Veranex Switzerland SA
Chemin de Rovéréaz 5
1012 Lausanne, Switzerland

PHONE | +41 21 311 20 59
EMAIL | MDD-training@veranex.com
WEB | www.veranex.com

ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good Clinical Practice

TRAINING FACTSHEET

Speaker:
Olivier Gschwend, PhD Scientific Affairs Manager

Date: October 8th & 9th 2024, Online
Duration: 8 hours
2x 8:00 – 12:00 AM US Eastern Standard Time
2x 2:00 - 6:00 PM Central Europe Summer Time

About the speaker:
With more than ten years of post-PhD experience and a strong publication record, Olivier is a highly qualified neuroscientist. He holds a Diploma of Advanced Studies (DAS) in Clinical Trial Management, Good Clinical Practice Implementation and Quality Processes from the University of Geneva. Throughout his career, Olivier has provided clinical and scientific services for a diverse range of Medical and In Vitro Diagnostic devices used to treat a multitude of pathologies. He has a strong experience in Clinical Evaluation of Medical Devices ranging from implantable to software devices, and from class I to III. This complements his other area of specialty related to Clinical Investigations, which includes clinical study design, statistical activities, writing and management of Clinical Trial Applications, and planning of PMCF activities. For the last two years, Olivier has been providing statistical support across for a variety of projects, and is responsible of the biostatistics and clinical data analysis at Veranex Switzerland SA.

This Good Clinical Practice (GCP) course, certified by Swissethics, fulfills the legal and regulatory requirements for both Investigator and Sponsor-Investigator level for clinical investigations of medical devices.

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TRAINING OBJECTIVES:

This training will enable you to link key regulatory and quality considerations when conducting clinical investigations on medical devices. The training is aimed at any person involved in clinical activities seeking to enhance their knowledge and competences within this field.

TRAINING CONTENT:

ISO 14155 addresses the design, conduct, recording, monitoring, and reporting of clinical investigations on medical devices in accordance with the principles of good clinical practice (GCP) when working with human subjects. The standard is established to ensure proper scientific conduct of clinical investigations and integrity of the study results, as well as to protect the rights, safety, and well-being of the human subjects involved in the investigation. The standard should be applied to all types of clinical investigations intended to assess the clinical performance or effectiveness and safety of medical devices.

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

- Regulatory context
- General introduction to ISO 14155:2020
  - Relation to ICH-GCP
  - GCP core principles as defined in ISO 14155:2020
  - Relation to GDPR
- Key changes introduced by ISO 14155:2020 (vs ISO 14155:2011) and how to transition
- Planning and design of clinical investigations
  - Substantiation of safety and performance claims
  - Clinical development stages
  - Clinical investigation design
  - Value of an adequate Clinical Development Plan
  - Statistical concepts and considerations for sample size calculation
- Roles and responsibilities of clinical investigation's stakeholders
  - Sponsor, Principal Investigator, Ethics Committee, Competent Authorities
- Essential documents throughout the clinical investigation
- Submission and authorization procedures
- Investigation site selection and initiation
- Safety reporting including adverse event classification
- Monitoring activities
- Clinical quality management
- Handling of investigational medical device
- Study close-out

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TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment

TRAINING FORMAT:

- Participants will receive an ISO 14155:2020 - GCP training certificate upon successful completion of the end of training assessment.

PREREQUISITE:

To attend the course, you are expected to self-train on Chapter VI and Annex XV of the MDR. You will be asked to complete an assessment related to clinical requirements of the MDR prior to the training. Any question related to the prerequisites will be addressed by the trainer.

WHO SHOULD ATTEND:

- Managers and employees working in Quality Assurance or Regulatory Affairs department of medical device manufacturer
- Managers and employees working in Research and Development department of medical device manufacturer
- Technical medical device consultants and associates
- Auditors of medical devices

PRICE:

EUR 625 incl. course material and certificate

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