medídee®

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

Performance Evaluation & In Vitro Diagnostic Devices (IVDs)

Duration**: 4 hours | 2:00 – 6:00 PM CET**
Date**: January 31st 2023, Online**
Speaker**: Dr Julianne Bobela**

Training objectives:

Once a device is used for diagnostic purposes on human specimens, the EU Competent Authorities expect clinical evidence, i.e. de clinical data and performance evaluation results, to support the safe and effective use of the device, as intended by its manufacturer and as indicated in the labeling, package insert and promotional material. A performance evaluation is the "assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device". A performance evaluation is conducted according to an established device-specific plan, the Performance Evaluation Plan (PEP), and the summative assessment of the identified clinical evidence is consolidated in the Performance Evaluation Report (PER).

The objective of this training is to provide a thorough understanding of what a performance evaluation is and what it consists of, and to provide information on how to strategize the collection of relevant clinical evidence on an IVD medical device.

Training content:

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

- Requirements relevant to a performance evaluation
- How to establish a performance evaluation plan
- What scientific validity is and how it is substantiated
- What data need to be provided to demonstrate analytical performance
- When clinical performance needs to be demonstrated and how clinical performance data is collected
- What information is provided in the performance evaluation report

Training format:

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

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Price:

EUR 415 incl. course material and certificate

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