IPI Academy

MANAGEMENT forum

Presented by
Management Forum

UK Conformity Assessed (UKCA) Marking for Medical Devices

21 October 2025

This course provides UK and global companies practical guidance on what you need to do to continue market access or gain market access with your medical device in the UK.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Since 1 January 2021, there have been a number of changes to how medical devices are placed on the market in the UK. With a substantial reform of the current UK regulatory framework for medical devices in 2025 and 2026 including the new Post-market surveillance (PMS) regulation for medical devices in Great Britain (GB) which will come into force on the 16th June 2025, the challenges facing medical device companies, regulators and conformity assessment bodies are growing. The new requirements will impact technical documentation, labelling, logistics and regulatory compliance.

Benefits of attending

- **Understand** the requirements to achieve UKCA
- **Know** the differences between UKCA and CE marking
- **Learn** how to align your conformity assessment procedures to meet UKCA and CE marking requirements
- **Consider** the requirements for the Northern Ireland market

Who should attend?

- Medical device professionals who wish to gain knowledge and understanding of the new UKCA requirements
- Regulatory affairs managers
- Medical device manufacturers
- Business development managers

Programme

UK Medical Device Regulation and your obligations

- The UK medical device regulations explained
- Transitional arrangements
- The use of standards in the UK
- UK guidance for medical devices

UKCA marking explained (placement of UK CA mark)

- Registering as a manufacturer to sell medical devices in the UK
- Registering medical devices in the UK
- The role of the UK responsible person
- UK conformity assessment bodies

Technical files and UK declaration of conformity

- UKCA technical file versus EU technical documentation, differences and similarities
- Aligning your conformity assessment procedures
- New Post-market surveillance regulation for medical devices in Great Britain

UKNI marking and the future

- The process in Northern Ireland
- Proposed future changes to UK regulations

Workshop – case study on obtaining the UKCA mark

Workshop feedback

Q&A

Presenter

Tina Amini

Dr. Tina Amini, a pharmacist with PhD in Pharmaceutics. She has over 30 years experience in Pharmaceutical and Medical Devices. She previously held the positions of Head of Notified Body and Senior Technical Specialist at LRQA Notified Body and Pharmaceutical & Medical Device Expert at bsi Notified Body, where she was responsible for Device Drug combination products, Conformity Assessment of a wide range of medical devices and onsite assessments of Quality Management System (QMS) as the lead auditor.

Tina has extensive experience of regulatory expertise for CE marking of medical devices, and has been involved in the classification of borderline products and consultation process with several EU competent authorities and EMA for device/drug products.

Prior to joining Notified Bodies, Tina worked in the Pharmaceutical Industry in a variety of disciplines where she took products through from discovery to commercialisation.

Course date

21 October 2025

Live online
09:30-17:00 **UK (London)** (UTC+01)
Course code 15077

GBP **649** ~~749~~
EUR **909** ~~1,049~~
USD **1,043** ~~1,199~~
Until 16 Sep

How to book

Online:
ipi.academy/2615

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

★★★★★

The course was very interesting and detailed. I'm very new to medical devices and I would have benefitted from an introductory course first. However, I have the tools I need to find answers to questions I might have.

Afi Sinclair
Regulatory Affairs Consultant
SincasPharma
Jun 26 2025

★★★★★

Very informative and covered everything we were expecting

Massimo Di Domenico
Director
Burnshield (Pty) Ltd
Jul 17 2023

★★★★★

I think the webinar is well executed.

Massimo Di Domenico
Director
Burnshield (Pty) Ltd
Jul 17 2023

★★★★★

extremely satisfied with all.

Anne-Marie Spence
Vascular Clinical Specialist EMEA
Argon Medical
Jul 17 2023

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@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