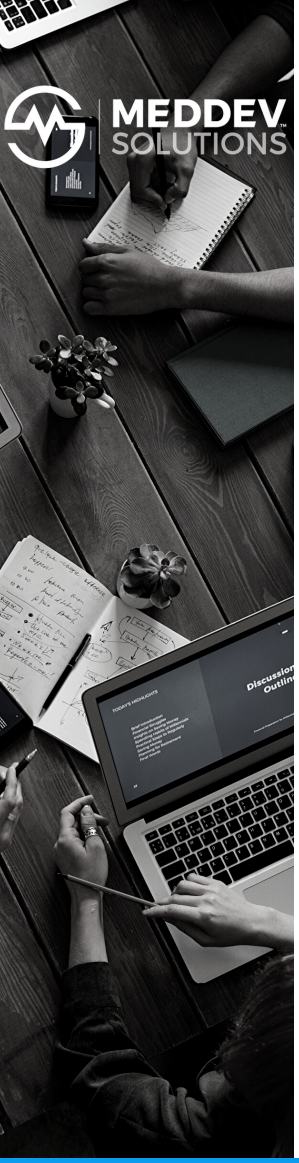

MEDDEV SOLUTIONS

COURSE OVERVIEW

2-DAY CLINICAL EVALUATION TRAINING FOR MEDICAL DEVICES

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

We 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 course you will be able to understand the theory of planning, conducting and producing a clinical evaluation report which will meet the requirements of the law.

All of our courses are structured to optimise your learning using accelerated learning techniques and practical exercises to consolidate understanding. You will be actively engaged with emphasis on questions and group discussions to further assist your understanding.

Learning Objectives

- Understand the additional requirements for clinical evaluation imposed by the Medical Device Regulation 2017/745
- Know how to address continuous updates of a clinical evaluation report in a practical way
- Understand where clinical evaluation fits in the legal framework
- Gain effective techniques for establishing that sufficient Information is presented in a clinical evaluation report

CONTACT OUR EXPERT TEAM TO SEE HOW WE CAN BE HELPING YOU AND YOUR BUSINESS

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www.meddevsolutions.co.uk
River House, Home Avenue, Newry, BT34 2DL

"AN EXCELLENT COURSE DELIVERED IN A FUN WAY WITH PLENTY OF EXAMPLES"

Agenda Overview

Day 1:
8:30am - Registration
9:00am - Regulation intentions
10:45am - Break
11:00am - Planning
12:30pm - Lunch
13:00pm - Data identification
14:45pm - Break
15:00pm - Data appraisal
16:30pm - Questions / End of Day 1

Day 2:
9:00am - Data analysis
10:45am - Break
11:00am - Clinical investigation
12:30pm - Lunch
13:00pm - PMCF
14:45pm - Break
15:00pm - Post-market surveillance
16:00pm - Questions / End of Day 2

What you will receive

- A copy of the course notes
- A Meddev Solutions Training course certificate
- Lunch and refreshments provided both days

Who should attend?

The content will have great value to individuals who are involved in any aspect of implementing or maintaining a clinical evaluation file.

- Quality Assurance professionals
- Quality Engineers
- Research and Design Engineers
- Clinicians
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Further information

This course can be delivered as an on-site training session tailored to your company's requirements.

Find out more:

Email: info@meddevsolutions.co.uk
Book online at meddevsolutions.co.uk/training

MED TECH AWARD TOP 10 MEDICAL DEVICE MANUFACTURING CONSULTING/SERVICE COMPANIES IN UK - 2020

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