





Regulated Software Research Centre

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The Regulated Software Research Centre (RSRC) is a worldrenowned research centre for medical device software engineering based in Dundalk Institute of Technology.

We work with industry and the standards community to provide frameworks that will allow medical device manufacturers to efficiently comply with existing regulations.



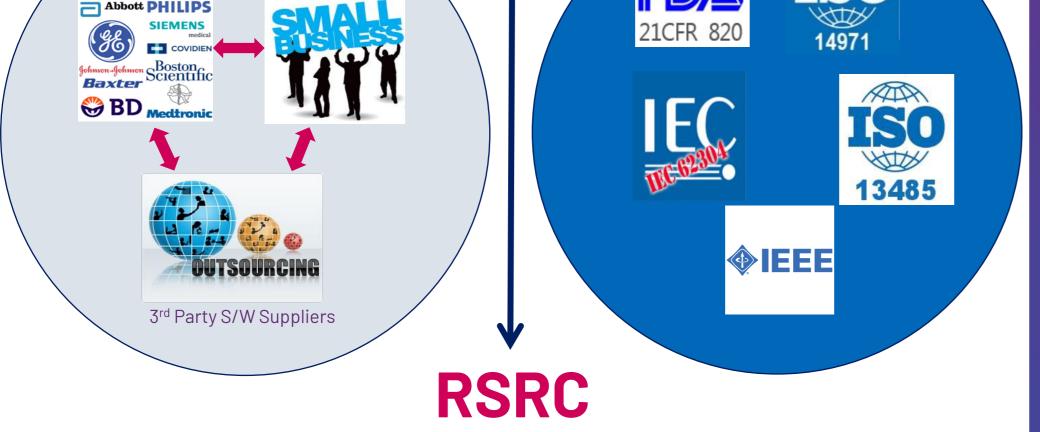
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Researchers within the centre work in a wide range of areas including:

- Medical Device Software Development Processes
- Traceability Processes
- Agile/Lean Practices
- Medical Device CyberSecurity including Privacy
- Risk Management of Medical IT Networks
- Medical Device Software Defects
- Al for Medical Devices (Process, Bias, Regulation)

performing both Basic and Applied Research.

We have successfully spun out three companies including the multi-award winning medical device software cybersecurity company Nova Leah.



³ OUR MISSION:

"To establish the Regulated Software Research Centre (RSRC) as a world leader in the development of methods and tools to assist medical device manufacturers comply with the regulatory requirements related to the development of medical device software, whether embedded within the device, standalone, or as part of a networked medical device while improving the efficiency of the medical device software development lifecycle."

In recent years this has expanded to include emerging technologies such as:

- Security
- Privacy
- Machine Learning
- Artificial Intelligence



We are actively involved with the International Medical Device Standards Community

• Successfully led the development of 5 International Standards, with 2 currently in development

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Formed in 2012, as of January 2024, the RSRC employs 11 full time PhD candidates and 4 PostDoctoral Researchers along with 7 internal academic PIs and multiple external academic and industry collaborators.

We have attracted over €22m in funding from multiple partners including:







Co-funded by the European Union



We continue to address the technical, processing and ethical challenges faced by developers, manufacturers and policy makers in the area of medical device software and beyond.





