AWARENESS TRAINING · PHARMACEUTICAL GMP

Drug Complaints and Recalls Training (US FDA)

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

Handle drug product complaints and recalls the way US FDA expects: complaint files under 21 CFR 211.198, investigations, field alert reports, returned goods and recalls under 21 CFR Part 7.

WHO IT IS FOR

Quality assurance and quality control staff, complaint handlers, regulatory affairs, supply chain and customer service teams of drug manufacturers and packagers supplying the US market, and anyone who takes part in a recall.

WHAT YOU WILL LEARN

- Explain what FDA requires of a drug complaint procedure and complaint file
- Decide when a complaint needs an investigation and when a field alert report is due
- Handle returned drug products and link complaints to CAPA and trends
- Describe recall classes I, II and III and how FDA classifies a recall
- Plan a recall strategy, communications, effectiveness checks and status reports
- Recognise the complaint and recall failures FDA cites in warning letters

MODULES (10)

1. Welcome: why complaints and recalls matter
2. The US rules at a glance
3. Receiving and recording complaints
4. Evaluating and investigating complaints
5. Field alert reports
6. Returned and salvaged products
7. Recalls under Part 7
8. Recall strategy and communications
9. Running and closing a recall
10. What FDA cites, a rehearsal and your 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 (109 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