COCIR SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR SEMINAR

MEDICAL DEVICE SOFTWARE

BETWEEN **US DEREGULATION** AND THE **LABYRINTH** OF **EU REGULATION**

FRIDAY **8 JUNE 2018** COCIR OFFICES, BRUSSELS

BENEFITS OF ATTENDING THIS SEMINAR:

- Learn what software is regulated by MDR and FDA legislation
- Understand how software is classified
- Gain insight into clinical evaluations of software, including machine learning and artificial intelligence
- Get best practices on cybersecurity

CONFIRMED SPEAKERS:

PAT BAIRD	Regulatory Head of Global Software Standards at Philips
KOEN COBBAERT	Chair of COCIR's Software Task Force, Agfa HealthCare
TIBOR DULISKOVICH	Physician, Medical Director at GE HealthCare
ZUZANNA KWADE	Medical Affairs Manager at Agfa HealthCare
BEN KOKX	COCIR Lead Member on cybersecurity, Director Product Security at Philips
TOBIAS SCHREIEGG	Vice-Chair of COCIR's Software Task Force, Siemens Healthineers

PRICE
250€ PP
60€ PP (SME)
FREE FOR COCIR MEMBERS AND NOTIFIED BODIES

REGISTER HERE

WHO SHOULD ATTEND

This seminar is primarily intended for industry, including SMEs, with an interest in software for healthcare purposes, and for Notified Bodies.

INTRODUCTION

Digital health products are soaring high. Software is rapidly breaking down the walls between doctors, hospitals and patients. Meanwhile regulatory walls are being raised in Europe and lowered in the US.

Without a doubt, the benefits of legislative controls for society are huge. But the regulatory labyrinth can be daunting to navigate for manufacturers, especially if software at the same time is subject to the medical device as well as the in-vitro diagnostic medical device or the pharmaceutical regulation. COCIR helps you find your way through the regulatory maze and offers you a view from above.

In four sessions, you will gain a solid understanding when and how European Medical Device and US FDA regulations apply to your software products, how to classify them, how to generate clinical evidence and how to keep your software secure. The training will focus on every categorical software variation, whether it is a mobile phone application, software embedded on hardware, cloud computing service, neural networks for continuous learning applications, software as part of a combination product or plugins that run on consumer electronics or platforms in the Internet of Things.

Our speakers are both theoretically knowledgeable on, and frequently practically engaged in, the creation of European and FDA guidance papers. This enables them to provide you with the latest authoritative insights on upcoming legislation and interpretative guidance documents. Participating companies with a marked interest in the interlinkage between medical devices and in-vitro devices as well as pharmaceutical regulation will thus discover that there is more than one way to fly above the legislative tides.

08:30	REGISTRATION AND COFFEE
09:00	**WELCOME**
09:05	**SOFTWARE QUALIFICATION** • Establishing when software is a medical device or an IVD • Understanding the borderline between medical devices and lifestyle and wellness apps • Exploring the borderline between IVD and Medical Device Software • Discussing the qualification of Drug-Device-Software-IT • Understanding when software drives or influences the use of a medical device or is an accessory of a medical device
10:30	COFFEE BREAK
10:45	**SOFTWARE CLASSIFICATION** • Clarifying revised classification rules for software and how this differs from before • Understanding which types of sofware are classified into which class • Outlining the risks of software being significantly up-classified in the new MDR and implications for industry
11:55	LUNCH BREAK
12:55	**CYBERSECURITY** • Exploring current best practices for cybersecurity of medical devices • Understanding the implications of new cybersecurity requirements in the MD Regulation (EU, US, China) • Outlining possibilities of information sharing between different actors in the healthcare eco-system • Discussing the tension between security and safety in the medical device field
14:20	BREAK
14:35	**CLINICAL EVALUATION OF SOFTWARE** • Understanding the impact of the Medical Device Regulation for clinical evaluation/investigation of medical device software • Clarifying how to generate sufficient clinical evidence, including using real-world data • Discussing the newly adopted IMDRF guidance on clinical evaluation of software as a medical device • Clinical evaluation of artificial intelligence software
15:55	**CONCLUSIONS**
16:00	END

REGISTRATION
http://www.cocir.org/?id=300