Sterling ACADEMY

Build the competence. Prove it with confidence.

COURSE BROCHURE

AWARENESS TRAINING · GOOD PRACTICE (GXP)

US FDA GMP Awareness for Pharmaceuticals (21 CFR Parts 210 and 211)

Self-paced online training (video) · 15 modules · about 105 min of video · about 3.5 hours in total · English, with captions

Understand US FDA current good manufacturing practice for medicines, and how everyday habits in production protect product quality and the patients who use it.

WHO IT IS FOR

Operators, storekeepers, laboratory staff, engineers, supervisors and managers in plants that make medicines for the United States

WHAT YOU WILL LEARN

- Explain what US FDA cGMP is, and who must follow 21 CFR Parts 210 and 211
- Describe the main areas the rules cover, from people and premises to production and the laboratory
- Understand why good documentation and data integrity matter: if it is not recorded, it did not happen
- Recognise deviations, contamination risks and mix-ups, and know how to report them
- Know what happens in an FDA inspection, and describe your own part in keeping medicines consistent and safe

MODULES (15)

1. Why US GMP matters
2. 21 CFR 210 and 211
3. The quality unit and the quality system
4. People: training, hygiene and gowning
5. Buildings, facilities and sanitation
6. Equipment, cleaning and calibration
7. Materials: from receipt to release
8. Production and in-process controls
9. Packaging, labels and expiry dates
10. The laboratory and OOS in plain terms
11. Records and ALCOA+
12. Data integrity on computers
13. Deviations, CAPA and change control
14. Warehouse, complaints, returns and recalls
15. An FDA inspection, and your part

PRICE

US$19 per learner

Per learner, by team size

1–10 learners	**US$19**
11–50 learners	**US$15**
51–200 learners	**US$13**

Excluding taxes.

DURATION

About 3.5 hours in total (107 minutes of video)

MODULES

15

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