

# TRAINING COURSES

## Changes implemented by MDR 2017/746 affecting IVD Manufacturers



This half day course is designed to give delegates an understanding of the key changes associated with IVDs in Europe, including:

- Quality management systems
- Scope of regulated IVDs
- Key compliance dates
- Classification and conformity
- Assessment requirements
- Person responsible for regulatory compliance
- Identification and traceability
- Performance evaluation requirements
- Vigilance and market surveillance

The course is delivered by our Director of Quality and Regulatory Affairs, Dr Edward Staunton, an IRCA Certified Lead Auditor who has trained numerous internal auditors, notified body auditors and lead auditors.

Personalised feedback is available for evaluation of training effectiveness if requested.

This course is available at your offices/facilities by arrangement.

**For further details or to arrange a quote  
for training contact:**

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