MEDILINK

PROFESSIONAL DEVELOPMENT

// MEDICAL DEVICE REGULATION TRANSITION

// MONDAY 18 MARCH 2024

// PENNINE HEALTHCARE, DERBY

COURSE OVERVIEW

Manufacturers who have not made a decision to transition their medical devices to meet the requirements of the new EU regulations and have not taken the relevant steps before the 26 May 2024 deadline, will not be legally able to continue selling their products into the European Union (and potentially other markets including the UK.

Delivered by IMed Consultancy, this interactive training course will prepare you for understanding whether it may be right for your business to make the decision to (re)certify your medical devices for sale in the EU. The workshop is focussed on existing manufacturers of medical devices, who currently CE mark their products and will give you practical insights to support your business in making this important decision.

TARGET AUDIENCE

- CEOs
- Managing Directors
- Business Leaders
- Regulatory Affairs
- Quality Assurance
- Design Assurance
- Design and Development
- Engineers
- Any other staff with responsibility or involvement with product compliance

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// COURSE PROGRAMME

TIME	EVENT
09:30	Registration & Refreshments
10:00	Welcome & Introductions
10:10	Considering EU Medical Device Regulation Transition - Key differences between current MDD and the new EU MDR - Transition timeline and requirements
11:15	Refreshments & breakout sessions - Maintaining CE marking - Key business & commercial benefits and drawbacks of transitioning - Potential alternative certification options available in the UK and markets outside of the EU
13:00	Lunch & Networking

LEARNING OUTCOMES

- Provide the tools to help your business decide whether or not it is right for your business to make the decision to (re)certify your medical devices for sale in the EU
- Understanding of the requirements, activities and deadlines needed to successfully transition products to the EU Medical Device Regulations.

COSTS

Member cost: £150
Non-Member cost: £215

All prices are excluding VAT

Course price includes, refreshments, lunch and on-site car parking.

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// COURSE PROGRAMME

TIME	EVENT
13:45	**EU MDR Quality Management System Updates Required** - Key considerations necessary to meet compliance requirements in your company QMS - Tips on what is necessary and how to meet notified body expectations
14:45	Break & refreshments
15:00	**EU MDR Notified Body Selection and Application** - Practical requirements needed to apply to and contract with a notified body - Learnings from prior applications, potential pitfalls to consider - Changes of notified body as part of transition from exiting certification to EU MDR
16:15	Q&A & Summary
16:30	Close

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// SPEAKER PROFILE

// TIM BUBB

// TECHNICAL DIRECTOR, IMED CONSULTANCY

With more than ten years' experience in QA/RA roles, Tim has breadth and depth of knowledge across the regulatory, engineering, clinical, design and development, and quality assurance disciplines. Tim has a passion for empowering innovation in medical devices, and brings insight and pragmatism to projects bringing complex lifesaving and life enhancing products to market.

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// SPEAKER PROFILE

// AL MILLS

// BUSINESS DEVELOPMENT DIRECTOR, IMED CONSULTANCY

After starting her Career in Sales in the City, as a lowly Finance Rep, Al soon climbed the ranks to National Sales & Marketing Director with a leading Premium Finance Business. After spending 15 years as a Sales & Business Growth Coach and Mentor, Al was keen to be part of a permanent team again and was looking for a company with major growth plans in a sector with a meaningful impact on others. Al now supports the business with zest and expertise leading the Sales, Marketing and Development activities and focusing on client and partner relationships development.
'I'm thrilled to be in such an exciting industry at a time so rich in change and innovation. I really believe that companies like IMed can make a valuable contribution to healthcare at a time of unprecedented social unity for good international health. I was impressed by IMed and the Team's skill at combining both commercial and patient focus, against a backdrop of high QA/RA standards.'

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