Contents of modules EU/GCP training

Module	Chapters	Contents of module
Introduction	1. Introduction E6 (R2) UPDATED 2. ICH-GCP E6 (R2) UPDATED 3. Principles of ICH GCP E6 (R2) UPDATED 4. EU legislation GDPR UPDATED 5. Roles & responsibilities 6. Clinical trials of a medicinal product 7. Abbreviations & terminology	• Introduction to medical research • Types of clinical research (interventional, therapeutic, multi / single center) • History of legislation and regulations clinical research (Code of Nuremberg, Declaration of Helsinki) • The principles ICH-GCP incl. R2 Addendum • Laws and regulation clinical research Europe (EU directives 2001 and 2005, EU Regulation 536/2014) • The roles in clinical research (sponsor, IEC, competent authority, monitor, auditor, investigator, research professional) • Additional requirements for clinical trials of a medicinal product • Phases of a clinical trial of a medicinal product • Abbreviations and terminology in medical scientific research
Design	1. Develop trial protocol E6 (R2) UPDATED 2. Select team members E6 (R2) UPDATED 3. Facilities at the trial site E6 (R2) UPDATED 4. DSMB and SOPs 5. Monitoring & auditing E6 (R2) UPDATED 6. Essential documents E6 (R2) UPDATED	• Protocol development and content • Select research team • Selection of investigators and research locations • Selection criteria for researchers and research locations • Create and store essential documents (Investigator Site File) • Risk inventory and assessment • Setting up quality assurance: monitoring plan, auditing, DSMB, SOPs
Preparation	1. Investigational product 2. Delivery, randomization and blinding 3. Prepare product information 4. Informing subjects GDPR UPDATED 5. Compensation and insurance 6. Agreements	• Packaging, labeling, importing and supplying investigational products • Compose product information (Investigator's Brochure, IMPD) • Draw up patient information and other trial documents • Contracts and Agreements • Privacy laws EU (GDPR) • Insurance (Trial Insurance and Liability)

Submission	1. Review procedure 2. IEC submission 3. Application dossier 4. Review 5. Terms and conditions	• Composition of standard research file • Composition and procedure reviewing committee • Review by ethics committee • Review by competent authority • Review deadlines and changes • Review process and approval • Terms and obligations after approval
Start study	1. Study start 2. Investigational product 3. Recruitment of subjects 4. Informing subjects GDPR UPDATED 5. Including the subjects 6. Screening 7. Vulnerable subjects	• Delegate tasks and Initiation Visit • Supply, storage and use of investigational product in a trial • Recruitment of subjects • Informing subjects • Informed Consent procedure • Randomization and coding • Privacy of data (GDPR) • Requirements for research with vulnerable subjects
Conduct	1. Safety 2. SAEs and SUSARs 3. Trial amendments 4. Documentation E6 (R2) UPDATED 5. Quality Management E6 (R2) UPDATED	• Amendments, deviations and changes in protocol and trial • Adding new research sites and investigators • Safety reports (AE / SAE / SUSAR) • Safety subjects medical care and DSMB • Documentation and data management (source, CRF, database) • Monitoring/ Auditing/ Inspection • Quality assurance and risk management (R2 update) • Progress reports
Close-out and archiving	1. Regular completion 2. Early termination 3. Archiving	• Regular completion of a trial • Preliminary closing of a trial • Report end of study • Requirements for Clinical Study Report • Storage and archiving trial documentation • Retention deadlines for trial documentation