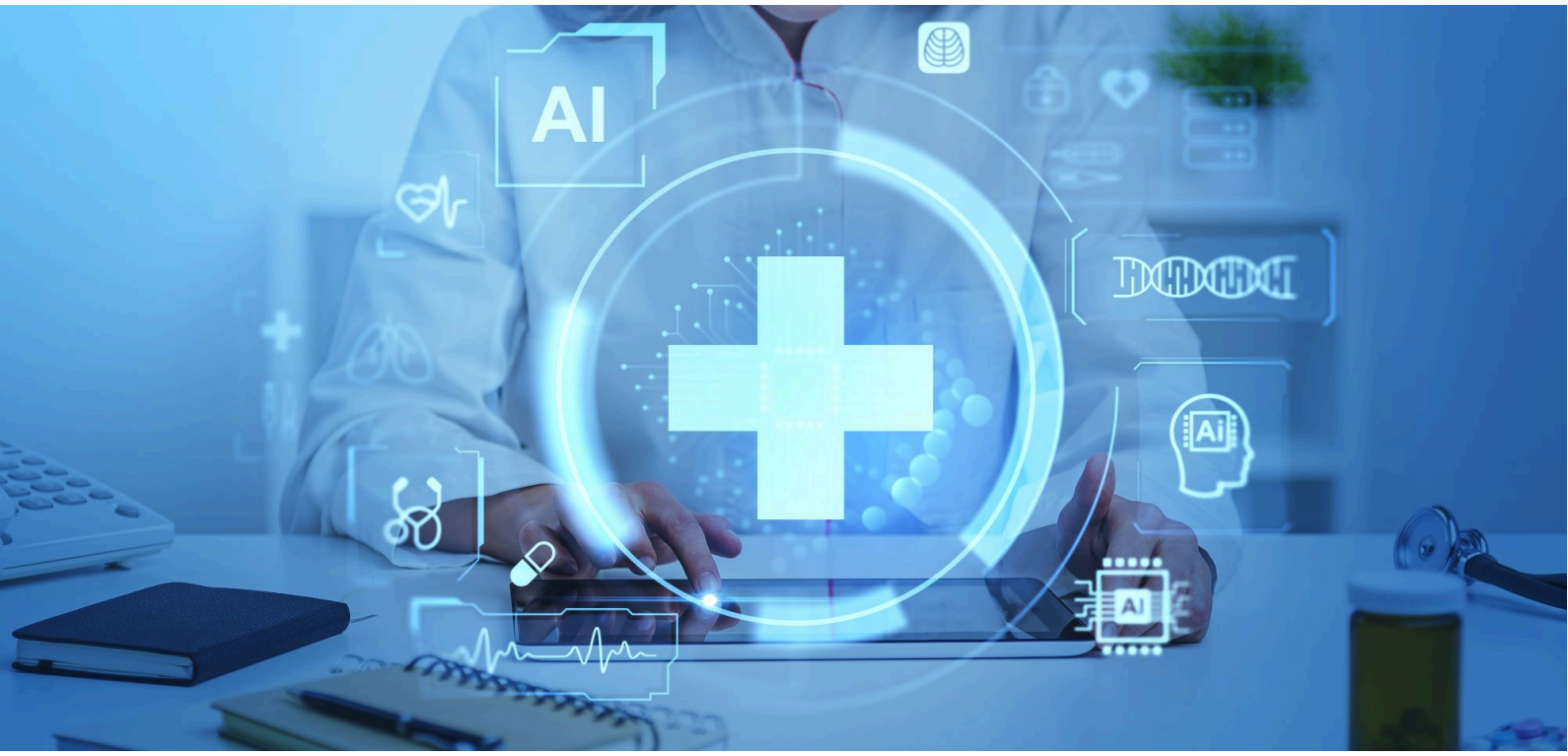
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Masterclass: Market Authorisation of AI-enabled Medical Devices

28-30 June 27
+ 7-9 December 27

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:
12 hours for your records

Certificate of completion

Course overview

Keeping up with the rapidly evolving regulations governing AI-based medical devices can be challenging. Many AI providers face uncertainty around regulatory requirements, implementation strategies, and investment decisions, particularly for advanced applications such as dynamic task specification, grounded reporting, and patient chatbots.

This masterclass provides a practical understanding of how artificial intelligence is applied in healthcare, the evolving legislative landscape, and current regulatory best practices. Participants will learn how to define and position AI use cases, understand applicable regulatory frameworks, and prepare their organizations for future compliance requirements.

