

RISK MANAGEMENT OF MEDICAL DEVICES – SPECIFICITIES OF IVDs TRAINING FACTSHEET



Speaker:
Dr Lydie Moreau
Project Associate

Date: June 21st & 22nd 2023, Online
Duration: 6 hours, 1:00 – 4:00 PM CEST
7:00 – 10:00 AM EDT

TRAINING OBJECTIVES:

- Dive into the main standard, key theoretical aspects and methodologies for risk management
- Use the main risk management tools (PHA, FMEA)
- Build a risk analysis through the example of a medical device
- Know how to build a risk management file together with the SOP on risk management

TRAINING CONTENT:

- Overview of theoretical aspects of risk management
- Exercise: Filling a PHA for a medical device example; discussion around IVD specificities Theory on FMEA methodology
- Exercise: Filling the risk analysis matrix using the FMEA methodology for a medical device example; discussion around IVD specificities
- Theory on risk acceptance criteria and mitigation measures
- Exercise: Completing the risk analysis matrix with mitigation measures for the medical device example • SOP and Risk management file (plan / report)

TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive a training certificate)

PRICE:

EUR 625 incl. course material and certificate

Registration: education-veranex.talentlms.com

Contact: training@medidee.com