A Regulatory Affair

Producing Certification Evidence for Medical Device Tools

01 THE CHALLENGE

In the medical devices industry, ensuring devices are safe to use is paramount. Placing an insecure device on the market could very easily cost lives. Yet some medical device manufacturers struggle to keep pace with the constant stream of regulations imposed on the industry.

A multinational manufacturer of optical health devices was using several software tools which formed part of their quality management system, including customer relationship management (CRM) systems and customised spreadsheets. These did not possess any formal evidence that proved compliance with FDA regulations, bringing into question whether the company could continue to use the systems effectively.

The manufacturer did not have the internal capacity to perform validation activities themselves, requiring external assistance to ensure their systems were formally certified for safe and effective use.

02 THE SOLUTION

Critical Software was tasked with defining a software validation strategy for the manufacturer. The static nature of the software needing validation meant that a manual strategy was more suitable and hence chosen for the project.

Test case specification was established at the beginning of the process. This meant identifying the initial environmental conditions, actions, and anticipated results of the tests so as to ensure successful certification.

These were all carried out within the guidelines set out in the FDA's CFR Part 820 series (the Quality Management Regulation), a fundamental requirement for quality management systems used in the context of medical devices.

Test procedure definition was then completed, identifying the way in which test cases would be implemented throughout the course of the project. This was finally followed by the execution of the tests, which in turn led to the production and compilation of certification documentation.

03 THE RESULTS

Critical's efforts meant the relevant software in use by the organisation could be fully certified.

The validation process identified a series of broader errors in the quality management system which, if left unchecked, would mean the system could not achieve certified status. Critical suggested a number of improvements to resolve these issues, including the widening of the tests' scope to unlock faster, more efficient validation while not compromising on quality.

04 THE TECHNOLOGY

- SAP-based tools
- Salesforce
- Customised Microsoft Excel templates
- Test case specifications
- Test procedures and reports
- Documentation to FDA standards

Critical software



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ABOUT CRITICAL SOFTWARE

Critical Software provides systems and software services for safety, mission and business-critical applications. We work closely with our clients, helping them to meet the most demanding standards for performance and reliability.

We were founded in 1998, with NASA our very first client. Today, we work across many international industries and have offices across the globe.

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We are CMMI Maturity Level 5 rated.
For a list of our certifications & standards visit our website.