The second part of the course focuses on the European Union Artificial Intelligence Act (EU AI Act) and its implications for the medical device sector. Participants will examine the geopolitical drivers behind AI regulation and understand how the EU AI Act interacts with AI legislation in other regions.

Under the EU AI Act, many AI systems used in medical devices are classified as high-risk. These systems must meet stringent requirements for human oversight, safety, fundamental rights, robustness, and accessibility before they can be placed on the European Union market. Throughout the course, participants will gain practical insight into how the AI Act complements existing medical device legislation and what organizations should consider when implementing its requirements.

By the end of the course, participants will better understand the EU AI Act and its impact on the medical device industry, including areas where regulatory expectations are well established and where important discussions are still evolving. Participants will leave with practical knowledge to navigate the changing regulatory landscape for AI-based medical devices.

Please note: this masterclass does not cover cybersecurity of AI-based medical devices.

Benefits of attending

- **Gain** an up-to-date understanding of regulations and standards for AI-based medical devices and healthcare data
- **Learn** best practices for developing AI-based medical devices and preparing regulatory submissions
- **Understand** how medical device legislation interacts with AI-specific legislation
- **Assess** the regulatory implications for different AI use cases
- **Learn** how to explain compliance strategies and product roadmaps in clear, accessible language
- **Identify** approaches to reduce regulatory and investment uncertainty

Who should attend?

This masterclass is intended for professionals involved in the development, regulation, governance, or implementation of AI-based medical devices, including:

- Regulatory affairs managers
- Business strategists
- Product and service managers
- Project managers
- Systems analysts
- Compliance officers
- Legal professionals
- Software engineers and architects
- Data governance specialists
- Data scientists
- Biomedical engineers
- Clinical research associates
- Clinical informatics managers Safety engineers
- AI ethicists

Please note: Participants will benefit most if they have a foundational understanding of the regulatory requirements for medical devices under the EU Medical Device Regulation (MDR), the In Vitro Diagnostic Medical Devices Regulation (IVDR), and applicable U.S. Food and Drug Administration (FDA) regulations.

Programme

Day 1

Introduction to Artificial Intelligence

This session introduces the fundamentals of artificial intelligence (AI), including how AI systems work, where they are used in healthcare, and the opportunities and challenges they present. Participants will explore the core principles of AI systems, from data-driven learning to reasoning and decision-making, and understand the algorithms that enable machines to perceive, learn, and support clinical and operational tasks.

The session also examines AI risks and the importance of responsible development and deployment. Participants will learn how AI has evolved, the disciplines that underpin modern AI technologies, and why regulatory and ethical considerations are essential to ensuring patient safety.

Topics include:

- What artificial intelligence is and how it is used in healthcare
- Key AI concepts, terminology and scope
- Machine learning, deep learning and natural language processing
- Common AI risks, including privacy, safety, security, reliability, interpretability, transparency, accountability, sustainability and human oversight
- Principles of responsible AI
- Historical development of AI and emerging trends

AI legislation as a global power play

Artificial intelligence is becoming a strategic driver of economic competitiveness, technological leadership and geopolitical influence. As governments develop regulatory frameworks, they also shape international standards, market access, and innovation ecosystems.

This session examines the geopolitical forces influencing AI legislation and explores how different regulatory approaches affect the healthcare sector. Participants will gain insight into the role of governments, standards organizations, and major technology companies in shaping global AI policy, as well as the implications for manufacturers of AI-enabled medical devices.

Topics include:

- AI regulation as a strategic policy instrument
- The Brussels Effect and the Beijing Effect
- Horizontal and sector-specific approaches to AI legislation
- Digital sovereignty and international competitiveness
- The role of standards and open-source software
- The influence of major technology companies on AI regulation
- Case study: AI supply chain resilience under export controls and cloud access restrictions
- Future developments in global AI governance

Best practices for developing AI-enabled medical devices

This session translates regulatory expectations into practical development activities. Drawing on international regulatory frameworks and real-world submission experience, participants will examine the full development life cycle of AI-enabled medical devices, from defining the intended use and algorithm through post-market monitoring.

The session emphasizes robust data governance, clinical evidence, statistical validity, and quality management throughout the product life cycle. Participants will also discuss common regulatory deficiencies and practical approaches to avoiding them.

