Clinical Evaluation for Medical Devices

At a glance

- 2-days of interactive training
- Instructor-led virtual classroom
- Certificate of completion
- Q&A session
- Copies of the slides and handouts
- On-site training available on request

Who should attend?

This training course is recommended for those involved in implementing or maintaining a clinical evaluation file.

- Regulatory Affairs Professionals
- Research and Design Engineers
- Quality Managers
- Quality Engineers
- Manufacturing Engineers
- Internal Auditors

COURSE OVERVIEW

Our industry leading experts will give you the necessary skills to ensure all the requirements of the law are met and provide an insight into how 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.

Our team performs clinical evaluation reviews for notified bodies, allowing us to give you insights into the common pitfalls.

100%
Achieved The Learning Objectives

Trusted Training Provider

97%
Recommend Our Virtual Classrooms

LEARNING OBJECTIVES

- Understand the additional requirements for clinical evaluation imposed by the MDR 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 CER
- Gain a solid understanding of what your QMS needs to cover

MEDDEV SOLUTIONS
A Trinzo Company

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"I can't fault this CER course, the delivery was excellent, as was the content and especially the trainer Rod. He clearly knows his stuff and that's what makes all the difference. This virtual training was the best I've ever done and I could find no fault whatsoever. I'd definitely recommend this course to colleagues."

"I really enjoyed the course, so many things finally clicked into place for me and I now feel much more confident in writing CER's. Worth every penny. Thank you so much!."

"The 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!"

COURSE AGENDA

1

Module One
- What is Clinical Evaluation?
- Definitions and Key Terminology
- Clinical Evaluation and the MDR
- What has changed under the MDR?
- Post Market Clinical Follow-up (PMCF)

2

Module Two
- Guidance for Clinical Evaluation
- Links to other processes
- Clinical Data Evaluation

3

Module Three
- Clinical Evaluation Plan
- Plan Objectives, Sources of Data & Claims
- ERs/GSPRs

4

Module Four
- Literature Search & Databases
- State of the Art
- Getting your questions right
- Clinical Evaluation Competencies

5

Module Five
- Identification of Data
- Appraisal & Analysis
- Risk of Bias
- Meta Analysis
- Clinical Evaluation Report

6

Module Six
- Clinical Investigation
- Ethics & Consent
- Best Practice
- The NB Perspective

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