IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Innovate: The MedTech Series – The 2024 EU AI Act

2 October 2025

This session will summarise the EU AI Act and its implications on the healthcare sector, including how to be compliant with the new regulatory framework.

Format:
Live online

CPD:
1.5 hours for your records

Certificate of completion

Overview

In August 2024, the European Union (EU) approved the Artificial Intelligence (AI) Act, the first legislation aimed at regulating AI applications whilst protecting EU citizens from the potential harms of AI. The regulation will take effect on 2nd August 2026 and will have a significant impact on the healthcare sector.

Legislative changes are also afoot across the globe. In the US, the FDA continues to update its guidance on AI-enabled device software. For example, in December 2024, the FDA published new guidance on Marketing Submission Recommendations for a Predetermined Change Control Plan (PCCP) for AI-Enabled Device Software Functions to provide a reasonable assurance of device safety and effectiveness Conversely, Asia-Pacific has adopted a light touch and voluntary approach to AI regulation, some jurisdictions like China have taken a more prescriptive approach.

According to a recent survey from Norstella, 66% of biopharma organisations say the skills required for their employees have changed due to the introduction of AI. Over 70% of industry leaders confirmed the main reason behind its limited adoption is a lack of expertise, followed by 43% having a lack of knowledge/awareness of AI and what it can do to improve pharmaceutical R&D processes. This session will summarise the European AI Act and its implications on the healthcare sector and what provisions and assessments organisations may need to put in place to be compliant with the new regulatory framework.

Key topics covered in this exciting talk include:

- An overview of the AI Act, the EU's Coordinated Plan on Artificial Intelligence, and its potential impact on the healthcare sector
- A look at what constitutes a high-risk AI system and provide examples of where this might impact the pharmaceutical drug development and medical device commercialisation strategy
- Discuss the minimum information regulators will require for Fundamental Rights Impact Assessments (FRIAs) and Data Protection Impact Assessments (DPIAs) and what measures organisations need to put in place to ensure they are fully compliant with the protection of personal data

Benefits of attending

This course provides greater clarity on the potential impact of the AI Act on pharmaceutical and medical device organisations and brings stakeholders up to speed on what constitutes high-risk AI systems. By joining, you will:

- **Review** the definition of AI and high-risk AI systems and provide real case studies where high-risk AI systems are utilised by pharmaceutical companies in the drug development process and medical device manufacturers in product development
- **Gain** a greater understanding of what the AI Act covers and what provisions and assessments organisations may need to conduct to be fully compliant with the new regulations
- **Explore** the implication of the EU AI Act on data protection and privacy and review the similarities/differences and information requirements for Fundamental Rights Impact Assessment (FRIA) and Data Protection Impact Assessment (DPIA) that organisations need to adhere to remain compliant

Who should attend?

This course is designed for a diverse audience. Whether you're a healthcare professional, a policymaker, or interested in how the EU AI Act will impact the healthcare sector, this course will offer you valuable insights.

Presenter

Cheryl Barton

Dr Cheryl L Barton is an independent consultant with over 35 years' research and business analysis experience. Following her senior research positions in academia and seven years with Merck, in which she was responsible for a variety of CNS research projects. Dr Barton joined Dutch investment bank ABN Amro NV as a senior equity analyst to provide coverage on pan-European companies and assessed the potential impact of new drug development on European Stocks. In 2002, Dr Barton founded PharmaVision to provide independent, tailor-made, life science and consumer health research to pharmaceutical companies, competitive intelligence specialists, investment institutions, and healthcare communication agencies. Dr. Barton regularly writes articles for Pharmtech regarding the latest advances in scientific technologies and regulatory issues that impact the Biopharma and MedTech industries.

Course date

2 October 2025	**Live online** 12:00-13:30 **UK (London)** (UTC+01) *Course code 15537*	GBP **175** ~~200~~ EUR **245** ~~280~~ USD **280** ~~320~~ **Until 25 Sep**

How to book

Online:
ipi.academy/3136

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

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- 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.

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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

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