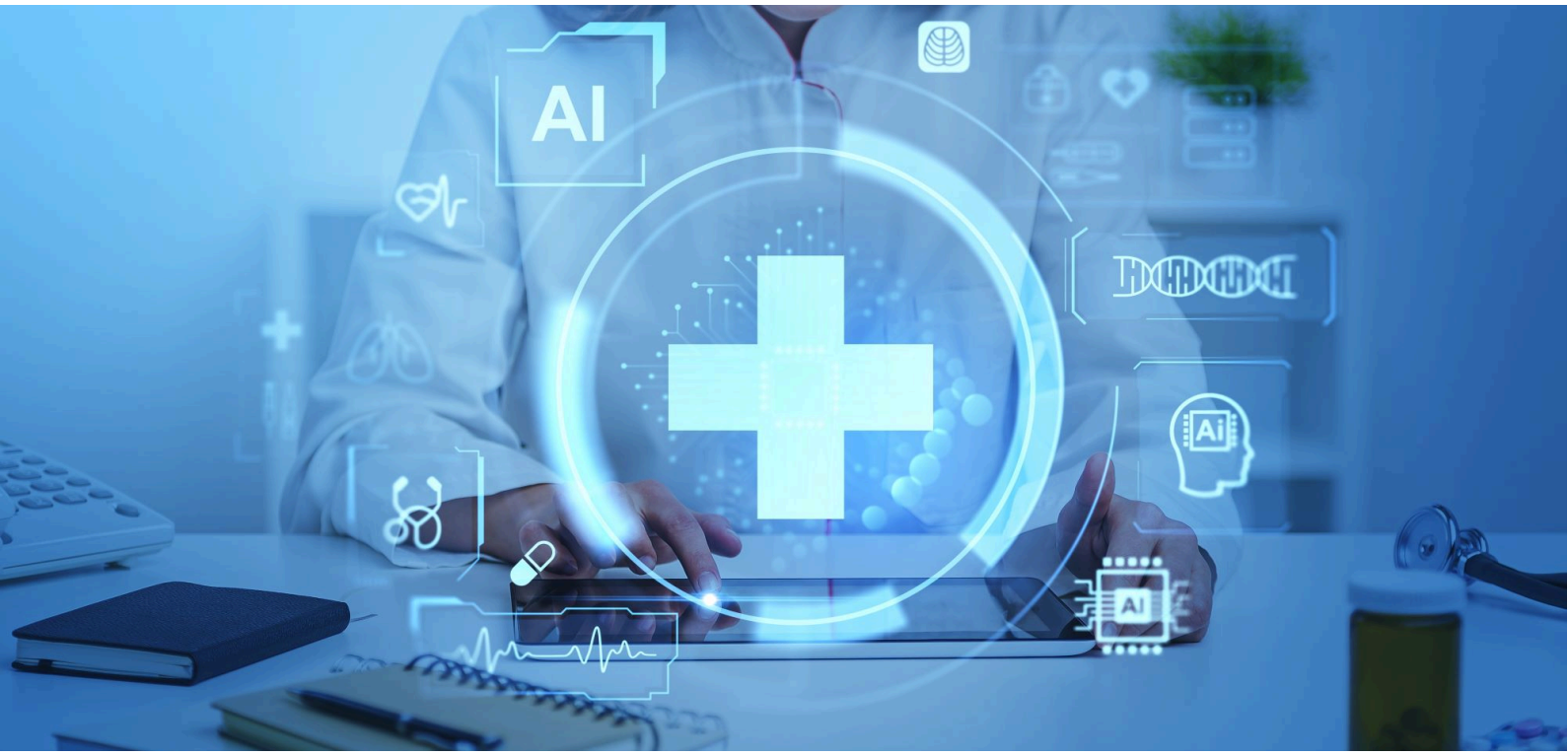
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Masterclass: Market Authorisation of AI-enabled Medical Devices

18-19 November 2025

This course provides essential guidance on navigating regulatory requirements and securing market authorisation for AI-based medical devices, covering key regulations, compliance strategies, and best practices for global market access.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Keeping up with the rapidly changing regulations applicable to AI-based medical devices takes time and effort. Many AI providers face regulatory, implementation, and investment uncertainties, particularly for advanced use cases like dynamic task specification, grounded reporting, and patient chatbots.

This course provides a comprehensive understanding of the legislative landscape and best practices, enabling you to shape your use cases and secure a prosperous future for your AI initiatives.

You will also delve into the intricate world of the European AI Act and its impact on the medical device domain. You will gain insight into the geopolitical forces behind the legislation and a better understanding of how it relates to and impacts other AI legislation worldwide.

