PMS

training by

AIM

This training aims to help notified bodies to implement best practices in their Post Market Surveillance according to the new regulations.

This will be supported in workshops where case studies will be discussed from a practical point of view focused on the different practices put in place and the difficulties encountered in order to harmonize the ways of proceeding and further improve the practices thanks to these exchanges.

WHEN ?

2 Sessions:
October 26th
09.00—17.00 CET
November 23rd
09.00—17.00 CET

3rd session :

Soon scheluded

HOW / WHERE ?

Remotely

LANGUAGE

English

The training is organized in groups of maximum 20 persons to ensure a good level of exchange.

PROGRAM

9.00 to 09.30 Welcome of participants

9.30 to 10.45 PMS overview of MDR requirements (including PMS plan with aim to find harmonisation)

MDR requires the lifecycle approach of all medical devices. Post-market surveillance functions as an umbrella for all activities after placing device on the market. This session aims at the common understanding of PMS requirements of the MDR, including the procedural aspects and the planning of the device specific activities.

by Agnes Horvath (CERTISO)

≈ Morning break ≈

11.00 to 12.15 PSUR & PMS reports

The PSUR and PMS Report Session will give Participants the knowledge and confidence to understand what is expected in the manufacturer's report, focusing on the required information that aligns with the MDCG Guidance for PSURs.

by Richard Holborow (BSI)

≈ Lunch ≈

13.30 to 14.45 Impact of PMS activities on TD

Post market activities are required through the device lifecycle. This session aims to identify and understand the impact of the PMS activities on the device Technical Documentation, including key elements to be updated, at which frequency and who is to be notified of them.

by Florianne Torset-Bonfillou (GMED)

≈ Afternoon break ≈

15.00 to 16.30 Case studies

in 3 rotating sub-groups (exchanges - presentation - adjustments and harmonisation) on 3 differents cases

16.30 to 17.00 Closing session

- Summary of main elements & Feedbacks

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).