Clinical Data Evaluation for Medical Devices

If you are actively involved with the creation and maintenance of clinical evaluation files, this 2 day course will enhance your level of understanding on the application of key methods to ensure that the requirements of the new MDR are met.

Our expert tutors will give you the necessary skills to ensure all the requirements of the law are met and provide an insight into how the clinical evaluation is integrated with risk management, post-market surveillance, the periodic safety update report, the summary of safety and clinical performance, trending and the CAPA system.

We perform clinical data evaluation reviews for notified bodies and can offer you insights into the common pitfalls. Plus you will get an understanding of what the requirements are really asking for.

"The CER course was great in confirming my current knowledge of Clinical Evaluation and expanding on this with the requirements for MDR. Rod was a great tutor full of knowledge, advice and enthusiasm for a subject which can be pretty dry!"

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

- PMCF
- Planning
- Data analysis
- Data appraisal
- Data identification
- Regulation intentions
- Clinical investigations
- Post-Market Surveillance
- Practical use of MEDDEV 2.7.1 rev4
- Methods of real-world literature review

Who should attend?

This course has excellent value for anyone involved in implementing or maintaining clinical evaluation files.

- 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.