Book before 22 March 2019
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Medical Device Software: Complying with the MDR and FDA Regulations

To book online go to: management-forum.co.uk/2149 W

Dates and venue

29-30 April 2019 **Ref: 10427**
20-21 November 2019 **Ref: 10616**

The Cavendish Hotel
81 Jermyn Street, London SW1 6JF
Tel: +44 (0)20 7930 2111
(Note: Entrance via Duke Street)

Programme schedule

Registration and refreshments: 09.00

	Day one	Day two
Start	09.30	09.00
Close	17.00	16.30

Accommodation

When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price, please mention that you are attending the Management Forum seminar when booking your accommodation.

Email: enquiry.cavendish@the-ascott.com
Web: www.thecavendish-london.co.uk

For information on alternative accommodation, please visit our website:
management-forum.co.uk/accommodation

Three ways to book

management-forum.co.uk | info@management-forum.co.uk | +44 (0)20 7749 4730

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 22 March 2019
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE Book AFTER 22 March 2019
£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 + VAT = £1528.98 • €1784.15 + VAT = €2140.98

Payment options

1. Invoice which can be paid by bank transfer or credit/ debit card
2. Online through our secure website when registering

In-house TRAINING

Management Forum in-house training

Coming to Management Forum for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email **inhouse@management-forum.co.uk**

To find out more, please visit: **management-forum.co.uk**

FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE: Management Forum Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Management Forum will refund the registration fee and disclaim any further liability.

For event cancellation policy and T&Cs see our website

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Book Before 22 March 2019 and SAVE £200/€280

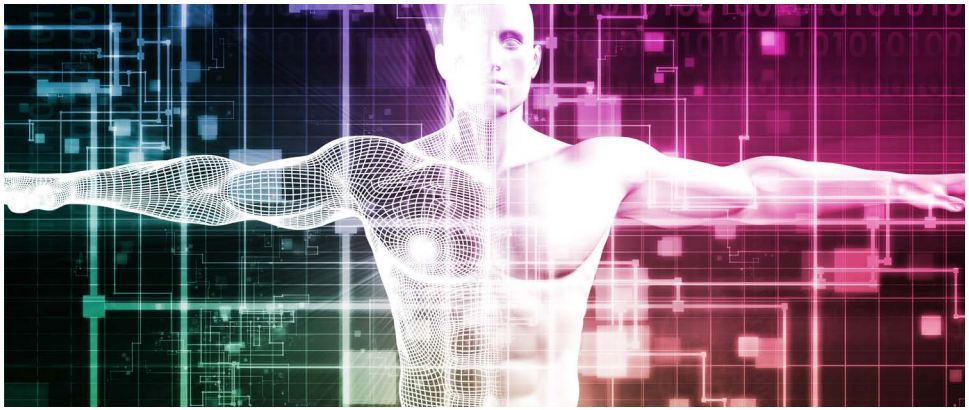
Includes: Practical and interactive sessions

MANAGEMENT forum

Medical Device Software: Complying with the MDR and FDA Regulations

A practical approach from industry experts

29-30 April 2019 • 20-21 November 2019 London



Benefits of attending:

- **Learn how** to qualify and classify software in Europe and the rest of the world
- **Get in-depth understanding** of the interpretations of MDR Classification Rules 10, 11, 12, 13, 15 and 22
- **Understand the implications** of the MDR and US Code of Federal Regulations for software
- **Gain regulatory guidance** on mobile apps, software as a service, cloud computing, artificial intelligence and continuous learning software
- **Learn how** to write 510(K) and technical files
- **Get a practical understanding** of quality management, design control and how it applies to agile software development
- **Hear the best practices** on cyber security, risk management, usability and validation
- **Learn the principles** of clinical evaluations for software as a medical device
- **Gain an insight** into state-of-the-art standards applicable to software

Expert faculty:

Koen Cobbaert
Chair of COCIR's Software Task Force

Peter Pringle
Independent Consultant, Product Enterprise Support

'Excellent content and a good choice of speakers.'
Malgorzata Wilinska, University of Cambridge

'A well-structured, well-presented programme.'
Peter Ogrodnik, Keele University

CPD CERTIFIED The CPD Certification Service

Medical Device Software: Complying with the MDR and FDA Regulations, 29-30 April 2019 • 20-21 November 2019, London

Introduction

This course provides a comprehensive appraisal of the regulations and requirements that apply to medical device software worldwide. The seminar will be highly interactive, using real-life examples and state-of-the-art practices identified by Notified Bodies in Europe. There will be in-depth coverage on how to prepare compliant technical file documentation for medical device software products and a review of software specification, risk management, architectures, usability and resulting design documentation. In addition, there will be practical tips on how to streamline the development process, understand the regulatory requirements and how Notified Bodies review technical files.

