IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Medical Device Software: Complying with the EU MDR, EU IVDR & FDA Regulations

25-29 January 27
+ 21-25 June 27

An introduction to medical device software regulations and requirements to include the latest EU and FDA guidance and risk management.

Format:
Live online

CPD:
30 hours for your records

Certificate of completion

Course overview

Master the critical decisions that shape your software's regulatory success. Every choice you make, from product claims to technology selection and regulatory positioning, can determine the outcome of your market authorisation process. Missteps can mean costly delays, increased development expenses and even denied market entry. This course gives you the clarity and confidence to avoid these pitfalls and ensure your innovation achieves its full global potential.

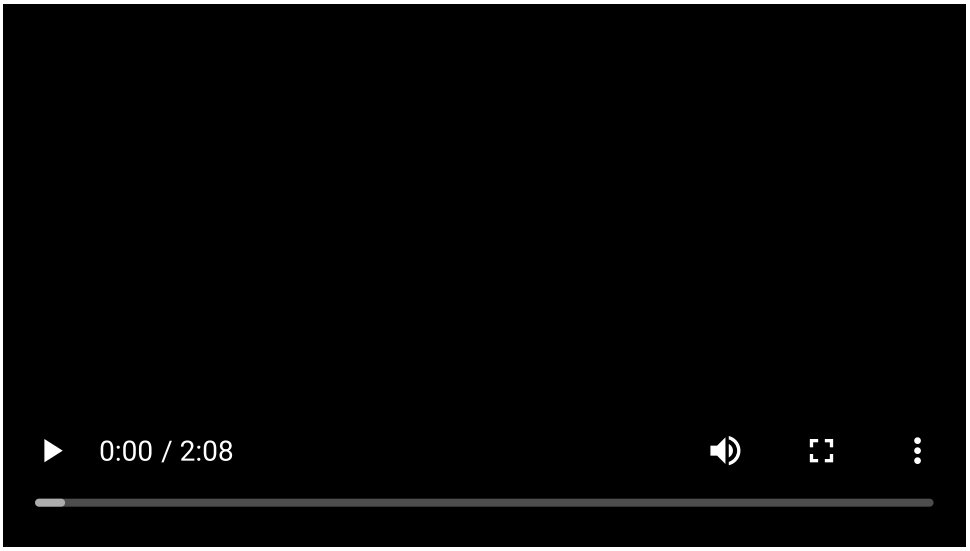
With emerging technologies such as digital therapeutics, machine learning and cloud computing, navigating the regulatory landscape has never been more complex. Distinguishing medical from non-medical software, defining clinical validation needs, understanding international regulatory differences and meeting diverse market authorisation requirements are just some of the challenges you will tackle.

This course offers a clear, practical understanding of global medical device software regulations. Through expert-led sessions, hands-on exercises and real-world case studies, you will gain the insights and skills needed to confidently steer your software through regulatory pathways and bring it successfully to market.

You will also explore best practices for developing and managing regulated software and learn how to implement them effectively without stifling innovation. Discover how to balance flexibility in the early stages of design with the rigorous oversight needed to deliver a final build that is safe, reliable and fully compliant. This nuanced approach is difficult to master without practical experience and informed guidance, and that is exactly what this course provides.

Led by industry experts with extensive hands-on experience, you will leave equipped with the strategies and knowledge to transform your development process and ensure your products meet the highest standards of quality and safety.

Don't miss this opportunity to strengthen your expertise and drive successful medical device software projects. Register today to secure your place.



Benefits of attending

- **Examine** the borderline between general health and wellness, medical and pharmaceutical software with confidence
- **Master** the criteria that qualify software as a medical device and avoid regulatory missteps
- **Understand** how claim and technology decisions are tied to market authorisation obligations
- **Identify** the pros and cons of splitting your software into platforms and modules
- **Expand** your understanding of EU and US market authorisation processes and obligations for software products
- **Find** out how to define and generate sufficient clinical evidence to bring and keep your software on the market
- **Get to grips** with configurable devices, accessories, systems and parts, and how strategic use can ease your administrative burden
- **Learn** best practices for compliant software development and management while keeping bureaucracy under control
- **Examine** essential techniques to boost product quality and maintain business continuity amid staff changes and evolving IT environments

Who should attend

- **Product & Strategy**
  - Business strategists
  - Product managers
  - Service and sales managers
- **Regulatory, Legal & Quality**
  - Regulatory affairs specialists and managers
  - Legal professionals
  - Compliance officers
  - Quality assurance engineers
- **Engineering, Development & Validation**
  - Software developers
  - System analysts
  - Technical writers
  - Biomedical engineers
  - Clinical validation specialists
  - Usability engineers
  - Risk management moderators
- **Project & Clinical Leadership**
  - Project managers
  - Clinical informatics managers
  - Clinical research associates
  - R&D engineers

*This course covers the foundational principles that apply across all software techniques. For those interested in delving deeper into artificial intelligence, machine learning, and generative AI, we offer the **Masterclass: Market Authorisation of AI-enabled Medical Devices**. Designed as a natural adjunct to this course, the masterclass builds on the concepts introduced here and explores their practical application in AI-driven healthcare solutions.*

Programme

Day 1

Welcome - introduction to the regulations

- Exploratory exercise to discover the borderline between medical device, pharmaceutical, and cosmetic regulation through a case study

Is it a medical device, or not?

