

Requirements for Courses on Research Ethics and GCP

Sponsor-Investigator Level

In addition to requirements for Investigator Level

Learning Objectives (•) and List of content (□)

- Describe the combined role of a sponsor-investigator in a clinical study
 - Short repetition of responsibilities of an investigator and a sponsor according to ICH-GCP E6 and Swiss law, incl. ordinances
- Develop a scientific question into a research hypothesis
 - Focused question
 - Clinical relevance
 - Use of prior evidence
 - Definition of study objectives and primary and secondary endpoints
 - Definition of efficacy and safety parameters
- Explain essential methodological and statistical considerations
 - Study design
 - Statistical methods
 - Sample size
 - Interim analysis
 - Level of scientific evidence
 - Measures to avoid bias and confounding
- Conduct feasibility assessments for a planned project
 - Resource management (patients, personnel, space, materials, competing studies)
 - Time management
 - Costs and funding; budgeting
 - Partners and collaborations; contracts
 - Liability/insurance statements
- Ensure quality of investigational medicinal products and medical devices
 - Requirements for pharmaceutical quality data
 - GMP/ISO requirements
 - Labelling requirements
 - Shipping requirements
 - Accountability, traceability, destruction, distribution and storage of drug/medical device
- Describe submission and reporting requirements towards competent authorities
 - Definition of studies that need approval by Swissmedic/BAG
 - Submission process and dossier structure
 - Reporting requirements, incl. Pharmaco- and Materiovigilance
- Ensure transparency and reproducibility of study procedures and documentation
 - QMS and SOP systems
 - Adequate training of staff
 - Documentation and change management
 - Study reports
 - Obligation to publish/disclose research results