IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Masterclass: Artificial Intelligence-based Medical Devices

26 July 2024
+ 7 November 2024

Many companies take part in the global 'race to AI' by continuously broadening the role of AI in their product portfolio. However, the rules of the game appear to be changing. The increased visibility of the technology's risks has led to calls for regulators to look beyond the benefits, and also secure appropriate legislation to ensure AI that is 'trustworthy'– legal, ethical, and robust and to ensure data is portable and qualitative. During this session, we will discuss the main players, trends, and challenges in the 'race' to AI regulation and how companies can move forward with an advantage.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Overview

In this course, we'll explore global legislative trends, providing an overview of current and proposed legislation and standards applicable to AI-based medical devices while taking lessons learnt from regulatory submissions of AI-based medical devices.

The European AI Act, soon to be upon us, will redefine specific medical devices as 'high-risk AI systems', ensuring they are legal, ethical, safe, and robust. Our course leader will demystify this Act, revealing its intricate interplay with existing medical device regulations, empowering manufacturers to secure their portfolios and gain a competitive edge. As you conclude this session, you'll emerge enlightened about the AI Act's profound impact on the medical device industry, its areas of consensus and ongoing debates.

As data is the lifeblood of AI-based medical devices we'll immerse you in contemporary data management and governance practices, aligning with standards and the proposed European Data Act and European Health Data Space.

Lastly, we'll explore adaptive AI-based medical devices, which dynamically adapt to clinical settings or individual patients. Discover their market presence, compliance with regulations, and strategies to earn trust with authorities.

This course offers a factual and comprehensive exploration of the evolving landscape of AI-based medical devices and the regulatory frameworks that govern them.

Benefits in Attending

- Get up to speed with current regulations and standards on AI and data
- Learn best practices for the development and regulatory submissions of AI-based medical devices
- Understand the interplay between medical device, AI and data legislations
- Gain insight into how upcoming legislations might impact your company's portfolio
- Learn how to convey in plain language how your company can comply and safeguard its product roadmaps

Who Should Attend

- Global Regulatory Senior Managers
- Team Lead in Global Medical Device Management
- Principal Regulatory Affairs Specialist
- Regulatory Affairs Managers
- Safety Scientists
- Scientific Support Specialists
- Software Engineers
- Head of Product Development
- Device Technical Lead
- IT Quality Advisers

Programme

Current legislative requirements for AI-based medical devices

- International overview of legislation and guidance
- Considerations for regulatory submissions
- Initiatives by medical device regulators
- Lessons learnt from regulatory submissions
- Future perspectives

Europe's proposed Artificial Intelligence Act

- Geopolitical considerations of AI legislation
- Introduction to the proposed European AI Act

Europe's proposed Artificial Intelligence Act con'd

- Impact of the proposed AI Act on medical device manufacturers, clinicians, and patients
- Interplay of proposed AI Act with medical device regulations

Europe's proposed Data Act and European Health Data Space

- Overview of the legislation
- Impact on healthcare

Standardization on AI and related data

- Standards in support of the proposed AI Act
- Interplay between horizontal and vertical standardization landscape
- Standards for AI-based medical devices
- Q&A

Programme

Machine-learning enabled medical devices

- Learning during clinical use
- Change considerations
- Legal instruments to accommodate change during use
- Q&A

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

26 July 2024	**Live online** 09:00-16:00 **UK (London)** (UTC+01) *Course code 13804*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 21 Jun**
7 November 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 14032*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 03 Oct**

How to book

Online:
ipi.academy/2599

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

★★★★★

Koen has a breadth and depth of experience in this area, and was great at sharing that in an very accessible manner.

Michelle Galea
External Projects Manager
Optos plc
Mar 6 2024

★★★★☆

I really appreciated the rich content of the slides, the level of information provided and the very clear overview of the regulator context, and the roadmaps.

Alexia Pleinecassagne
RAQA Specialist
Medimaps Group SA
Nov 9 2023

★★★★☆

This was exactly what I needed.

Mickael Vuagnoux
QA Engineer
GE Healthcare
Nov 8 2022

★★★★☆

Great presenter, great content. It's clear that Koen has extensive and very relevant experience in the field. He's an engaging presenter with useful insights.

Michelle Galea
External Projects Manager
Optos plc
May 13 2022

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:

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

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

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@ipi.academy