IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Market Authorisation of Software as a Medical Device (SaMD) and Medical Device Software (MDSW)

10-11 November 2025

Learn the critical regulatory requirements and best practices for obtaining market authorisation of Software as a Medical Device (SaMD) and Medical Device Software (MDSW) in global markets.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Join this two-day training course to master the intricate decisions on product claims, technologies, and regulatory positioning that software manufacturers face.

These choices significantly impact the market authorisation process and can determine your success. Avoid missteps that lead to delays, increased costs, and denied market entry. Ensure your innovation reaches its full potential worldwide.

Emerging technologies like digital therapeutics, machine learning, and cloud computing add layers of complexity. Distinguishing between medical and non-medical software, understanding international differences, and meeting diverse market authorisation requirements are some of the significant challenges you'll encounter.

In this course, you will gain a clear understanding of global medical device software regulations. We'll provide practical insights, hands-on exercises, and case studies to guide you through the intricate decisions needed that affect your market authorisation processes. You'll leave equipped to confidently bring your software to market and ensure its regulatory success.

Benefits of attending

By attending this course, you will:

- **Examine** the borderline between general health and wellness, medical and pharmaceutical software.
- **Master** the criteria that qualify software as a medical device
- **Learn** how claim and technology decisions are linked to market authorisation obligations
- **Get to grips** with the regulatory concepts of configurable devices, accessories, systems, and parts, and how leveraging them for your regulatory positioning can impact your administrative burden
- **Identify** the pros and cons of splitting your software into platforms and modules
- **Expand** your understanding of the EU and US market authorisation process and its obligations for software products
- **Get up to date** with how different distribution models such as direct download, app stores, cloud-based, and subscription models bring different economic operator obligations
- **Understand** a health institution's obligations, opportunities and limitations for in-house development
- **Place** yourself in the shoes of a start-up and weigh your regulatory options, strategy, timing, and budget decisions

Who should attend?

- Business strategists
- Product and service managers
- Sales and marketing managers
- Regulatory affairs managers
- Legal professionals
- Compliance officers
- Research and development engineers
- Clinical research associates
- Project managers
- Clinical informatics managers of hospitals

Programme

Day 1

Introduction to the regulations

- Overview of 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 authorization 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 fulfillment centers
- 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 standard
- Common specifications
- GSPR Checklist
- Software labeling
- 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 Guidances specific to software
- FDA expectations for machine learning software

Case study on US market authorisation

Discussion - international go-to-market considerations

Presenter

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.

Course date

10-11 November 2025

Live online
09:00-17:00 **UK (London)** (UTC+00)
Course code 15438

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 06 Oct

How to book

Online:
ipi.academy/3093

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

Email:
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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

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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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