Book before 4 October 2019
and SAVE £300/€420

## Medical Device Software: Complying with the MDR and FDA Regulations

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

### Dates and venue

20-22 November 2019 **Ref: 10616**
28-30 April 2020 **Ref: 10803**

The Rembrandt Hotel
11 Thurloe Place
London SW7 2RS
Tel: +44 (0)20 7589 8100

### Programme schedule

Registration and refreshments: 09.00

Day one: 09.30 - 17.00
Day two: 09.00 - 16.30

### Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this, please state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

**Email:** ***reservations_rembrandt@sarova.co.uk***
**Web:** ***www.sarova-rembrandthotel.com***

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 4 October 2019
£1549.00 + VAT = £1858.80 • €2169.00 + VAT = €2602.80

**FULL PRICE** Book AFTER 4 October 2019
£1849.00 + VAT = £2218.80 • €2589.00 + VAT = €3106.80

**Multiple booking discount for 2nd or subsequent delegates - 15%**
£1571.65 + VAT = £1885.98 • €2200.65 + VAT = €2640.78

**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

7885

Book before
4 October 2019
and SAVE £300/€420

Includes: Practical and interactive sessions

MANAGEMENT forum

# Medical Device Software: Complying with the MDR and FDA Regulations

## A practical approach from industry experts

**20-22 November 2019 • 28-30 April 2020 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, investigations and PMS 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

**Zusanna Kwade** Medical Affairs Manager, Agfa Healthcare and COCIR Co-Lead of Clinical Evaluation Software

'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

# Medical Device Software: Complying with the MDR and FDA Regulations, 20-22 November 2019 • 28-30 April 2020, London

## Why you should attend

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

## Expert faculty

**Koen Cobbaert**
Chair of COCIR's Software Task Force

**Zusanna Kwade**
Medical Affairs Manager, Agfa Healthcare and COCIR Co-Lead of Clinical Evaluation Software



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

## Day one

09.00 ▶ **Registration and refreshments**

09.30 ▶ **Welcome and introductions**

10.00 ▶ **Introduction to the regulations**

10.15 ▶ **Software qualification**
- MD and IVD definitions
- Annex XVI products
- In-vitro diagnostic software
- Multi-functionality software
- Cloud computing and software as a service
- Intended purpose
- Excluded functionality

11.00 ▶ **Refreshments**

11.15 ▶ **Software qualification (continued)**
- Borderline with lifestyle and fitness software
- Combination products
- Population health and educational software
- Resource and workflow management vs clinical decision support software
- Clinical decision software
- Quiz

12.30 ▶ **Lunch**

13.30 ▶ **Software classification**
- Implementing rules
- Classification rules
- IMDRF SaMD risk type determination
- Case studies
- Quiz

15.00 ▶ **Refreshments**

15.15 ▶ **General principles to bring medical device software to the EU market**
- Bringing your device to the market
  - Go-to-market process – MD and IVD
  - Go-to-market process – combination products
  - In-house use by health institutions
  - Engage with a Notified Body
  - Implement a quality management system
  - Controlling your suppliers and subcontractors
  - UDI number
  - EUDAMED
  - Declaration of Conformity
  - Person Responsible for Regulatory Compliance
- Keeping your device on the market
  - Assuring the traceability of your product
  - Distributors, importers, authorised representatives and their liability
  - App stores and digital distribution platforms
  - 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
  - Quiz

16.30 ▶ **Introduction to General Safety and Performance Requirements (GSPR)**
- GSPR
- Harmonised standards
- Common specifications
- GSPR checklist

17.00 ▶ **End of day one**

## Day two

09.00 ▶ **Interpretation of GSPR and their implications for software**
- Reduce risk as far as possible
- State of the art
- Single fault condition
- IT environment and mobile platforms
- Diagnostic and measuring function
- Repeatability and reliability (e.g. of machine learning)
- Lifetime of a device
- Information on the manufacturer's website
- Instructions for use
- Label

10.00 ▶ **Technical file**
- Content
- Practical construction of a technical file

## Day two (continued)

10.15 ▶ **General principles to bring medical device software to the US market**
- US Code of Federal Regulations and its implications for software
- 510(k) process
- FDA guidances specific to software

11.00 ▶ **Refreshments**

11.15 ▶ **Practical construction of a 510(k)**

11.30 ▶ **Go-to-market strategy**
- Regulations in the rest of the world (Brazil, Canada etc.)
- Market access and reimbursement of digital technology
- From health app to medical device software
- Considerations for software-hardware combinations
- Using the modular approach to your benefit
- Tools that allow customers to build their own devices: rules engines, programming and runtime environments, libraries for dataflow programming and machine learning
- When a customer becomes a manufacturer

