PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Good Laboratory Practice Training (US FDA 21 CFR Part 58)

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 5.5 hours in total · English, with captions

Run nonclinical laboratory studies to US FDA good laboratory practice, from 21 CFR Part 58 organisation, study director and QAU duties to facilities, test articles, protocols, records, reports and FDA inspections.

WHO IT IS FOR

Study directors, scientists and technicians in toxicology, pharmacology and bioanalytical laboratories, quality assurance unit staff, archivists, testing facility managers, and sponsor staff who place or monitor nonclinical studies for FDA submissions.

WHAT YOU WILL LEARN

- Explain when 21 CFR Part 58 applies and what it requires of a testing facility
- Describe the duties of testing facility management, the study director and the quality assurance unit
- Apply Part 58 to facilities, equipment, SOPs, animal care and test and control articles
- Write and follow a protocol, record raw data and handle changes correctly
- Prepare a final report and keep records, specimens and samples as Part 58 requires
- Prepare for an FDA GLP inspection and respond to Form FDA 483 observations

MODULES (13)

1. Welcome, and why GLP matters
2. Part 58: scope and definitions
3. Management and personnel
4. The study director: single point of control
5. The quality assurance unit
6. Facilities and equipment
7. SOPs, reagents and animal care
8. Test and control articles
9. The protocol and the conduct of the study
10. Raw data and data integrity
11. The final report, archives and retention
12. FDA inspections and disqualification
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 5.5 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