



TRAINING

Substance based device regulation

Duration: **4 hours** | 1:00 – 5:00 PM CET

Date: **February 23rd 2023, online**

Speaker: **Dr Cornelia List**

Training objectives:

The goal of this training is to provide participants with an introduction of substance-based devices and its associated challenges under the EU Medical Devices Regulation (Regulation (EU) 2017/745). The training is aimed at anyone who seek to enhance their knowledge and competences within this field.

Training content:

By attending this training, you will receive an introduction on what is a substance-based product and how it qualified as such. After a general introduction of substance-based devices and its requirements to be considered for a regulatory pathway the focus will lie on substance-based medical devices falling under rule 21.

- Regular regulatory pathway of substance-based products
- Qualification of a substance-based product
- Risk classification (in case of a substance-based medical device)
- Additional requirements
- Examples
- Exercise

Training format:

- Presentations with interactive discussions
- End of training assessment

Price:

- EUR 415 incl. course material and certificate

Registration: education-veranex.talentlms.com

Contact: training@medidee.com