In Vitro Diagnostic Regulation (EU) 2017/746

The IVDR will replace the current EU Directive on in vitro diagnostic medical devices (98/79/EC) and will be effective in all EU member and EFTA states.

This 2 day training course focuses on the application of the key principles and practices required for the new In Vitro Diagnostic Medical Devices Regulation.

You will gain an appreciation for the changes and new requirements of the IVDR and take away practical skills and guidance on how to transition to the new regulation that you can implement into your organisation immediately.

"I have been attending Medical Device trainings for 20 years and I can truly say this was the best course I have ever taken.

The trainers are subject matter experts who were able to effectively communicate and explain core and technical concepts while keeping the audience engaged. The course materials are well designed with an abundance of examples and color coding for navigation ease. I highly recommend this course."

Upon successful completion of the course you will receive a Meddev Solutions course certificate.

Find out more:
info@meddevsolutions.co.uk
www.meddevsolutions.co.uk/training

Course Content

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

Who should attend?

This course will enhance the level of understanding for those actively engaged with IVDs and placing them on the market.

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

Available as
In-House • Public • Virtual

Bespoke
Our experts can customise this course purely for your business needs.