The AI Act classifies many AI systems used in medical devices as 'high-risk AI systems', mandating stringent criteria related to human oversight, safety, fundamental rights, robustness, and accessibility before entering the Union market. Our course leader will demystify the European AI Act, shedding light on its complex interplay with existing medical device regulations. You will gain insights that empower you to implement the Act, secure your portfolio, and gain a significant competitive edge in the evolving landscape of AI-based medical devices.

By the end of this course, you will have a clear understanding of the profound impact of the European AI Act on the medical device industry. You will be equipped with practical insights to navigate the regulatory landscape with confidence.

Benefits of attending

- **Get up to speed** with current regulations and standards on AI-based medical devices and data
- **Learn** best practices for the development and regulatory submissions of AI-based medical devices
- **Understand** the interplay between medical devices and AI legislation
- **Consider** the impact on medical device use cases
- **Learn** how to convey in plain language how your company can comply with and safeguard its product roadmaps
- **Identify** the avenues available to mitigate the regulatory and investment uncertainties

Who should attend?

- Business strategists
- Product and service managers
- Project managers
- System analysts
- Regulatory Affairs Managers
- Compliance officers
- Legal professionals
- Software Engineers and Architects
- Data Governance Specialists
- Data Scientists
- Biomedical engineers
- Clinical research associates
- Clinical informatics managers of hospitals
- Safety Engineers
- AI Ethicists

Please note: To get the most out of this masterclass, participants should have a basic understanding of how medical devices must comply with EU MDR, EU IVDR, and FDA Regulations.

Programme

Day 1

Introduction to Artificial Intelligence

Geopolitical considerations of AI legislation

- Reasons to regulate AI
- The Brussels Effect and the first-mover advantage
- Impact on SMEs
- Horizontal versus vertical legislative approaches
- Big Tech's stakes in AI regulation
- Standardisation: the new battlefield
- The Beijing Effect

Regulatory requirements for AI-based medical devices

- Overview of AI initiatives by healthcare regulators worldwide
  - International: Organization of Economic Cooperation and Development (OECD), World Health Organization (WHO), International Medical Device Regulators Forum (IMDRF)
  - National or regional: Brazil, Canada, China, European Union, Japan, Singapore, South Korea, Taiwan, Thailand, United Kingdom, United States of America
  - Notified body initiatives

Best practices for developing AI systems

- Putting healthcare legislative initiatives on AI into practice
- Lessons learned and common pitfalls from regulatory submissions of AI-based medical devices
- Describing your use case, application, algorithm, and its impact on clinical care
- Data considerations: origin, acquisition, identity, access, collection, attributes, shifts over time, limitations, bias, processing, augmentation, relevance and independence, annotation, testing, reference standards, integrity, and data protection
- Training, tuning, and testing
- Clinical evaluation
- Statistical analysis: generalisability, subgroup analysis, and statistical power
- Usability considerations, including interpretability and explainability
- Post-market considerations: updates, monitoring, and complaints handling
- Diagnostic tools versus prognostic and predictive tools

State-of-the-art data governance and data management

Day 2

EU Artificial Intelligence Act

- AI Act messages for the board
- Scope
- Provider obligations
- Deployer obligations
- GPAI model provider obligations
- Standards and guidelines
- Notified body obligations
- Authorised representative obligations
- AI Act governance
- Regulatory sandboxes and Testing and Experimentation Facilities
- Timelines

Implementing the EU Artificial Intelligence Act

- A reference checklist with activities, timelines, and considerations to help medical device manufacturers and their economic operators implement the AI Act

Standardisation landscape

A reference overview of horizontal and vertical standards, highlighting their relevance or irrelevance for manufacturers of AI-enabled medical devices and their role in supporting the AI Act

Adaptive AI-based medical devices

- The role of machine-learning enabled medical devices (MLMD) in healthcare
- Learning during clinical use
- Change considerations
- Predetermined Change Control Plan
- Significant changes to adaptive AI-based medical devices

Generalist Medical AI systems

- Foundation Models, including LLM, NLP,NLG, RAG
- Role of GMAI systems
- Regulatory challenges and solutions for GMAI systems
- GPAI model provider obligations following the EU AI Act
- GPAI models throughout the value chain
- How can GenAI providers create trust
- Finding answers to your challenges
  - Regulatory sandboxes
  - EU Testing and experimentation facilities

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

18-19 November 2025

Live online
09:00-16:30 **UK (London)** (UTC+00)
Course code 15450

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 14 Oct

How to book

Online:
ipi.academy/3120

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

★★★★★

Loved it! I wouldn't change a thing! I wish I had attended this course sooner. I wanted a practical approach for complying with the EU AI act. [Speaker] did a fantastic job delivering on this topic — his knowledge of the subject matter is outstanding. I'd wholeheartedly recommend this course to other regulatory professionals.

Diana Sherlock
Sr. Regulatory Affairs Specialist
4DMedical
Apr 4 2025

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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