



TRAINING

EN ISO 13485:2016 – Quality Management System (QMS)

Duration: **6 hours** | 2 x 2:00 – 5:00 PM CEST | 2 x 8:00 – 11:00 AM EDT

Date: **April 4-5th 2023, Online**

Speaker: **Dr Lydie Moreau**

Training objectives:

- Understand the QMS principles and the links between the different QMS processes
- Define a QMS architecture
- Establish a roll-out plan for leading the implementation of a QMS
- Dive into the details of each process during dedicated sections

Training content:

- Introduction to ISO 13485:2016: why implementing a QMS, QMS benefits, the certification process
- Implementation Phases of the ISO 13485
- Visit of the architecture of a QMS
- Diving into the requirements of the sections on Management responsibility, Resource management, Product realization and Measurement, analysis and improvement
- Building and reviewing concrete examples of key QMS documents (quality manual, standard operating procedures...)

Training format:

- Presentations with interactive discussions through several exercises
- End of training assessment

Price:

- EUR 625 incl. course material and certificate

Registration: training-veranex.talentlms.com

Contact: training@medidee.com

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