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Clinical investigations on Medical Devices

Requirements of ISO 14155:200

Duration: 2 days I 2:00 – 5:00PM CEST
Date: June 29th & 30th, 2021

Training objectives:

This training is organized into 2 modules with a duration of 3 hours each to provide participants with an extended understanding of the requirements introduced by ISO 14155:2020 – including presentation of the practical aspects pertaining to the implementation of the new requirements to the procedures of your organization. The course will enable you to link key regulatory and quality considerations when conducting clinical investigations on medical devices. Furthermore, the linkage between the concepts of Good Clinical Practice (GCP) and the principles of the ISO 14155 standard will be outlined.
This training is aimed at sponsors, investigators, clinical trial managers, clinical research coordinators, etc. involved in clinical activities who seek to enhance their knowledge and competences within this field.

Training content:

ISO 14155 is addressing the design, conduct, recording, monitoring, and reporting of clinical investigations on medical devices and how to apply GCP when working with human subjects. The standard is established to ensure proper scientific conduct of clinical investigations, as well as protecting the rights, safety, and well-being of the human subjects included in the investigations. The principles of the standard should be applied to all types of clinical investigations intended to assess the clinical performance, effectiveness, and safety of medical devices. By attending this training, you will receive in-depth knowledge on the following topics:

- General introduction on ISO 14155:200
  - Relation with ICH-GCP
  - Key concept of GCP as defined in ISO 14155
- Key changes introduced by ISO 14155:2020
  - New definitions and ethical considerations
  - Increased focus on a risk-based approach during clinical investigations
- Considerations regarding clinical study design
  - Clinical development stages
  - Adequate linkage of device safety and performance claims to study end-points
  - The value of an adequate Clinical Development Plan

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- Clinical investigation stages as depicted in the standard
  - Planning, submission, registration
  - Study conduct and monitoring activities
  - Close-out and reporting obligations

- Understanding PMCF and connection to clinical investigations
  - How to identify gaps in clinical evidence where PMCF can be used
  - Considerations of PMCF design - endpoints/ sample size/ follow up period

- GDPR compliance during study conduct

- Adverse event classification and reporting obligations

- Roles in the clinical investigation and their responsibilities
  - Sponsor, principal investigator, Ethics Committee, Competent Authorities

- Clinical quality management
  - Measures to ensure proper documentation procedures
  - Deployment of Data Management Committee

- Handling of Investigational Medical Device

The training is delivered by Mrs Cécile Rod, Project Associate at Medidee Services.

Price: CHF750-.
Location: Online Training

Contact & registration: training@medidee.com