There will be sessions on the practical implication of risk management and usability and an analysis of the differences between FDA guidance and MDR guidance on medical device software. Software recalls, the use of apps in medical devices, the implications of the new draft usability standard and advice on how to validate your system design will also be covered.

Who should attend?

- Senior management and project leaders
- Software product managers, researchers, developers and clinical experts
- Software development process managers
- IT managers and integrators
- Internal and external auditors and/or consultants
- Regulatory affairs professionals
- Quality system and quality assurance personnel
- Technical and medical writers
- GUI designers

In-house training

This course is also available in-house and can be tailored to your specific needs. To find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email **inhouse@management-forum.co.uk**

A certificate of attendance for professional development will be given to each participant who completes the course

Expert faculty

Peter Pringle is a consultant with international hospital experience; he has managed projects in installation, process and software. His medical software experience brings a unique understanding of the quality systems and configuration control that is required to make a project right first time. Since May 2000 he has operated as an independent (Accredited Business Link & MHRA) consultant. He has established an expertise in developing project proposals and stimulating co-maker and e-business relationships with many companies, also developing and submitting major project proposals for several clients with considerable success. From 1986 to 2000 he worked in the radiotherapy division of Philips Medical Systems (purchased by Elekta of Sweden) whose main products consist of a range of computer-controlled linear accelerators for the treatment of cancer. Peter is qualified in ISO 13485/ 9000/14000/ 14971 and prepares FDA pre-audits, establishing technical documentation for product compliance to the Medical Device Directive. He also advises companies on software development procedures and documentation.

Koen Cobbaert is chair of COCIR's software task force, 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 stand-alone software and is today co-authoring the software classification guidance for Rule 10 and 11 under the Medical Device Regulation. He also co-authored the FAQ on 62304:2006. Koen works for Philips Healthcare as quality and regulatory manager. He was previously with Agfa Healthcare as a 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.

Day one

09.00 ▶ **Registration and refreshments**

09.30 ▶ **Welcome**

09.45 ▶ **Introduction to the regulations**

10.00 ▶ **Medical device software qualification and classification**
- MD and IVD definitions
- Annex XVI products
- In-vitro diagnostic software
- Multi-functionality software
- Cloud computing and software as a service
- Intended purpose
- Exempted functionality
- Borderline with lifestyle and fitness software
- Combination products – MD software to pharma
- Population health and educational software
- Drive or influence the use of a medical device
- Quiz

11.30 ▶ **Software classification – EU**
- Classification rules and the related definitions
- Helsinki procedure and the borderline manual on qualification and classification
- Implementing rules
- Classification rules for active devices
- Interpreting Rules 10, 11, 12, 13, 15 and 22
- Classification under the IVDR

12.30 ▶ **Lunch**

13.30 ▶ **Software classification case studies – EU**
- Case studies
- Quiz

14.00 ▶ **Classification according to the FDA**

14.20 ▶ **Bringing medical device software on the EU market**
- Go to market process MD and IVD
- Go to market process combination products
- In-house use by health institutions

14.40 ▶ **Notified Bodies and the evidence they consider**
- Engaging with a Notified Body
- Implementing a Quality Management System
- Standards to consider
- General safety and performance requirements
- Technical file and clinical evaluation assessment
- UDI number
- Translations
- Declaration of Conformity

15.00 ▶ **Practical construction of a technical file**

15.45 ▶ **EUDAMED registration and distribution chain responsibilities**
- EUDAMED
- Person responsible for regulatory compliance
- Assuring the traceability of your software
- Distributors, importers and authorised representatives
- Controlling your suppliers and subcontractors

16.15 ▶ **On the market**
- Complaint handling system
- Medical incident reporting
- Monitoring critical components or platforms updates
- Post-market surveillance requirements
- Unannounced Notified Body audits
- Service updates, upgrades and other changes

16.45 ▶ **End of day one**

Day two

09.00 ▶ **Bringing medical software on the US market**
- US Code of Federal Regulations and its implications for software
- Process and practical construction of a 510(K)
- A case study

09.45 ▶ **Rest of the world (Brazil, Canada etc.)**

10.00 ▶ **Standards and their implementation – a software perspective**
- ISO 14971 Risk management
- IEC 62304 and IEC 82304 Software lifecycle and safety
- IEC 60601 Electrical equipment
- IEC 62366 Usability of medical devices
- EN ISO 15223-1/ /ISO 15223 Symbols
- IEC 27000 etc. Security standards
- User manuals

12.30 ▶ **Lunch**

13.30 ▶ **Fundamental principles design control**

14.00 ▶ **Design activities in detail**
- Project management, development planning and change management
- Requirements management
- Risk management
- Clinical evaluation
  - IMDRF on clinical evaluation
  - FDA expectations
    - PACS, mobile apps
    - Clinical decision support
    - Computer-aided detection and diagnosis
  - MEDDEV on clinical evaluation
- Architecture and design
- Development
- Configuration management
- Verification and validation
- Usability

16.30 ▶ **End of course**

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