards. The three lightweight assessment methods have been successfully implemented in industry. Commercialisation funding has been provided to facilitate the development and roll out of the complete Medi SPICE model. The RSRC has also published its research studies and findings in peer reviewed book chapters, journals and conference papers.

The medical device industry has been identified by the IDA and Enterprise Ireland as a key growth sector for the Irish economy. At present the industry is mainly focused upon manufacturing. This is despite the fact that Ireland has a significant IT sector. A key goal of the RSRC is to help grow the medical device software industry in Ireland. This includes assisting not only those organizations currently developing medical device software, but also indigenous companies and multi-nationals based in Ireland who wish to enter this highly regulated market. Dr McCaffery has been working with the IDA to help attract new multi-national medical device companies to locate in Ireland. ∎

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Peter Donnelly
CEO, BioBusiness

"BioBusiness feel that the research work of the RSRC greatly assists the growth of the Irish medical device software industry. They acknowledge that this research is becoming increasingly important due to the amendment to the EU Medical Device Directives which states that standalone software may now be considered a medical device."

Dr. Fergal McCaffery

REGULATED SOFTWARE RESEARCH CENTRE

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