- Medical device and in vitro diagnostic device definitions, their terminology, and software considerations
- Intended purpose and claim specificity
- Borderline between medical device software and lifestyle and fitness software

Software qualification

- Modules and software with multiple functions
- Functional exemptions
- Population health and educational software
- Search engines, Q&A tools, and chatbots
- Resource and workflow management software
- Clinical decision software

International comparison

- Software as a Medical Device (SaMD) according to the IMDRF
- SaMD ≠ Medical Device Software
- IMDRF SaMD risk stratification framework and its pitfalls
- International differences (US, Canada, South Korea, …)

Case studies on qualification

Considerations for placement on the market

- Placing and making available on the market
- Subscription models, cloud computing, and software as a service
- Pros and cons of the modular approach
- Software platforms
- Software accessories, systems, components
- Legal status of wearables

Case study on regulatory positioning

Case study on wearables

Borderline with medicine legislation

- Companion diagnostics, medication management, and adherence apps
- Digital therapeutics
- Borderline with pharmaceuticals, combination products

Case study on borderline with medicine legislation

Day 2

EU market authorisation of medical device software

- Overview of EU market authorisation process
- Engaging with a Notified Body
- UDI versus Basic UDI
- EUDAMED
- Declaration of Conformity
- Person Responsible for Regulatory Compliance
- Authorized representatives
- Economic operators: distributors, importers, and service fulfilment centres
- App Stores and Digital Distribution Platforms
- Software traceability
- Monitoring critical components or platform updates
- Software recalls
- Unannounced Notified Body Audits
- Service updates, upgrades, and other changes

Case study on software distribution

Case study: a great idea for a start-up!

General Safety and Performance Requirements for software

- Harmonised standards
- Common specifications
- GSPR Checklist
- Software labelling
- Use of language and symbols
- IT environment and mobile platforms
- Repeatability and reliability of machine learning software
- Instructions for use

Practical Construction of a Technical file

- Content
- Example

US Market authorisation (FDA)

- US Code of Federal Regulations and its Implications for Software
- 510(k) process and de novo process
- FDA Guidance's specific to software
- FDA expectations for machine learning software

Case study on US market authorization

Discussion – International go-to-market considerations

Day 3

Classification of Medical Device Software

- Implementing Rules
- Classification rules
- Software that drives or influences the use of a (hardware) medical device
- Classification Rule 11
- IMDRF SaMD risk type determination
- IMDRF SaMD risk stratification framework and its pitfalls
- Classification Rules 13, 15, and 22

Case studies – Classification

Borderline cases

- Borderline manual on qualification and classification
- Helsinki procedure
- Dispute resolution and fair competition

Software Development Models

- Symptoms and root causes of poor design control
- Waterfall vs Agile, iterative, and spiral development
- Principles of good design control
- Stage-gated models

Best practices to manage design activities

- Project Management
- Development Planning
- Change Management
- Requirements Management
- Architecture & Design
- Development
- Configuration Management
- Verification & Validation
- Defect Management
- Design Reviews

State-of-the-art standards for regulatory compliance

Software Development Standards for regulatory compliance

- IEC 62304 Software Lifecycle Management
- IEC 82304-1 General Requirements for Product Safety

Managing software suppliers and subcontractors

- Managing software suppliers
- Outsourcing design activities
- Identifying critical suppliers
- Managing software platforms and plugins
- Using open-source software
- Using legacy software

Q & A

Programme

Day 4

Core concepts in clinical evaluation of medical software

- The regulatory framework of gathering clinical evidence for devices. International differences (EU, US, UK, …)
- Clinical evaluation during software lifecycle
- Clinical vs performance evaluation
- Direct and indirect benefits and risks

Setting the right scope and level of evidence for medical software

- Validation of clinical association, technical performance and clinical performance
- Role of the standards and scientific literature
- Considerations for AI/ML-based devices

The literature review process

Case Studies – clinical evaluation of medical device software

Assessing and documenting clinical evidence: The Clinical Evaluation Report

Clinical and performance studies

- When is a clinical investigation needed for medical device software
- Selecting appropriate study design
- Application of standards
- Clinical performance studies
- Regulatory and ethical considerations

