AWARENESS TRAINING · PHARMACEUTICAL GMP

Complaints and Product Recalls Training (EU GMP)

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

Handle complaints, quality defects and product recalls the way EU GMP Chapter 8 expects: from receiving a complaint and investigating root cause to risk-based decisions, notifying authorities and recalling batches.

WHO IT IS FOR

Quality assurance staff, Qualified Persons and their teams, complaint and quality defect handlers, regulatory affairs, distribution and supply chain teams of manufacturers and importers supplying the EU market.

WHAT YOU WILL LEARN

- Explain the principles and scope of EU GMP Chapter 8
- Receive, record and assess complaints and suspected quality defects
- Investigate quality defects and find their root cause
- Make risk-based decisions and involve the Qualified Person at the right time
- Notify competent authorities and plan and run a product recall
- Test recall arrangements and learn from recalls and defects

MODULES (10)

1. Complaints and recalls: why Chapter 8 matters
2. The EU framework at a glance
3. People and organisation
4. Receiving and assessing complaints
5. Investigating a quality defect
6. Root cause and CAPA
7. Risk-based decisions and the QP
8. Informing the competent authorities
9. Running a recall
10. Testing recalls, a rehearsal and the exam

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 (110 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