MDR CLINICAL DATA training by

TEAM NB

AIM

This training is aimed to help notified bodies deal with new MDR clinical requirements in their assessments.

Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favored during the 4 presentations and during the cases studies sessions.

The following topics will be covered: general requirements of the MDR, NBs role in reviewing clinical data, review of the key elements from guidances and PMCF evaluation requirements.

WHEN ?

- June 1st & 2nd; 2021
  13.30 — 17.30 CET
- June 28th & 29th; 2021
  13.30 — 17.30 CET
- September 6th & 7th; 2021
  13.30 — 17.30 CET
- **January 2022,**
  19th & 20th;
  in 2 afternoons
  13.30 — 17.30 CET

WHERE ?

Remotely

LANGUAGE

EnglishThe trainings are organised in groups of maximum 20 persons to ensure a good level of

PROGRAM

1st afternoon

13.30 –13.45 Welcoming session

13.45 to 14.45
Requirements of MDR in general
by* Richard Holborow *(BSI)

- Clinical risk versus regulatory classification – Impact on the amount of clinical data
- Clinical Data Requirements for non-implantable Class IIa and IIb devices
- Clinical Data Requirements for implantable and Class III devices
- Common issues on statistics

14.45 to 15.45
Role of NB in reviewing clinical data
by* Matthias Fink *(TÜV SÜD)

- Assessment requirements related to clinical processes
- Sufficient clinical data: Legacy devices versus new MDR Applications
- Equivalence

15.45 to 16.00 — Break

16.00 to 17.00
Key messages of guidances, common specifications and harmonized standards
by Christoph Ziskoven (TÜV Rheinland)

- Clinical evaluation: A current overview of best practices for scientific methods and documentation under MDR

2nd afternoon

13.30 to 14.30
Post market requirements evaluation
by Yvonne Ndefo (NSAI)

- PMCF Requirements: Specific PMCF according to Annex XIV Part B deemed not necessary

14.30 to 14.45 — Break

14.45 to 16.45 Case studies

- in 3 rotating sub-groups (exchanges — presentation - adjustments and harmonisation)

16.45 to 17.15 Closing session

- Summary of main elements
- Feedback and suggestions

REGISTRATION FEE

- 1500 Euros / person for non members
- 250 Euros / person, for Team-NB members **only**

The fee includes the participation to an on-line MCQ to prove Continuing Professional Development. Depending on results a certificate or an attestation will be delivered.

REGISTRATION

Send an email to assistant@team-nb.org with participant information (name & email)

PAIEMENT

The receipt of the paiement will cofnirm the registration of the participant.
Team-NB Account - IBAN n°:
BE09 340 1 5174 8757
SWIFT code : BBRUBEBB

INVOICE

The sent of an invoice will be done (please mention your VAT number).