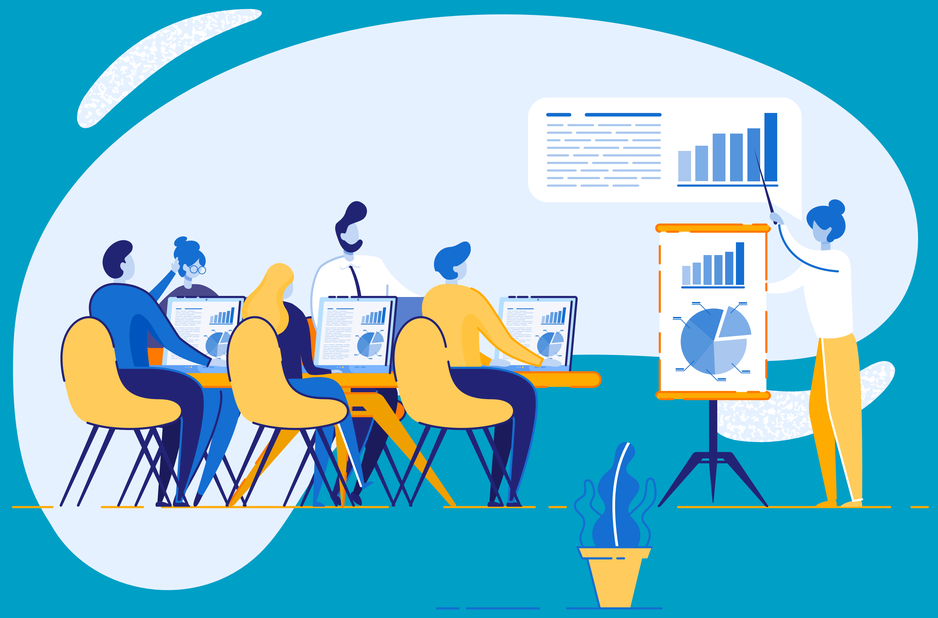
TRAINING COURSES

Changes implemented by MDR 2017/745 affecting Medical Device Manufacturers



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

- **Legislative and operational Basis of CE Marking**
- **New Classification and conformity routes**
- **New Safety and Performance requirements**
- **Updated requirements for Technical Documentation (incl. UDI and Clinical Evaluation)**
- **EUDAMED and Statutory Reporting**
- **Health care institute in house manufacturing**
- **Responsible person**
- **Identification within the supply chain**
- **Electronically Programmed Systems**
- **Implant Card**

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:

Email Dr Edward Staunton
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Kinesys Consulting Ltd