



Presented by
Management Forum

UK Conformity Assessed (UKCA) Marking for Medical Devices

15 April 2026
+ 21 October 2026

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, the landscape for placing medical devices on the UK market has undergone significant change. With further major reform to the UK's regulatory framework for medical devices scheduled for 2025 and 2026, the sector is entering a critical period of transition. A key milestone in this reform is the introduction of a new Post-Market Surveillance (PMS) regulation for medical devices in Great Britain, which came into force on 16 June 2025.

These developments present growing challenges for medical device manufacturers, regulators, and conformity assessment bodies alike. The evolving requirements will directly impact technical documentation, labelling, logistics, and overall regulatory compliance.

This course, designed for medical device manufacturers, provides essential guidance to help stakeholders understand and navigate the UK Conformity Assessed (UKCA) marking process in the context of these regulatory shifts, ensuring readiness, compliance, and strategic alignment in an increasingly complex regulatory environment.

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 dates

15 April 2026

Live online

09:30-17:00 **UK (London)** (UTC+01)

Course code 16167

GBP ~~649 749~~

EUR ~~909 1,049~~

USD ~~1,043 1,199~~

Until 11 Mar

21 October 2026

Live online

09:30-17:00 **UK (London)** (UTC+01)

Course code 16450

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](tel:+442077494749)

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 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 Ltd
Jun 26 2025



Very good and very clear



Brian Mzila
Quality Manager
Alexion Pharma UK Ltd
Oct 21 2025



Generally it was good.



Sandra Nicoll
Director Regulatory Affairs & Quality UK & Ireland
Alexion Pharma UK Ltd
Oct 21 2025



Orla Lennon
Senior Manager, Regulatory Affairs
Alexion/AstraZeneca RDU
Jun 26 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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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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