IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (EU) 2017/746

2-day course

Course Outline

Meddev Solutions Limited are delighted to offer an In Vitro Diagnostic Medical Devices Course. This course focuses on the application of the key principles and practices required for the new In Vitro Diagnostic Medical Devices Regulation.

The course is designed to enhance the level of understanding for those actively engaged with IVDs and placing them on the market. Our expert tutors give you the necessary skills to perform the changes required to meet the new regulation.

By the end of this practical and interactive course, delegates will understand the changes and new requirements of the IVDR, they will be able to plan and conduct the changes and upgrades required to the quality management system and the technical files for in vitro devices.

Learning objectives include:

- Requirements for manufacturers and economic operators
- Classification and recognition of devices
- Risk analysis and trending
- Safety and performance requirements
- Routes to conformity
- EUDAMED
- The Unique Device Identifier (UDI)
- Performance evaluation
- Post-market surveillance and associated reports

Upon successful completion of the course, each delegate will receive a Meddev Training course certificate and detailed course notes.

Purpose built teaching facility

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

Who should attend?

The content will have great value to individuals who are involved in any aspect of implementing or maintaining regulatory compliance with the new Regulation.

- Quality assurance professionals
- Quality Engineers
- Research and design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Find out more:
Call: +44 (0)28 3005 0613
Email: info@meddevsolutions.co.uk
www.meddevsolutions.co.uk

MEDDEV SOLUTIONS
www.meddevsolutions.co.uk
30 Monaghan Street, Newry, BT35 6AA