

Test and Verification Solutions Ltd helps Creo Medical prepare for Medical Device Certification

Creo Medical, a manufacturer of clinically innovative medical devices, engaged [TVS](#) to establish a unit testing strategy for the software it was developing for its CROMA system, an electrosurgical unit that delivers Bipolar Radiofrequency power for the purpose of cutting and Microwave power for the purpose of coagulating tissue to staunch bleeding vessels. [TVS](#) was subsequently contracted to undertake unit testing of the software which 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, which was 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 class C, the highest level of integrity, as the software controls both the cutting and coagulating of tissue during surgical operations.

[TVS](#) 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, 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 Fujitsu microprocessor so that the limited resources on, and availability of, the target boards would not become a bottleneck. In addition, host testing could easily be undertaken offshore to provide a cost effective solution.

After developing the unit test strategy, [TVS](#) 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 TVS 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 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.

Craig Gulliford, Creo Medical CEO, commented, “We engaged [TVS](#) as they have specialist knowledge of testing safety-related software and had a detailed understanding of the Cantata test tool. They didn’t let us down. They quickly grasped the software design and provided us with an effective and efficient way forward for software unit testing. They kept us fully informed of progress at all times and achieved the timescales we were keen to meet so that we can progress the certification of the CROMA system for human use.”

Francis Amoah, Creo Medical Product Design Director, also highlighted the good working relationship established with [TVS](#): “Although the test team was offshore, we were in regular contact with them and the use of Bugzilla to track any defects in detailed design specifications and code uncovered by unit tests worked extremely well. Jim Thomas, the TVS Director of Software Testing, also met with us regularly to ensure that we were kept up to date and any issues we had were addressed quickly. Overall it was a positive experience for us and we would use TVS again when we need software test expertise and resource.”

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.

About QA Systems

[QA Systems](#) offers developers, software testers and quality managers both its own products, which are marketed worldwide, and suitable products from partners: whether for static or dynamic testing, requirements engineering, architectural analysis or software metrics. In order to provide its customers with optimum service, QA Systems advises companies and offers long-term and individual support before, during and after the introduction of software. In addition, the transfer of knowledge is promoted in the QA Systems Academy, where experts such as Dr Scott Meyers and Professor Les Hatton pass on their know-how and expertise to others.

About TVS

[TVS](#) provides services and products to organisations developing complex products in the micro-electronics and embedded systems industries. Such organisations use TVS to verify their hardware and software products, employ industry best practice and manage peaks in development and testing programmes. TVS [embedded software testing services](#) includes onsite/offshore testing support including assistance with safety certification. TVS [hardware verification services](#) include onsite/offshore verification support and training in advanced verification methodologies. TVS also offers [Verification IPs](#) and its own [Verification \(EDA\) signoff tool \(asureSign™\)](#).

Note to Editors

Further information on TVS products and services is available at www.testandverification.com.

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