## Understanding Medical Device Regulations for Software Products

# AGENDA

**2nd May 2019**

**Thorpe Park Hotel, Century Way, Leeds, LS15 8ZB**

During this course, you will gain a solid understanding of the European Medical Device Regulation. Whether your software is an app or a cloud computing service, whether it comprises firmware for integration in a medical device, artificial intelligence or an application for the Internet of Things, this course will deepen your knowledge on how the regulation affects your product. With scene-setting introductions and highlighted case extracts, the practical implications of the law will become clear. You will learn which requirements are relevant for you and lean how to choose the optimal route to market your software under the medical device regulation.

09:30 **Registration; refreshments available**

10:00 **Introduction to the regulations**

10:30 **Medical device qualification**

11:45 **Introduction to medical device software classification**

12:00 **Bringing medical device software on the EU Market legally**

** Lunch **

13:00 **General Safety & Performance Requirements (GSPR)**

14:30 **Controlled design of health software**

15:15 **Introduction to clinical evaluations and investigations**

16:00 **Practical construction of a technical file**

16:15 **Q&A, close**

PRESENTER: KOEN COBBAERT

Koen is quality & regulatory manager at Philips Healthcare. He represents COCIR (the European Trade Association representing the medical imaging, radiotherapy, health ICT and electro-medical industries) in numerous work groups at European level and chairs its software taskforce.

Koen drafts European guidance for classification of medical device software and other aspects of the MDR.

He has over 15 years of hands-on experience in establishing regulatory strategies, writing technical files and 510(k)s, performing worldwide regulatory submissions and moderating risk management and clinical evaluation discussions for software applications.

**** To secure your place please email clare.lankester@medipex.co.uk. Delegate fee £295 + VAT ****