CLINICAL EVALUATION COURSE

2-day course

Course Outline

Meddev Solutions Limited are delighted to offer a 2-day Clinical Evaluation Course. This course focuses on the application of key methods to ensure that the requirements of the new Medical Device Regulation are met.

This course is designed to enhance the level of understanding for those actively involved with the creation and maintenance of clinical evaluation files. Our expert tutors give you the necessary skills to ensure all the requirements of the law are met and 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.

By the end of this practical and interactive course, delegates are able to understand the theory of planning, conducting and producing a clinical evaluation report which will meet the requirements of the law.

Learning objectives include:

- Practical use of MEDDEV 2.7.1 rev4
- The limits of MEDDEV 2.7.1 rev4
- The additional requirements for clinical evaluation imposed by the Medical Device Regulation
- Methods of real-world literature review
- Techniques for establishing that sufficient Information is presented in a clinical evaluation report
- Post-market requirements
- How to address continuous updates of a clinical evaluation report in a practical way
- Conducting post-market clinical follow-up
- Where clinical evaluation fits in the legal framework

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 a clinical evaluation.

- Quality assurance professionals
- Quality Engineers
- Research and design Engineers
- Clinicians
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Find out more:
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