AWARENESS TRAINING · PHARMACEUTICAL GMP

EU GMP Inspection Readiness Training

Self-paced online training (video) · 10 modules · about 115 min of video · about 3 hours in total · English, with captions

Prepare your site and team for an EU GMP inspection by a competent authority: how inspections are planned and run, how deficiencies are classified, GMP certificates, self-inspection and credible responses.

WHO IT IS FOR

Site heads, Qualified Persons, quality assurance and quality control managers, production and engineering supervisors and the inspection support team of manufacturers in and outside the EU that supply the EU market.

WHAT YOU WILL LEARN

- Explain the legal basis and types of EU GMP inspection
- Describe how sites in third countries are inspected for the EU market
- Run self-inspections that find problems before inspectors do
- Host an inspection and present people, processes and records with confidence
- Understand critical, major and other deficiencies and respond credibly
- Explain GMP certificates and statements of non-compliance in EudraGMDP

MODULES (10)

1. Why EU inspection readiness matters
2. The legal basis and the Compilation
3. How inspections are planned
4. Sites outside the EU
5. Self-inspection under Chapter 9
6. The site master file and key records
7. Opening meeting and the plant tour
8. Answering, documents and the QP
9. Deficiencies, the final meeting and your response
10. Certificates, outcomes and your readiness 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 (114 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