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
  o 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
  o Focused question
  o Clinical relevance
  o Use of prior evidence
  o Definition of study objectives and primary and secondary endpoints
  o Definition of efficacy and safety parameters

• Explain essential methodological and statistical considerations
  o Study design
  o Statistical methods
  o Sample size
  o Interim analysis
  o Level of scientific evidence
  o Measures to avoid bias and confounding

• Conduct feasibility assessments for a planned project
  o Resource management (patients, personnel, space, materials, competing studies)
  o Time management
  o Costs and funding; budgeting
  o Partners and collaborations; contracts
  o Liability/insurance statements

• Ensure quality of investigational medicinal products and medical devices
  o Requirements for pharmaceutical quality data
  o GMP/ISO requirements
  o Labelling requirements
  o Shipping requirements
  o Accountability, traceability, destruction, distribution and storage of drug/medical device

• Describe submission and reporting requirements towards competent authorities
  o Definition of studies that need approval by Swissmedic/BAG
  o Submission process and dossier structure
  o Reporting requirements, incl. Pharmaco- and Materiovigilance

• Ensure transparency and reproducibility of study procedures and documentation
  o QMS and SOP systems
  o Adequate training of staff
  o Documentation, trial master file and change management
  o Study reports
  o Obligation to publish/disclose research results