

Title / Titel

Legal Requirements for the Verification and Validation of Healthcare Applications

Speaker(s) / Referent(s)

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

Software developer, QA-Team, Head of Development

Keywords / Stichwörter

Medical Software, Verification, Validation, IEC 62304, Healthcare

Abstract / Zusammenfassung

Executive summary

This presentation provides a consolidated overview on the legal requirements for validation and verification of healthcare applications.

Introduction

Today it is unthinkable to abandon software in healthcare. Examples for applications are hospital information systems, applications for image processing, and analysis of medical data, as well as software as an integrated part of medical devices such as pace makers or dialysis machines. At the same time we are observing that:

- The usage of medical software is spreading,
- The complexity of the systems is rising,
- The number of problems related to medical software is escalating.

As a consequence legislators, authorities and standardization committees increase the number of standards and laws that – additionally – are becoming more and more specific for medical software. Certification and authorization of medical products presuppose conformity and compliance with these requirements.

Legal background

First, this talk provides an overview on relevant standards, laws and regulations. We are going to introduce and discuss:

- ISO 13485
 - ISO 14971
 - ISO 62304
 - ISO 60601-1-6, IEC 62366
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Each of these documents addresses verification and validation. However, the documents differ in the level of detail and the specificity to medical software. We will evaluate how the requirements stated in these laws, standards and regulations can be summarized and will provide a consolidated overview.

Benefits for the delegates

- Repetition of standards, laws and regulations that are relevant for testing of medical software
- Find most suitable medical software life cycle processes models that are compliant with all relevant legal requirements
- Get input how to choose software engineering methodologies and tools supporting these processes,
- And thereby increase efficiency and effectiveness of quality assurance

Biography / Biografie

Prof. Dr. Christian Johner is a physicist with 15 years experience in healthcare specialties, software engineering, and medical technologies. As co-founder of the company, Calcucare (owned by Fresenius Medical Care) he headed the development and certification of medical software and medical devices.

Christian Johner is a professor and lecturer for software engineering and validation at the universities of Konstanz, and Krems, Austria. Also as consultant he is focused and dedicated to development processes, distributed and multi-tier healthcare applications, and quality assurance as a mean of business management.

Prof. Dr. Johner is founder and owner of the "Institut für Informationstechnologien im Gesundheitswesen" which offers a postgraduate master study course "Information Technologies in Healthcare" as on the job training.

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