

**TRAINING**

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

Duration: 2 days - 2 x 3 hours

Date: March 2022

Training objectives:

This training is organized into 2 modules with a duration of 3 hours each with the goal of providing participants with an extended understanding of ISO 14155:2020 – including Good Clinical Practice. 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.

Training content:

ISO 14155 addresses 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 involved in the investigation. 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:

- 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
 - Value of an adequate Clinical Development Plan
 - Statistical concepts
- Clinical investigation stages as depicted in ISO 14155:2020
- 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

- Safety reporting including adverse event classification
- Monitoring activities
- Clinical quality management
- Handling of investigational medical device
- Study close-out

Group and individual exercises are planned throughout the course. At the end of the training, you will fill out a quiz about ISO 14155:2020 and will receive a training certificate.

Prerequisite:

To attend the course, you are expected to self-train on [ISO 14155:2020](https://www.iso.org/standard/72430.html) as well as Chapter VI of the [MDR](https://www.mdr.europa.eu/), and to complete a quiz related to clinical requirements of the MDR. Any question related to these readings and to the quiz may be addressed to the trainer and discussed during the sessions.

Price: CHF750.-

Location: Online

Contact & registration: training@medidee.com

This training, certified by Swissethics for Sponsor-Investigator level for clinical investigations with medical devices, fulfils the legal and regulatory requirements.