COCIR Seminar
Medical Device Software

Friday 8 June 2018
Speakers Book

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Qualification and Classification of Software

Name
Koen Cobbaert

Title
Quality & Regulatory Affairs Manager and Manager Risk Management Process

Organisation
Agfa HealthCare
COCIR Chair Medical Device Software Task Force

Biography

Koen Cobbaert is chair of COCIR's software task force, COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. In that role he co-authored the first and second edition of MEDDEV 2.1/6 on the qualification and classification of standalone software and is today co-authoring the software classification guidance for Rule 10 and 11 under the Medical Device Regulation. In that role Koen also co-authored the FAQ on 62304:2006.

In his day to day job Koen works for Agfa Healthcare as regulatory affairs and quality assurance professional in the development of software applications for use in general radiology, nuclear medicine, cardiology and orthopaedics. He has submitted a variety of technical files and 510(k)s for software-only medical devices. He guards process compliance for solution development processes and is himself responsible for managing Agfa's risk management, clinical evaluation and regulatory monitoring process. Koen has a master in electrical engineering and risk management.

Qualification and Classification of Software

Name
Pat Baird

Title
Regulatory Head of Global Software Standards

Organisation
Philips

Biography
Pat works at Philips as the Head of Global Software Standards. Pat likes to think of his job as "Policy Engineering" – understanding the unmet needs (and frustrations) of regulators and developers, and working to develop standards, whitepapers, and training to meet those needs. Past roles have included software developer, engineering manager, project manager, lead engineer, and most recently he was the Director of Risk Management at Baxter Healthcare.

Drawing on 20 years' experience in product development, he has published and presented over 50 papers regarding product development. He has an MBA and a Masters in Healthcare Quality and Patient Safety from Northwestern University.

Clinical Evaluation of Software

Name
Tibor Duliskovich

Title
Medical Director

Organisation
GE HealthCare
COCIR Co-lead on clinical evaluation of software

Biography
Tibor works at GE Healthcare as Medical Director, Patient Safety Center of Excellence. Previous roles include Sr. Product Manager, Enterprise Imaging Informatics at Philips Healthcare and Medical Director at Aspyra, Inc. Tibor completed clinical literature evaluation summaries (CESR) to support safety and performance claims for CE mark per MEDDEV 2.7/1 of supported products. He also conducted post-market safety risk assessments, supported MDR reportability determinations, and presented recalls at the Post-Market Safety Review Board (PSRB).

Tibor published several articles related to radiation safety and diagnostic performance and participated as industry expert in the International Medical Device Regulators Forum (IMDRF) guideline development on Software as a Medical Device. Tibor has a Medical Doctor from Semmelweis Medical University, Budapest.

Clinical Evaluation of Software

Name
Zuzanna Kwade

Title
Medical Affairs Manager

Organisation
Agfa HealthCare
COCIR Co-lead on clinical evaluation of software

Biography
Zuzanna holds a PhD in Biochemistry and has more than ten years of experience in clinical and medical research. She is the co-author of several white papers on regulatory aspects of clinical research.

Since 2016, she has been actively involved in Clinical Evaluations according to MEDDEV 2.7.1 (Rev.4) for multiple devices, including high risk hardware devices and medical software. She also represents COCIR in the European Union Task Force on clinical evaluation of software.

Cybersecurity

Name
Tobias Schreiegg

Title
Regulatory Affairs Manager

Organisation
Siemens Healthineers
COCIR Vice-chair Medical Device Software Task Force

Biography
Tobias is working as Regulatory Affairs Manager at Siemens Healthineers. He is actively contributing to activities on software in several trade associations, including COCIR, MedTech Europe and ZVEI. He currently holds the position of vice-chair of the COCIR Medical Software Task Force.

Before his current position, he worked at Siemens as Project Consultant and in Product Management. Previous experiences include positions as radiographer, surgical assistant and EMT.

Cybersecurity

Name
Ben Kokx

Title
Director Product Security

Organisation
Philips
COCIR Co-lead on cybersecurity

Biography
Ben Kokx joined Philips Healthcare in 2001 as a software designer for the interventional X-Ray business unit, and soon became responsible for the security features of these products. Ben is a member of the Philips Healthcare global product security team since the start of the program in 2003. Over the years, he worked as a product security and privacy officer in both business and market positions.

Since 2012, Ben works in the central Product & Services Security Office where he, as Director of Product Security, is responsible for the product security policies, processes and standards across the Philips organization. He represents COCIR in the European Union Task Force on cybersecurity requirements under the MDR.