Veranex

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IN VITRO DIAGNOSTIC (IVD) FOR PHARMA AND BIOTECH: In house devices (LDT)/CDx in Europe

TRAINING FACTSHEET

Speaker:
Dr Silvia Anghel
Head of IVD Group

Date: May 2nd 2024, Online
Duration: 2 hours | 3:00 – 5:00 PM CEST
9:00 – 11:00 AM EST

TRAINING OBJECTIVES:

The training will clarify some of the interfaces that have been created between medicinal products oriented clinical trials and the requirements for assays used in the context of clinical trials by the recent application of the European In Vitro Diagnostic Regulation (EU 2017/746).
The training is targeting Regulatory and Clinical Affairs managers from Pharmaceutical companies that oversee the setting clinical trials, management of assays during clinical trials and/or ensure the post-market accessibility of patients to companion diagnostic tests as well as Medical Laboratory managers that are acting as Central Laboratory during clinical trials.
The objectives of the training are:

- Understand EU IVD Regulation (EU 2017/746 EC, IVDR)
- Understand how the clinical trials will be impacted by the requirements of IVD Regulation.
- Understand the options for ensuring the availability of a test device on the EU market.

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TRAINING CONTENT:

- EU Regulatory Framework for In Vitro Diagnostic (IVD) devices
- Qualification and Classification as In Vitro Diagnostic device
- Go to Market process for CE-marked device versus In house developed test (LDT)
- Pro & Cons CE-marked devices versus LDTs
- Requirements of assays used during clinical trials

TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive a training certificate)

PRICE:

EUR 225 incl. course material and certificate

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