Post-Market Surveillance and Post-Market Clinical Follow up

- Post-market regulatory requirements
- The role of Real-World data and Real-World Evidence
- Implementing Post-Market Clinical Follow-up for medical device software
- Successfully bringing together Risk Management, Clinical Evaluation and Post Market Surveillance

Q & A

Day 5

Software usability

- Managing the human element of risk
- Designing for happiness
- Terminology, Roles and Responsibilities
- Human factors Engineering
- User Experience Design (UXD)
- Process

Presenters



Koen Cobbaert

Koen Cobbaert works for Philips as a quality, regulatory, and standards expert. Through trade associations COCIR and DITTA, he represents the industry at the European Commission and the IMDRF on matters related to software and artificial intelligence. He also contributes to various standardisation organizations focusing on software and artificial intelligence.

In the legislative domain, Koen chairs COCIR's and DITTA's software focus groups, representing its members at respectively the European Commission MDCG workgroups on Borderline and Classification and New Technologies and at the international level at the International Medical Device Regulators Forum (IMDRF) workgroup on artificial intelligence. Koen is also an advisor in the SaMD workgroup at the Global Harmonization Working Party (GHWP). Currently, Koen is engaged in various proposed EU legislation relating to artificial intelligence and data (AI Act, Machinery Regulation, General Product Safety Directive, Data Act, European Health Data Space…). Aside from various publications through trade associations, Koen also edited the book Software as a Medical Device, published through the Regulatory Affairs Professionals Society (RAPS).

In the standardization domain, Koen is a member of CEN-CENELEC's Industry Advisory Forum, and he is delegated as a Belgian expert to IEC JTC 1 SC 42 on artificial intelligence, CEN-CENELEC JTC21 on artificial intelligence, ISO TC215 JWG7 on health informatics, and to the IEC SC62A Advisory group on Software, Networks, and Artificial Intelligence (SNAIG).

Koen has a Master of Science in electrical engineering and safety risk management. He has over 15 years of hands-on experience establishing regulatory and market-access strategies for medical device software, performing worldwide regulatory submissions, and moderating risk management and clinical evaluation for software applications for general radiology, oncology, neurology, cardiology, orthopaedics, and clinical pathology. He has worked on software applications for pattern recognition, computer-aided detection, reasoning engines, clinical pathways, and other clinical decision support systems, including mobile apps, embedded software, and software operating in the cloud.



Zuzanna Kwade

Zuzanna Kwade is Software Clinical Evaluation Lead at Dedalus Healthcare. Zuzanna holds a PhD in Biochemistry and has 15 years of experience in clinical and medical research. She is the co-author of several white papers on regulatory aspects of clinical research and clinical evaluation.

Since 2016, she has been actively involved in Clinical Evaluations according to MEDDEV 2.7.1 (Rev.4) for multiple devices, including high risk hardware devices and medical software. She also represented COCIR in the European Union Task Force on clinical evaluation of software and co-authored MDCG2020-1 guidance on clinical evaluation of MDSW.

Course dates

25-29 January 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 16977*	GBP **2,199** ~~2,699~~ EUR **3,079** ~~3,779~~ USD **3,539** ~~4,319~~ **Until 30 Nov**
21-25 June 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17251*	GBP **2,199** ~~2,699~~ EUR **3,079** ~~3,779~~ USD **3,539** ~~4,319~~ **Until 26 Apr**

How to book

Online:
ipi.academy/2149

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

I thought the content was incredibly comprehensive and very detailed. The speakers were knowledgeable and engaging.

Emma Richardson
QA Coordinator
Brainomix
Jun 22 2026

★★★★★

Overall this course was excellent, and I found it extremely useful. I would highly recommend it. I wanted to understand the processes for developing compliant medical device software. I definitely got the necessary information to understand this better. Both excellent speakers and clearly extremely knowledgeable on the subject matter. Very impressive. I thought it would focus more on the development process (e.g. detail around how to implement EN 62304), but what this course demonstrated was that there is a lot more to consider. So that was a useful learning experience as well.

Tom Clarke
Director
ISO Sense Consulting Ltd.
Nov 18 2024

★★★★★

Both speakers extremally knowledgeable and fantastic teachers. thoroughly enjoyed the course! Fantastic all around!

Neisha Kearney
Quality Associate
Axial
Jul 22 2024

★★★★☆

[Speakers had] huge expertises. I accomplished what I wanted to achieve from this course.

Wicem Boumalouka
Chef de Projet
Guerbet LLC
Nov 18 2024

Run this programme in-house for your whole team

Coming to IPI Academy 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, all 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.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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