AWARENESS TRAINING · GOOD PRACTICE (GXP)

GMP Change Control Training

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

Manage GMP changes from proposal to closure: raise the request, assess impact with quality risk management, check regulatory filings, approve, implement, validate where needed and confirm that the change worked.

WHO IT IS FOR

Change owners and approvers, QA and regulatory affairs staff, production, engineering, validation, QC, IT and supply chain staff, and managers in pharmaceutical, biotech and API manufacturing.

WHAT YOU WILL LEARN

- Recognise which changes need change control, and raise a clear change request
- Assess the impact of a change on product, process, validation and documents
- Use quality risk management to decide the depth of assessment
- Identify when a change needs a regulatory filing before it is made
- Approve, implement and close changes with the right records
- Review whether a change achieved its aim without unintended effects

MODULES (10)

1. Why change control matters
2. What counts as a change
3. The change request
4. Impact assessment
5. Regulatory filings
6. Approval and the plan
7. Making the change
8. After the change
9. Special cases
10. Your role, the whole method

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 (108 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