MDTI

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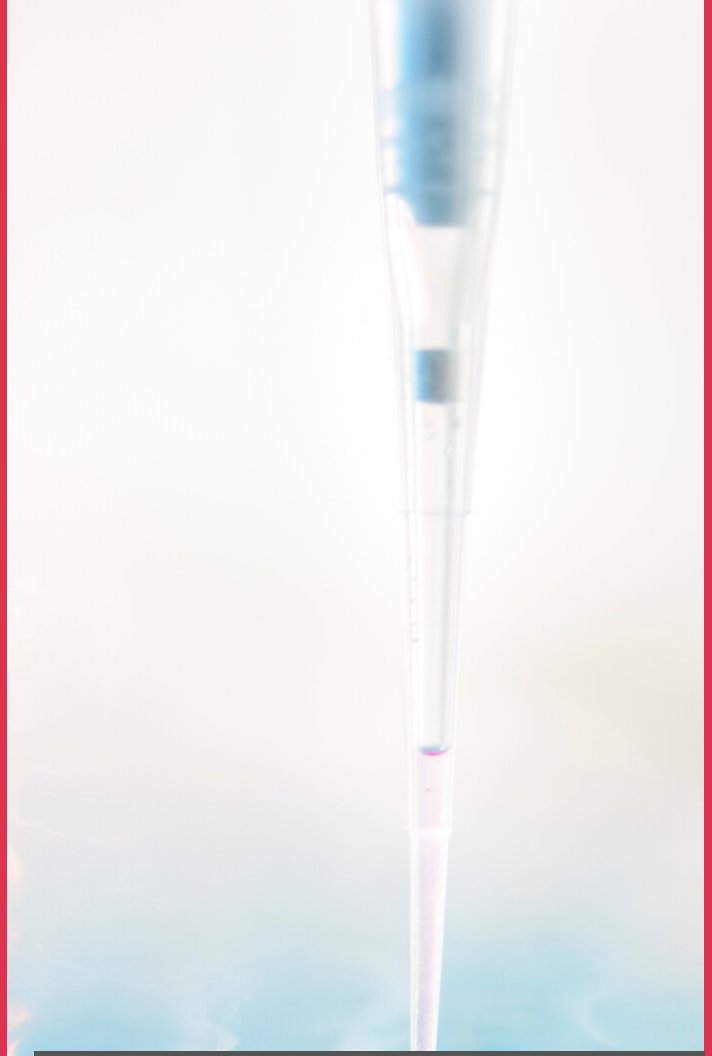
Navigating the Regulations for Health Apps and Medical Device Software

4-week Online Academy

Starts 5 October 2020



MEET THE TRAINER

KOEN COBBAERT

Koen Cobbaert represents COCIR in numerous work groups at European level. COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electro-medical industries. In 2009 COCIR created its software task force, which Koen has been chairing ever since. He put on paper the first draft of the qualification decision tree, which was later successfully adopted by the Member States in “MEDDEV 2.1/6 on the qualification and classification of standalone software”.

Koen Cobbaert 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 for general radiology, oncology, neurology, cardiology and orthopaedics, computer algorithms for pattern recognition, computer aided detection, reasoning engines, decision support, clinical pathways, general systems such as HIS, LIS, IVD, PACS, EPR and mobile apps.

Koen Cobbaert has a Master in Risk Management and Electrical Engineering. Currently Koen Cobbaert works for Philips Healthcare as quality and regulatory manager.

Agenda

Module 1: Is it or is it not a medical device?

- Part 1.1: Introduction
- Part 1.2: Medical Device Regulations
  - Understanding the legal background
  - Examining the MD and IVD definitions
  - Being aware of Annex XVI products
  - Distinguishing in-vitro diagnostic software
  - Dealing with multi-functionality software
  - Positioning cloud computing and software as a service
- Part 1.3: Intended purpose
  - Establishing intended purpose
  - Understanding which functionality does not qualify for MD
  - Determining which software is and which isn’t a MD
  - Examining the borderline with lifestyle and fitness software
  - Crossing the border from MD software into pharma
  - Handling population health and educational software
  - Distinguishing resource and workflow management from clinical decision software

Agenda

- Part 1.4: Accessories, parts, components, systems … and in-house manufacturing
  - Learn how accessories, parts, components and systems are regulated and how these terms apply to software
  - Learn when health institutions that configure, customize or train medical device software are considered to perform “inhouse manufacturing” and become subject to regulations

Module 2: What class does your medical device software have?

- Part 2.1: Introduction
  - Introduction to the classification rules and the related definitions
- Part 2.2: Implementing rules
  - Understanding how the implementing rules impact the use of the classification rules
  - Software that drives or influences the use of a (hardware) medical device
  - Understanding how medical device software (MDSW) relates to software as a medical device (SaMD) and to software for a medical device (SfMD)
  - Learning what rules apply to MDSW
- Part 2.3: Classification Rules
  - Learning why most independent software is assigned class B under the IVDR
  - Interpreting Rule 10, 11, 12, 13, 15 and 22
- Part 2.4: Case studies
  - Applying the rules to examples

Agenda

Module 3: Route to market medical device software (Europe)

- Part 3.1 Bringing your device on the market
  - Go to market process MD & 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
- Part 3.2 Keeping your device on the market
  - Assuring the traceability of your product
  - Distributors, importers, authorized 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

Agenda

- Unannounced Notified Body Audits
- Service updates, upgrades and other changes

Module 4: Other regulations that may apply to health software products (Europe)

- Part 4.1: Product legislation
  - General product safety
  - Machinery
  - Personal protective equipment
  - Toys
  - Radio equipment
  - Low voltage equipment
  - Electromagnetic compatibility
- Part 4.2: Advertising, marketing and selling health software
  - Consumer protection
  - Health apps related to medicinal products
  - Health apps that are medical devices
  - Health apps that are not medical devices
- Part 4.3: Data Protection
  - General Data Protection Regulation
  - Manufacturer responsibilities

Agenda

- Part 4.4: Legal Requirements
  - MDR, NIS, GDPR & Cybersecurity Act
  - Security standards
- Part 4.5: Product liability
  - Consumer protection
  - Defective products
  - Compensation

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For information or to book a course please contact our Training Consultants

Elysia Ndubuisi
Elysia.Ndubuisi@informa.com
+44 (0)20 3377 3943

Jordanna Van Lint
Jordanna.VanLint@informa.com
+44 (20) 701 74734