MyGxPtraining

GCP Basic Training

Based on ICH E6(R3)

✓ **Duration:** Approx. 3–4 hours	✓ Flexible learning schedule
✓ **Format:** 100% online | Self-paced learning	✓ Practical examples, exercises and videos
✓ **Language:** English	✓ **Certificate**: Issued in English
✓ **Access:** 3 months	✓ TransCelerate-listed GCP training

Course Objective

This course provides a concise, practice-oriented introduction to the key requirements of ICH E6(R3), covering participant protection, roles and responsibilities, data integrity, safety and quality. Realistic examples demonstrate how to apply GCP requirements effectively in everyday clinical trial practice. The training meets the TransCelerate minimum criteria and is listed in the GCP Training Mutual Recognition Program.

Target Audience

Designed for new employees, professionals transitioning into clinical research and individuals beginning their careers in clinical research, clinical operations, study coordination, quality management and quality assurance.

Particularly suitable for:

Clinical trial site staff, professionals requiring GCP refresher training, and employees of pharmaceutical, biotechnology and research organisations, university hospitals and contract research organisations (CROs).

Course Content

✓ **GCP Fundamentals & Regulatory Framework:** Objectives of GCP, ICH E6(R3), the EU Clinical Trials Regulation (EU CTR) and the Declaration of Helsinki
✓ **Ethics & Informed Consent:** Participant protection, risk–assessment, ethics committees and informed consent
✓ **Roles & GCP Principles:** Sponsors, investigators, trial sites, monitors, QbD and risk-based approaches
✓ **Documentation & Systems:** Essential records, source data, electronic case report forms (eCRFs), data integrity and training
✓ **Safety & Compliance:** Adverse events (AEs), serious adverse events (SAEs), suspected unexpected serious adverse reactions (SUSARs), protocol deviations, noncompliance and reporting requirements
✓ **Quality & Investigational Medicinal Products:** Monitoring, oversight, audits, inspections, randomisation and blinding
✓ **Course Completion:** Final knowledge assessment and certificate issued in English

COURSE PRICE

€340

per person

Enrol Online and Start Learning at Your Own Pace

Register at www.mygxptraining.at. Complete the course online at your own pace. Upon successfully passing the final assessment, you will receive your certificate in English in digital format. **Group discount:** 10% for 5–10 course places. For 11 or more participants, we offer a customised corporate quotation.