12.30 ▶ **Lunch**

13.30 ▶ **Software development models**
- Introduction
- Symptoms and root causes of poor design control
- Waterfall vs agile, iterative and spiral
- Principles of good design control
- Stage-gated model

▶ **Design activities**
- Project management
- Development planning
- Change management
- Requirements management
- Architecture and design
- Development
- Configuration management
- Verification and validation
- Defect management
- Design reviews

▶ **Software development standards**
- EC 62304: Software life cycle management
- EC 82304-1: General requirements for product safety

14.45 ▶ **Safety and essential performance of electrical medical equipment IEC 60601 and Appendix H**

15.00 ▶ **Refreshments**

15.15 ▶ **Security risk management**
- Introduction: hacking an infusion pump
- Terminology
- Characteristics of security
- Security risk controls (a selection)
  - Organisational risk controls
  - Audit logs
  - Server and application hardening
  - Demilitarised zone architecture
  - Public key infrastructure
  - Passwords
  - Multi-factor authentication
  - Encryption
  - Virtual private networks (VPN)
  - Cloud-based data exchange
  - Mobile and voice exchange
  - User roles and privileges
  - Network monitoring and intrusion detection
  - Web service and web application protection
  - Remote network access and maintenance
- Information security management system
  - Assuring information integrity, security and privacy (ISO/IEC 27001)
  - Determining probability, threat, vulnerability and impact
  - Determining risk acceptability
  - Information sharing
  - MDS2 form
  - Security error messages
  - ISACs and ISAOs
  - Secure development life cycle (IEC 62443)
  - Example of a secure design process
  - Patching strategy
  - Preventing malware delivery and execution
  - Vulnerability scanning (pen testing)
- Legal requirements
  - MDR, NIS, GDPR and Cybersecurity Act
  - Security standards

16.15 ▶ **IEC 80001: Application of risk management to IT-networks incorporating medical devices**

17.00 ▶ **End of day two**

## Day three

09.00 ▶ **Introductions**

09.20 ▶ **Safety risk management**
- Process and terminology
  - Terminology
  - Process
  - Roles
- Risk identification methodologies
  - Checklists
  - Grey box
  - Hazard and operability analysis (HAZOP)
  - Failure mode and effects analysis (FMEA)
  - Fault tree analysis (FTE)
- Risk control
  - Inherently safe design
  - Preventive measures
  - Corrective measures
  - Mitigations
  - Safety notices
  - Disclosures of residual risk
  - Risk control strategies
- Risk assessment and evaluation
  - IMDRF terminology
  - Determining severity and probability of harm
  - Determining if a risk is acceptable
  - Benefit-risk assessment
  - Deliverables
- Manufacturer accountability
  - Risk management throughout the product life cycle
  - Normal, abnormal and misuse
  - ESCs, SOUPs and COTS
  - Platform changes and failures
- Risk perception and communication

11.00 ▶ **Refreshments**

11.15 ▶ **Usability of medical devices**
- IEC 62366
- Formative and summative testing
- Cognitive walk-throughs
- Heuristic evaluations
- User evaluations

11.45 ▶ **Clinical evaluations of medical device software**
- Definitions, purpose, deliverables
- Process and key characteristics
- Methodology
- Data sources
- Role of validation and usability
- Use of real-world evidence
- Considerations for artificial intelligence and continuous learning software

12.30 ▶ **Lunch**

13.30 ▶ **Practical construction of a clinical evaluation plan and report**

14.00 ▶ **Introduction to clinical investigations**
- When is a clinical investigation needed for medical device software?
- Roles and responsibilities
- Selecting appropriate study design
- Regulatory and ethical considerations
- Diagnostic clinical performance studies
- Sustaining the quality of clinical studies
- Handling clinical data
- Analysis and reporting

14.45 ▶ **Refreshments**

15.00 ▶ **Post-market surveillance (PMS)**
- Post-market regulatory requirements
- Components of an effective PMS
- Process interface with CAPA, NC, vigilance, service, periodic safety updates, trend reporting
- Implementation of PMS
- Post-market clinical follow-up

15.45 ▶ **Process interfaces**
- Successfully bringing together risk management, clinical evaluation and post-market surveillance to streamline ways of working

16.30 ▶ **End of course**



© Management Forum Ltd