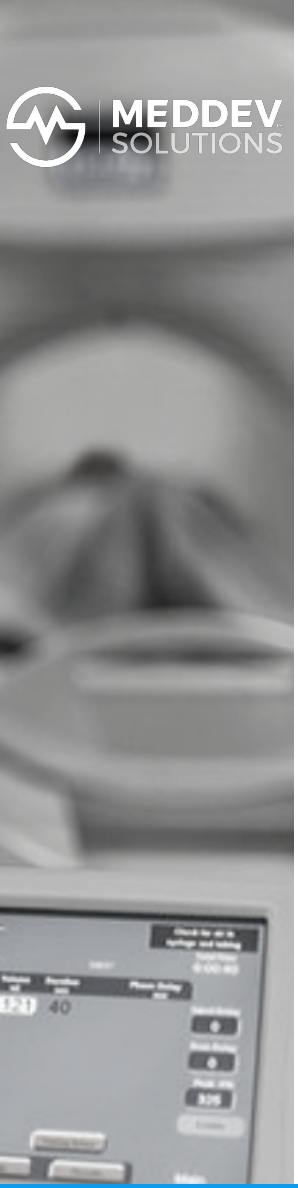


COURSE OVERVIEW

2-DAY MEDICAL DEVICE REGULATION (MDR) TRAINING (EU) 2017/745

If you sell medical devices into Europe, you probably already know that CE marking is changing. But do you fully understand what the impact is for your business, products and your supply chain?

If you are not 100% sure or would like to refresh your knowledge, this training course is most definitely for you. Our expert trainers will take you through the regulation, not just from an industry perspective, but also from a Notified Body perspective, which means you get the benefit of understanding what both sides are looking for.

All of our courses are structured to optimise your learning using accelerated learning techniques and practical exercises to consolidate understanding. You will be actively engaged with emphasis on questions and group discussions to further assist your understanding.

Learning Objectives

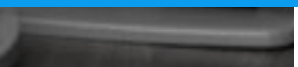
- Gain a solid understanding of the regulation and the changes
- Know what you need to do for your business and products to meet the regulation
- Practice and discuss the concepts in a collaborative environment

Agenda Overview

Day 1:
8:30am - Registration
9:00am - Introduction to the MDR
10:45am - Break
11:00am - Medical Devices
12:30pm - Lunch
13:00pm - Manufacturer's Articles
14:45pm - Break
15:00pm - Classification
16:30pm - Questions / End of Day

Day 2:
9:00am - Routes to conformity
10:45am - Break
11:00am - Safety & Performance Requirements
12:30pm - Lunch
13:00pm - PMS, PSUR, Vigilance & Clinical
14:45pm - Break
15:00pm - .PMS, PSUR, Vigilance & Clinical
16:00pm - Questions / End of Day 2

THIS COURSE INCLUDES THE MEDDEV SOLUTIONS MDR GUIDEBOOK



Book today at meddevsolutions.co.uk/training

www.meddevsolutions.co.uk
River House, Home Avenue, Newry, BT34 2DL

"AN ESSENTIAL TOOL FOR ANY DEVICE MANUFACTURE SELLING INTO EUROPE"

MEDDEV SOLUTIONS

The MDR Guidebook

This course comes with your own copy of the Meddev Solutions MDR Guidebook, the ultimate MDR reference and tool-book, intended to be your companion to refer to time and time again.

It contains a number of useful tools that will help you guide through the MDR, such as:

- Device classification guidance
- QMS requirements tables
- Technical Documentation requirements
- Clinical Requirements tables
- General Safety & Performance Checklists
- Annex & Article guide

What you will receive:

- A copy of the course notes
- Indexed copy of the MDR
- Your own copy of the Meddev Solutions MDR Guidebook
- A Meddev Solutions Training course certificate
- Lunch and refreshments provided both days

Who should attend?

The content will have great value to individuals who are involved in any aspect of implementing or maintaining a QMS.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers

Further information:

This course can be delivered as an on-site training session tailored to your company's requirements.

Find out more:

Email: info@meddevsolutions.co.uk

Book online at meddevsolutions.co.uk/training

MED TECH REVIEW TOP 10 MEDICAL DEVICE MANUFACTURING CONSULTING/SERVICE COMPANIES IN UK - 2020

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