

Title / Titel

Regulatory Compliance in Medical Device Software Development

Speaker(s) / Referent(s)

Eva-Maria Reiter

Siemens Healthcare Sector, IM IKM, VP QM

Skill Level / Wissensniveau

Introduction

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

Software Medical Device Manufacturers:
Process Manager, Quality Manager, Regulatory Affairs Managers

Keywords / Stichwörter

Processes, Standards and Laws, Requirements, Regulatory Compliance, Efficiency

Abstract / Zusammenfassung

To ensure safety and effectiveness of their products manufacturers of medical devices have to comply with international statutory requirements. These requirements range from product specifications via process requirements to generic requests for certified QM systems. Thus all areas of software product lifecycle management may be affected.

All too often the implementation of such regulatory requirements is considered burdensome and bureaucratic. But in today's world of lean and agile processes the challenge is to comply with both: cost efficient and pragmatic processes as well as regulatory compliance.

The question is: Is it possible to achieve this aim, or is it too ambitious?

Biography / Biografie

- First experiences related to medical devices as consultant since 1990
 - Since 1999 with Siemens Healthcare, Erlangen, all areas of Quality Management, Process Management and Regulatory Affairs: currently VP QM for RIS PACS solutions
 - Certification Auditor MDD, ISO 13485, ISO 9001, CMDR, DQS Medizinprodukte GmbH, Frankfurt
 - Since 2009 member of ZVEI Ausschuss Wissenschaft und Technik; and Chair ZVEI AK Medical IT & Communication Systems (MICS).
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Contact information / Kontaktinformationen

SIEMENS AG Healthcare Sector

Eva-Maria Reiter
- Vice President QM -

IKM
Quality Management
H IM IKM QM
Henkestraße 127
D-91052 Erlangen
Erl_N, H5.4.504

Telefon: +49-9131-84-2680
Telefax: +49-9131-84-8691
E-mail: Eva-Maria.Reiter@siemens.com
