PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Qualified Person Training (EU GMP Annex 16)

Self-paced online training (video) · 12 modules · about 3 hours of video, plus practice exercises · about 5.5 hours in total · English, with captions

Understand batch certification by the EU Qualified Person under Annex 16, from the legal duties and qualifications to imported batches, shared responsibilities, reliance on audits, unexpected deviations and the release of each batch.

WHO IT IS FOR

Qualified Persons, trainee and deputy Qualified Persons, quality assurance managers, batch record reviewers, importers and marketing authorisation holders, and quality staff at manufacturers outside the EU that supply the EU through an importer.

WHAT YOU WILL LEARN

- Explain the Qualified Person's legal duties, qualifications and position
- Follow the batch certification process from manufacture to saleable stock
- Share and confirm responsibilities between sites and Qualified Persons
- Certify imported batches, including EU testing and third-country sampling
- Assess unexpected deviations and rely on third-party audits correctly
- Record certification and issue batch certificates and confirmations

MODULES (12)

1. Welcome: the last signature
2. The Qualified Person in EU law
3. Who may act as a Qualified Person
4. The three steps of batch release
5. Multi-site manufacture and confirmations
6. Importation, EU testing and mutual recognition
7. Sampling in a third country
8. What the QP must secure (1)
9. What the QP must secure (2)
10. Third-party audits and unexpected deviations
11. Release, the register and certificates
12. 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 5.5 hours in total (3 hours of video)

MODULES

12

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