PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

ICH E6(R3) GCP Training with Investigational Products

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Run clinical trials to ICH E6(R3) good clinical practice, from roles, ethics review and consent to quality by design, monitoring, data governance and the full life cycle of investigational products.

WHO IT IS FOR

Clinical research associates and monitors, clinical project and trial managers, investigators and site staff, clinical trial supply and pharmacy staff, clinical QA staff, and sponsor and CRO managers who plan, run or oversee clinical trials.

WHAT YOU WILL LEARN

- Explain the ICH E6(R3) principles and how Annex 1 and Annex 2 apply them
- Assign and oversee sponsor, service provider, investigator and ethics committee responsibilities
- Apply quality by design, critical to quality factors and risk-based quality management
- Control investigational products through labelling, blinding, supply, storage, accountability and return
- Plan risk-based monitoring and handle protocol deviations, safety reports and noncompliance
- Keep trial data and essential records reliable, traceable and ready for inspection

MODULES (13)

1. Welcome, and why GCP matters
2. ICH E6(R3): structure, status and principles
3. Roles, agreements and oversight
4. Ethics review and informed consent
5. Quality by design and risk management
6. Investigational products: making and labelling
7. Randomisation, blinding and unblinding
8. Supplying and accounting for the product
9. Investigator conduct and safety reporting
10. Monitoring, audit and noncompliance
11. Data governance and essential records
12. Annex 2: decentralised and pragmatic trials
13. Putting it together, and the exam

PRICE

US$99 per learner

Per learner, by team size

1–10 learners	**US$99**
11–50 learners	**US$79**
51–200 learners	**US$69**

Excluding taxes.

DURATION

About 6 hours in total (3 hours of video)

MODULES

13

FORMAT

Self-paced online training (video)

LANGUAGE

English, with captions

ACCESS

12 months

CERTIFICATE

Sterling Academy Certificate of Completion

Scan for the course page, prices and enrolment