Topics include:

- Regulatory foundations
  - Regulatory obligations for AI-enabled medical devices
  - Applying AI legislation within existing medical device frameworks
  - Lessons learned from regulatory submissions
  - Common regulatory deficiencies and how to avoid them
- Defining the AI solution
  - Defining the intended use and clinical purpose
  - Describing AI use cases and algorithms
  - Assessing clinical impact
- Data governance
  - Data origin and acquisition
  - Data identity and traceability
  - Data access and collection
  - Data quality and integrity
  - Data annotation
  - Data protection
  - Dataset relevance and independence
  - Bias and fairness
  - Dataset shifts over time
  - Data limitations
  - Reference standards
  - Data augmentation
  - Testing datasets
- Model development
  - Training AI models
  - Model tuning
  - Performance testing
  - Validation strategies
- Clinical evidence
  - Clinical evaluation
  - Statistical analysis
  - Generalizability
  - Subgroup analyses
  - Statistical power
- Human factors
  - Usability engineering
  - Interpretability
  - Explainability
- Post-market activities
  - Performance monitoring
  - Model updates
  - Complaint handling
  - Post-market surveillance
- Clinical applications
  - Diagnostic AI
  - Prognostic AI
  - Predictive AI

Including practical examples, regulatory case studies, and discussion of implementation challenges.

Participants will work through the development life cycle, applying best practices to realistic regulatory scenarios and discussing practical considerations for preparing AI-enabled medical devices for market authorization.

Programme

Day 2

EU Artificial Intelligence Act

The European Union Artificial Intelligence Act (EU AI Act) is the world's first comprehensive regulatory framework for artificial intelligence. It introduces new obligations for organizations that develop, deploy, and manage AI systems, including manufacturers of AI-enabled medical devices.

This session provides a practical introduction to the EU AI Act and its implications for the medical device sector. Participants will understand the Act's risk-based approach, economic operators' responsibilities, and the relationship between the AI Act and existing sector-specific legislation. The session translates legal requirements into practical regulatory, technical, and organizational considerations that support implementation.

Topics include:

- Overview of the EU AI Act
  - Objectives and scope of the EU AI Act
  - Risk-based regulatory framework
  - Impact on software development processes
  - Implications for AI-enabled products and portfolios
- AI system classification
  - Prohibited AI systems
  - High-risk AI systems
  - General-purpose AI (GPAI) models
  - Limited-risk and minimal-risk AI systems
  - Practical examples and classification exercises
- Roles and responsibilities
  - Obligations of providers
  - Obligations of deployers
  - Importers and distributors
  - Authorized representatives
  - Responsibilities of subcontractors and research partners
  - Transparency requirements
  - Human oversight
  - Logging and record-keeping
  - Post-market monitoring
- Interaction with other legislation
- General-purpose AI models
  - Integration of GPAI models into medical devices
  - Responsibilities of GPAI providers
  - Responsibilities of medical device manufacturers
  - Conformity assessment considerations
  - Technical documentation requirements under the AI Act and MDR/IVDR
- Standards and implementation
  - Harmonized standards
  - Codes of practice
  - Technical documentation expectations
  - Preparing for conformity assessment
- Organizational readiness
  - Governance structures
  - Process adaptation
  - Resource planning
  - Collaboration with notified bodies
  - Preparing quality management systems
- Notified bodies
  - Role of notified bodies under the AI Act
  - Conformity assessment of high-risk AI systems
  - Expectations for technical documentation
  - Quality management systems
  - Post-market obligations
- Governance and implementation timeline
  - Key milestones
  - Transition periods
  - Future regulatory developments

Including practical interpretation of the legislation, regulatory examples, and discussion of implementation challenges.

Participants will examine practical scenarios, review regulatory expectations and discuss how organizations can prepare for compliance while integrating AI into existing medical device development processes.

Implementing the EU Artificial Intelligence Act

This session presents a practical implementation roadmap for medical device manufacturers and other economic operators. Participants will work through the activities, timelines, and organizational considerations needed to comply with the EU AI Act and integrate its requirements into existing quality and regulatory systems.

Topics include:

- Implementation roadmap
- Organizational responsibilities
- Gap assessment
- Compliance planning
- Documentation requirements
- Quality management integration
- Implementation timelines
- Practical implementation checklist

AI standards

Standards are becoming increasingly important in demonstrating compliance with AI and medical device regulations. However, not all published standards carry the same regulatory significance or provide equal value during product development and conformity assessment.

This session examines a selected set of AI standards that have attracted particular attention from regulators and notified bodies. Participants will learn how to distinguish between standards essential for regulatory compliance and those that provide supporting guidance, enabling them to make proportionate, well-informed implementation decisions.

