COCIR
Advancing Healthcare

LAST STEPS TOWARDS THE MEDICAL DEVICE REGULATION

Tuesday 3 March 2020

COCIR OFFICES, BRUSSELS

BENEFITS OF ATTENDING THIS EVENT

- **Gain** insight into the latest developments in the MDR implementation process
- **Develop** your network with industry experts, regulators, Notified Bodies and other stakeholders
- **Understand** what you still need to do to prepare and get ready
- **Use** the opportunity to ask specific questions about clinical evaluation, transitional provisions, Artificial Intelligence or other topics

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

PRICE
300€ PP
60€ PP (SME)
FREE FOR COCIR MEMBERS, REGULATORS & NOT-FOR-PROFIT ORGANISATIONS

REGISTER HERE

WHO SHOULD ATTEND

This event is primarily intended for manufacturers of medical devices and medical software, including SMEs, who are in the process of getting ready and timely becoming compliant to the forthcoming Medical Device Regulation.

DRAFT PROGRAMME

The Date of Application of the Medical Device Regulation is close. The aim of this event is to build awareness on latest progress made towards the implementation of the Medical Device Regulation.

The event is open to anybody involved and interested to learn more on latest developments and the implementation of the Medical Device Regulation. It is a great opportunity to openly discuss any last questions or unsolved issues with experts in the field, including representatives of the European Commission, Competent Authorities, Notified Bodies, healthcare providers and manufacturers.

09:30	WELCOME COFFEE
10:05	SESSION 1 **STATE-OF-PLAY OF MDR IMPLEMENTATION** This session will take a holistic view at the implementation of the Medical Device Regulation. The aim is to identify the major gaps that are remaining and discuss what joint efforts are necessary to solve these challenges to ensure a timely and successful implementation of the Regulation.
11:20	SESSION 2 **TRANSITIONAL PROVISIONS** With the Date of Application coming very close, understanding the transitional provisions, the so-called "grace period" becomes crucial. This panel will discuss how industry can make best use of the grace period and what exactly the obligations for legacy devices are, as well as the implications of the delay of EUDAMED.
12:30	LUNCH BREAK
13:30	SESSION 3 **CLINICAL EVALUATION & INVESTIGATIONS** This session will assess the progress in implementation of requirements related to clinical evaluation & investigations. These include the concept of equivalence, sufficient clinical evidence, as well as general guidance on clinical evaluation and Post-Market Clinical Follow-Up.
14:40	COFFEE BREAK
15:00	SESSION 4 **MEDICAL SOFTWARE & ARTIFICIAL INTELLIGENCE** This session will address any remaining questions for developers of medical software. In particular, this session will help to further understanding of the regulatory opportunities and challenges for Artificial Intelligence-based software, as well as the existing industry practices and standards.
16:45	**CONCLUSIONS**

REGISTRATION

https://www.cocir.org/cocir-regulatory-affairs-day-2020-cybersecurity-seminar