Medidee Services SA
Chemin de Rovéréaz 5
1012 Lausanne | Switzerland

PHONE I +41 21 311 20 59
EMAIL I training@medidee.com
WEB I www.medidee.com

Market Access and Management of Clinical Activities in US

Duration: **3.5 hours | 1:30 – 5:00 PM CET**
Date: **January 19th 2023, Online**
Speaker: **Julianne Bobela**

Training objectives:

The goal of this training is providing participants with an extended understanding of FDA requirements for studies conducted inside the US, outside the US (OUS) and for multi-site investigations conducted both inside the US and OUS. The course will enable you to link key regulatory and quality considerations when conducting clinical investigations on medical devices. The training is aimed at any employee involved in clinical activities who seek to enhance their knowledge and competences within this field.

Prerequisite:

To attend the course, you are expected to have attended the ISO 14155 training and be trained on ISO 14155:2020 and on the European Medical Device Regulation 2017/745 (MDR, Chapter VI).

Training content:

- Regulatory Framework for medical device clinical trials
- Clinical studies/Investigational Device Exemptions (IDE)
- Bioresearch Monitoring Program (BIMO) Compliance Programs - Inspecting clinical trial files for Medical Devices in US
- Practical examples

Training format:

- Presentations with interactive discussions
- End of training assessment

Price:

- CHF 350 incl. course material and certificate

Contact & registration: training@medidee.com