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Impacts of In Vitro Diagnostic Regulation 2017/746 on Quality Management System

Duration: **4 hours | 1:00 – 5:00 PM CET**
Date: **February 9th 2023, Online**
Speaker: **Dr Simone Musiu**

Training objectives:

The objective of this training is to provide a general understanding of the European legislation on In Vitro Diagnostic Medical Devices, be familiar with the typical terminology, and understand which are the implications of the Regulation on In Vitro Diagnostic Medical Devices and the Quality Management System (QMS).

Training content:

By attending this training, you will receive in-depth knowledge on the following topics:

- Introduction to the new the European Regulation 2017/746
- Introduction to the QMS and ISO 13485
- Qualification and Classification of an IVD device
- Conformity Assessment route and market pathway
- Transitional provisions
- QMS requirements
- Notified bodies status

Training format:

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

Price:

EUR 415 incl. course material and certificate

Registration: education-veranex.talentlms.com
Contact: training@medidee.com