PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

API GMP Training (ICH Q7)

Self-paced online training (video) · 14 modules · about 3 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Apply ICH Q7 good manufacturing practice to active pharmaceutical ingredient manufacture, from the API starting material and the quality unit to production, laboratory controls, validation, change control and distribution.

WHO IT IS FOR

Production, QA and QC staff, validation and engineering teams, supplier and regulatory staff and managers at API and intermediate manufacturers, and the finished-product teams who qualify and audit API suppliers.

WHAT YOU WILL LEARN

- Define where API GMP starts and how its stringency increases through the process
- Set up the quality unit, its responsibilities and the product quality review
- Control materials, suppliers, production steps, in-process controls and blending
- Apply laboratory controls, impurity profiles, stability programmes and retest dates
- Run validation, change control, reprocessing and reworking the ICH Q7 way
- Prepare an API site for FDA and EU GMP inspections and customer audits

MODULES (14)

1. Welcome: why API GMP matters
2. Where API GMP applies
3. The quality unit and the quality system
4. People, buildings and utilities
5. Equipment, cleaning and computer systems
6. Documentation and batch records
7. Materials management
8. Production and in-process controls
9. Packaging, labels, storage, distribution
10. Laboratory controls and stability
11. Validation and change control
12. Rejection, re-use, complaints, recalls
13. Contractors, agents and special APIs
14. Putting it together

PRICE

US$99 per learner

Per learner, by team size

1–10 learners	**US$99**
11–50 learners	**US$79**
51–200 learners	**US$69**

Excluding taxes.

DURATION

About 6 hours in total (3 hours of video)

MODULES

14

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