

Tessolve helps Creo Medical Prepare for Medical Device Certification



Creo Medical, a manufacturer of clinically innovative medical devices, called upon Tessolve Semiconductors (TSLV) to establish a unit testing strategy for the software it was developing for its CROMA system, an electrosurgical unit that delivers bipolar radio frequency power for the purpose of cutting and microwave power for the purpose of coagulating tissue to staunch bleeding vessels.


Tessolve was subsequently contracted to undertake unit testing of the software that was completed on schedule, enabling Creo Medical to proceed with certification of the CROMA system software to the medical device software safety standard, IEC 62304.

In late 2013, the Creo Medical product development team sought advice on unit testing of the software it was developing for the CROMA system, to be written in C to run on a 32-bit microcontroller.

The Creo Medical team had already purchased Cantata from QA Systems, an established unit-testing tool for safety-related software certified up to the highest safety integrity level for a number of safety standards including IEC 62304. The safety class of the CROMA software had already been established as safety class C, which delivers the highest level of integrity, as the software controls both the cutting and coagulating of tissue during surgical operations.

Tessolve assessed the software architecture and design, advised on the content of detailed software design specifications so that unit tests could be developed directly from the specifications without the need to view code. In addition, Tessolve also set unit test coverage criteria to be met and devised a host/target-based unit test approach. Because of the software safety class, targets of 100% statement and modified condition/decision coverage (MC/DC) were agreed.

The host/target test approach adopted enabled the use of memory-mapped register access in the design to be accommodated when testing on both host and target platforms without the need to modify the unit software. Host testing would allow unit tests to be developed rapidly by an independent test team before executing them on the target microprocessor so that the limited resources on, and the availability of, the target boards would not become a bottleneck. In addition, host testing could easily be undertaken offshore to deliver a cost-effective solution.



After developing the unit test strategy, Tessolve provided Creo Medical with a fixed price proposal for undertaking the unit testing using an offshore test team in India. This was accepted by Creo Medical and the unit test work began at the end of 2013. A Tessolve engineer spent three weeks on-site working closely with the Creo Medical product development team to establish and agree the detailed unit test and management processes before returning to India to lead the test team. The unit test project proceeded smoothly with any issues uncovered being addressed quickly and Creo Medical kept informed of progress with detailed weekly status reports. The completed unit tests were delivered to Creo Medical at the end of the first quarter in 2014 meeting the schedule that had been set.

About Creo Medical

Creo Medical is a medical device manufacturer based in Chepstow, South Wales. Founded in 2003, (formerly MicroOncology Ltd) they develop, manufacture and commercialise clinically innovative medical device technologies. They can draw on over 100 years of employee experience from the medical device sector and are committed to developing clinically relevant technologies. www.creomedical.com

About QA Systems

QA Systems' fundamental goals are to accelerate and improve software development. Operating on a global scale, QA Systems has over 350 blue-chip customers, spanning a range of sectors, including aerospace & defence, automotive, medical device and railways. The company supplies and supports its own tools, in addition to carefully selected products from strategic business partners, for static or dynamic testing, requirements engineering, architectural analysis and software metrics. www.qa-systems.com