# MEDICAL DEVICE REGULATION (MDR) INC. GUIDEBOOK

## 2-day course

Course Outline

Meddev Solutions Limited are delighted to offer a 2-day overview and application of the Medical Device Regulation. 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, then this course is most definitely for you. Our expert trainers can 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.

This course is structured to optimize your learning using accelerated learning techniques and exercises to consolidate understanding. Candidates will be actively engaged with emphasis on questions and group discussions to further assist their understanding.

### Purpose built teaching facility


This course is hosted at 3form Design:
*The Chapel, 58 London Street, Whitchurch, RG28 7LN*

### Learning objectives include:

- Your questions answered!
- To have 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 some of the concepts in a collaborative environment
- Discuss concepts to further your understanding
- Have some fun whilst learning the regulation (a rare concept!)

### Course overview:

- The story so far – where we are at and why we have had to make changes
- Medical devices covered by the regulation (these have changed!)
- Classification of your devices
- How to achieve conformity through selection of appropriate Annexes
- What your importers, distributors and authorized representatives need to do
- Clinical Data Evaluation
- Technical File documentation
- What labeling is required on your devices (including UDI)
- Risk Management Files and how the process works
- Vigilance activities
- Post Market Surveillance
- What reporting is required under the new regulation

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## MDR Guidebook:

The Meddev Solutions MDR Guidebook is 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


## 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 y Managers
- Manufacturing Engineers
- Regulatory professionals

## Our Tutors:

Our expert tutors have a wide range of global industry experience specialising in Medical Devices in all classes covering active and non-active, sterile devices and software.

Working both within industry and on behalf of Notified Bodies we can provide you with solutions that meet both your requirements and those of the regulators.

## Course Timetable:

| | **Morning session** | | | Lunch | **Afternoon session** | | |
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| Day 1 | Introduction to MDR | Tea | Medical devices | | Manufacturer's Articles | Tea | Classification |
| Day 2 | Routes to conformity | | Risk Safety and performance requirements | | PMS, PSUR, Vigilance and Clinical | | Test of understanding |

Upon successful completion of the course, each delegate will receive a Meddev Training course certificate, detailed course notes, MDR and the Meddev Solutions MDR Guidebook (RRP £225)

**Find out more:**
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