

FDA 510(k) Services

Customer

A medical device manufacturer utilizing unique polymer sensing arrays in the detection of bacterial and fungal infections.

Business Problem

The company had two devices, each detecting a different infection. The software for the first device had been developed through use of third party contractors. The software was not of a sufficient quality (through design, development or documentation) for a FDA 510(k) pre-market submission to be successful. The second device was just starting the specification cycle, and the company wanted to use an approach that would ensure FDA compliance from the start of the project.

Tessella Solution

For the first device Tessella put together an experienced team of test engineers who performed a thorough Validation and Verification (V&V) exercise on all code in the system. This took the form of audit and review of the current status of the code, followed by an extensive testing program. This testing involved writing test harnesses to mimic cross-device protocols, component level and system level testing as well as failure mode testing. All the V&V exercise was fully documented to the standards required by the FDA for a 510(k) pre-market submission.

The second device was still in the early stages of development in software terms. The customer needed guidance on project management, as well as expertise on software engineering and additional resources to accomplish the device development.

Tessella initially supplied experts in software development to FDA standards. They

performed a device assessment to set the project on firm foundations. This involved Hazards Analysis as a requirements stream as well as gathering user and system requirements.

The overall project was developed following the Rational Unified Process (RUP) and made use of the Rational Toolset for requirements tracking and design. In order to show development according to a set process a parallel quality system development was started. In essence this was to produce software development procedures based on Tessella experience and making best use of the RUP and the Rational Toolset. The system was implemented with full change control, and traceability through requirements (including the initial Hazards Analysis), software requirements, design and into the code.

A program of module, component, system and functional testing was implemented. Use was made of test harnesses to automate the testing of each component, and full records of component versions, test input and output was kept.

Tessella also provided a team of experienced software developers. As with all Tessella technical staff this team had experience and an understanding of working within a quality system – which is essential for a FDA compliant software development.

Results and Benefits

Both devices have now been submitted for assessment, and the first has already received 510(k) clearance from the FDA.

Without Tessella's expertise in the full software development lifecycle, and excellent knowledge of the issues around FDA 510(k) compliance the devices would not have been in a suitable form for FDA consideration.