Sterling ACADEMY

Build the competence. Prove it with confidence.

COURSE BROCHURE

AWARENESS TRAINING · PHARMACEUTICAL GMP

FDA Inspection Readiness Training

Self-paced online training (video) · 10 modules · about 110 min of video · about 3 hours in total · English, with captions

Prepare your drug manufacturing site and your people for a US FDA CGMP inspection: how FDA inspects, hosting the investigator, records requests, Form 483 observations, responses and warning letters.

WHO IT IS FOR

Site heads, quality assurance and quality control managers, production, engineering and warehouse supervisors, subject matter experts who face investigators, and the inspection support team of drug manufacturers supplying the US market.

WHAT YOU WILL LEARN

- Explain how and why FDA inspects drug manufacturing sites
- Recognise what investigators review and the observations FDA cites most
- Organise the front room, back room and records requests during an inspection
- Prepare subject matter experts to answer questions clearly and accurately
- Understand the Form 483 and write a timely, credible response
- Explain warning letters and import alerts and build an inspection readiness plan

MODULES (10)

1. FDA inspections: why readiness matters
2. FDA's authority to inspect
3. How FDA chooses and plans inspections
4. Records requests and remote assessments
5. Before the inspection: self-inspection, records
6. Day one: arrival and the two rooms
7. During the inspection: questions and records
8. The closeout and the Form 483
9. Responding to a 483, and classification
10. Warning letters, import alerts and your plan

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 hours in total (112 minutes of video)

MODULES

10

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