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# Risk Management of medical devices – specificities of IVDs

Duration**: 8 hours | 2 x 1:00 – 5:00 PM CEST | 2 x 7:00 – 11:00 AM EDT**
Date**: May 15-16th, Online**
Speaker**: Dr Lydie Moreau**

## Training objectives:

- Be able to implement the requirements of ISO 14971 in combination with the IVD Regulation ((EU) 2017/746, IVDR) for in vitro diagnostic medical devices.
- Be able to integrate the requirements of ISO 14971 and of the IVDR in the Quality Management System.
- Be able to plan, implement and document risk management activities, in a practical way using a systematic and consistent approach.
- Be able to conduct risk analyses for in vitro diagnostic medical devices in accordance with ISO 14971.

## Training content:

- Regulatory framework (EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020 and IVDR)
- Implementation of ISO 14971 and of the IVDR into the Quality Management System
- Risks Management techniques (Preliminary Hazard Analysis; Fault Tree Analysis; Failure Mode Effect (and Criticality) Analysis)
- Harms that are specific to IVDs
- Methods for the identification of hazards
- Risk analysis process, including
    - Identification of hazards
    - Risk estimation
    - Identification of risk control measures
    - Assessment of residual risks
    - Evaluation of the overall residual risk
- Benefit-risk determination
- Review of risk management
- Post-market surveillance and risk management
- Compiling the Risk Management File, as part of the IVDR Technical Documentation
- Hands on exercise on example

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## Prerequisite:

Have a good understanding of the IVD development, manufacturing or use.

## Training format:

- Presentations with interactive discussions
- Group and individual exercises
- End of training assessment

## To whom it is addressed:

- Manufacturers of in vitro diagnostic medical devices
- Employee participating to Risk Management of IVDs
- Employee conducting development and manufacturing of IVDs
- Safety officers / PRRC as per Article 15 of the IVDR
- Employee working in the field of IVDs Quality Management
- Employee in Regulatory Affairs in charge of assessing the compliance of the Technical Documentation with IVDR
- EU Representatives

## Price:

EUR 775 incl. course material and certificate

Registration: education-veranex.talentlms.com
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