

Title / Titel

Quality attributes in IEC 62304 - a practical implementation of a process standard

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To whom is the presentation addressed? / An wen richtet sich der Beitrag?

Project Manager

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Abstract / Zusammenfassung

There are major differences in the development and production of hardware and software. The quality parameters for hardware, for example a screw, can be typically measured directly, like size, weight or other dimensions, that are related to the quality of the screw. Quality parameters for software cannot be measured directly, that's why the ISO 9126 defines a set of six main attributes, like functionality and reliability, with 34 sub attributes for different aspects of software quality.

The manufacturing industries have developed high sophisticated methods to predict the reliability of their products during development in the past decades. Similar methods for software are currently not available. As development and production cannot be separated as clearly as for hardware, the process used for the software development has the biggest impact on the quality.

The IEC 62304 is a process standard that describes necessary steps in the development process for medical software, depending on the risk assigned to the items and units. The standard has become mandatory for all companies developing software for medical applications last year and software has moved more into the focus of the notified bodies after it was identified as major root cause for incidents documented by the BfArM

Companies with mature development processes will regard the IEC 62304 as state of the art development, while others keep complaining about the documentary ballast, as they do the required process steps at the wrong point of time or with the wrong intensity. But compliance does only provide a basic level of quality for those attributes, which are supported by the IEC 62304.

For a detailed analysis, a quality model was developed, where one or more quality attribute was assigned to each process step. The model also shows a reference to the development phase like requirements, architecture and implementation.

While the analysis of the complete model shows, that all development phases are supported at similar levels, it became very obvious that mainly external quality attributes are supported, like functionality, reliability and safety. Only 25 percent of the process steps mentioned in the IEC 62304 support internal quality attributes like maintainability or portability. This confirms the initial assumption, that compliance to the standards leads to a basic quality level, but does not fully support all aspects important for a manufacturer, external attributes as well as internal. Therefore it is highly recommended to extend development processes beyond the requirements and scope of standards for medical devices.

Biography / Biografie

Markus Manleitner has been more than 10 years in the business of software test and software quality. Currently he is working in a regulated environment for a german medical device manufacturer of life supporting systems. During his professorship at the University of Applied Sciences in Hamburg he shares his knowledge with students in a course for Software Engineering and Quality. Besides that is Manleitner chairman of the technical comitee "Software quality in medical devices" for the association of german engineers, VDI, where several medical device manufacturers discuss issues of software quality and share their experiences.

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