Topics include:

- Regulatory significance
  - Standards recognized by regulators
  - Standards commonly referenced by notified bodies
  - Standards supporting conformity assessment
- Practical application
  - Selecting standards appropriate to the intended use
  - Understanding overlaps and complementary requirements
  - Identifying limitations of individual standards
  - Balancing regulatory expectations with practical implementation
- Implementation strategy
  - Prioritizing standards
  - Developing a proportionate standards strategy
  - Supporting technical documentation
  - Preparing for regulatory review

EU Support Structures for AI Medical Devices

Europe is developing an extensive ecosystem of initiatives that support the development, validation, and deployment of AI-enabled medical devices. These initiatives provide access to datasets, testing environments, regulatory expertise, technical infrastructure and collaborative networks.

This session explains how manufacturers can use these support structures throughout product development while recognizing that participation does not replace regulatory requirements for market authorization.

Topics include:

- Data laboratories
- Data intermediation services
- Data altruism organizations
- Testing and Experimentation Facilities (TEF Health)
- AI Factories
- European Digital Innovation Hubs
- Union AI testing support structures
- Regulatory sandboxes
- Public-private partnerships
- Access requirements
- Practical applications during development and validation
- Limitations of publicly funded support initiatives

Programme

Day 3

Real-world performance testing for AI-enabled medical devices

AI is challenging the traditional regulatory model for medical devices. Historically, manufacturers have been expected to demonstrate safety and performance before market access. But increasingly versatile GenAI, adaptive AI, and agentic systems raise a harder question: what if an AI system can perform tasks that were not fully specified when it was developed?

This session explores how regulators are responding by developing adaptive staged gateways that combine controlled real-world deployment with evidence generation, continuous monitoring, and life cycle oversight.

We will compare developments in the UK, EU, US, China, and Singapore, including regulatory sandboxes and supervised real-world testing.

Attendees will gain practical insight into questions such as:

- When and where do these pathways become available?
- What evidence is still needed before deployment?
- How should human oversight, monitoring, updates, and rollback work?
- How might responsibilities shift between manufacturers, healthcare providers, and regulators?

The session concludes with what this means for manufacturers: where these pathways may create opportunities for earlier evidence generation and which capabilities product teams may need to build.

Topics include:

- What are staged adaptive real-world testing pathways?
- What needs to they address?
- How do they work?
- When and where are they operational?
- What regulators plan routine monitoring of real-world performance?
- How might real-world monitoring impact you, and how can you prepare?

Natural Language Processing Systems

Natural language processing (NLP) is transforming the way healthcare organizations capture, interpret and generate clinical information. From AI scribes and clinical documentation to text classification, retrieval-augmented generation (RAG) and large language models (LLMs), these technologies are creating new opportunities while introducing new regulatory and validation challenges.

This session examines the application of NLP and generative AI in healthcare, with a particular focus on evaluating the performance, reliability and clinical suitability of LLMs. Participants will explore common challenges, including hallucinations, partial correctness and model variability, together with approaches for evaluating AI systems using automated methods, expert review, synthetic data and real-world data.

Topics include:

- Regulatory landscape
  - Regulatory considerations for generative AI
  - Emerging regulatory expectations for NLP systems
  - Regulatory implications for healthcare applications
- Clinical validation
  - Clinical validation of generative AI for healthcare
  - Defining appropriate validation objectives
  - Performance evaluation in clinical settings
- Evaluation methodologies
  - Assessing large language models for healthcare
  - Evaluation metrics and benchmarking approaches
  - Measuring accuracy, robustness and consistency
  - Hallucinations and partial correctness
  - Model variability and reproducibility
- Validation strategies
  - Human-in-the-loop evaluation
  - Automated evaluation methods
  - Real-world datasets
  - Synthetic datasets
  - Strengths and limitations of different evaluation approaches
- Case study
  - Clinical validation using synthetic data
  - LLM-as-a-judge methodologies
  - Practical considerations for implementing evaluation frameworks

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 dates

28-30 June 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17267*	GBP **1,399** ~~1,699~~ USD **2,251** ~~2,719~~ EUR **2,319** ~~2,739~~ **Until 03 May**
7-9 December 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17566*	GBP **1,399** ~~1,699~~ USD **2,251** ~~2,719~~ EUR **2,319** ~~2,739~~ **Until 12 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

★★★★★

He's great and knowdgeable, and very clear to teach and lecture. He takes the time to reply and bring clarity.

Juan Verde
MD, MSc
IHU Strasbourg
Jun 29 2026

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Juan Verde
MD, MSc
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Jun 29 2026

★★★★☆

I think he was great delivering the materials and content

Tin Ho Clarence Ng
Regulatory Officer
Odin Medical
Jun 29 2026

★★★★★

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.

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ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com