IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Advanced Regulatory Affairs for Medical Devices

Planning your regulatory strategy to comply with the Medical Device Regulation (MDR)

Format:
Bespoke training

CPD:
12 hours for your records (depending on your requirements)

Certificate of completion

Course overview

Explore the MDR's updates enhancing patient safety and understand its revised requirements and processes to navigate the evolving regulatory environment effectively.

This course is crucial for professionals already versed in medical device regulatory affairs, offering indispensable guidance on transitioning products from the current Medical Device Directive (MDD) framework to the new Medical Device Regulation (MDR).

Emphasising regulatory strategy and lifecycle management, this course includes in-depth sessions on regulatory pathways, technical documentation, clinical evaluations, and investigations. Participants will also delve into requirements for the vigilance system, post-market surveillance (PMS), and post-market clinical follow-up (PMCF) studies.

Through interactive case studies and practical workshops, delegates will solidify their knowledge and engage in discussions with two experienced medical device experts, navigating the complexities of regulatory compliance effectively.

This course serves as an ideal continuation from our comprehensive three-day program, An Introduction to the Medical Device Regulation, offering advanced insights and practical skills essential for regulatory professionals in the evolving medical device landscape.

Who should attend

This course will provide experienced medical device professionals with the practical regulatory knowledge to apply life cycle management in an MDR environment, particularly those who play a key role in transitioning their products to the MDR, including:

- Medical device regulatory affairs professionals
- Vigilance and PMS managers
- Clinical evaluation/investigation specialists
- Project managers

Reviews

★★★★★

I thought it covered a vast area in great detail and was evenly paced. Both speakers were excellent and extremely helpful during question time

Andrea Beasley
Senior Manager, Global Trade Compliance and Logistics
CooperVision Manufacturing Ltd
Oct 9 2023

★★★★★

Everything good. Even though all different countries' people took this course, but the speakers considered many details for them until end of course. I am really thankful that you gave us opportunities to have much time and appreciated with you.

Heejun Hong
Student
Dongguk University, Republic of Korea
Sep 27 2022

★★★★☆

[I liked] the speed, the content. The workshops: had some nice discussion in the breakout room with participants that joined with a microphone (and camara). Clarification on PMCF.

Jennie Mettivier Meijer
Project Manager Medical Devices & Quality Systems
BioTop Medical
Sep 27 2022

★★★★☆

Both speakers are excellent communicators and pleasant persons. Slides were clear.

Teresa Lopes
Manager Medical Devices
BioTop Medical
Sep 27 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:



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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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