MDR Clinical Training for Manufacturers

AIM

Clinical Evaluation Review Training for Manufacturers: lesson learnt and the do's and don't's based on non-conformities examples.

This training is directed towards manufacturers/ participants who already have experience in creating CER and/or are involved in CE submission. Therefore, the training will focus more on real cases examples and less on introduction or citing regulations.

The topics are presented by MDR experts of designated notified bodies.

The content was elaborated by MDR experts of 3 notified bodies, namely **BSI, CeCertiso, Dekra**

This training is intended for participants who are members of a manufacturer's clinical team and have experience in creating CERs and/or are involved in CE submission. Therefore, can you consider this expertise for registrations.

WHEN ?

Wednesday
2025, November 20th
09:00-13:00 CET

WHERE ?

Remotely

LANGUAGE

English

PARTICIPANTS

limited to 50 organisations with up to 2 connections of staff member

Prerequisite : Expert members of a Manufacturer's clinical team

Priority for SMEs registration (25 places reserved) until September 26th

In case we reach the limit, an additional session will be programmed

PROGRAM

8.30 to 8.45 Welcome and logistic information

8.45 to 9.35
Clinical evaluation routes
In this session, we will explore the different clinical evaluation routes (Equivalence, Article 61.10, Clinical Investigation, Sufficient Clinical Evidence, etc) available to the manufacturers and discuss the common non-conformities identified by the NBs.

by Ágnes Horvath (CE Certiso)

9.35 to 10.25
How to build sufficient clinical evidence?
In this session we will explore the interrelationship between SOTA, benefit-risk analysis, and safety and performance criteria and discuss the common non-conformities identified by the notified body during their assessment.

by Nunung Nur Rahmah (Dekra NL)

≈ Morning break ≈

10.40 to 11.30
Post market surveillance and PMCF
In this session, we will explore the interrelationship between PMS and Clinical Evaluation and discuss the common non-conformities identified by the notified body during their assessment of PMS plans, Periodic Safety Update Reports (PSUR) and PMCF plans and reports.

by Breda Kearney (BSI)

11.30 to 12.00 Q&A session

12.00 to 12.30 Closing session

REGISTRATION FEES

550 Euros / organisation
for up to 2 persons max.

Reduction for EU-SMEs
(SME EU assessment report to be sent)
275 Euros / organisation
for up to 2 persons max.

The fee includes
- the release of a Certificate of attendance (delivered on request) and
- the presentations in pdf format which will be sent to the participants after the training

REGISTRATION

Fulfill the form accessible at the address :
www.team-nb.org/ManufacturerTraining

INVOICE

An invoice will be sent to companies registered on the website after the deadline for priority registration of SMEs.

PAYMENT

The receipt of the payment on the basis of the invoice sent will confirm the registration of the participant.