Sterling ACADEMY

Build the competence. Prove it with confidence.

COURSE BROCHURE

PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

EU GMP Essentials Training

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

Apply the EU GMP Guide, EudraLex Volume 4 Part I, from the pharmaceutical quality system and personnel to documentation, production, quality control, outsourcing, complaints, recalls and Qualified Person certification.

WHO IT IS FOR

Production, quality assurance and quality control staff, engineers, warehouse and validation staff, supervisors and managers in medicine and active substance manufacturers that supply the EU, inside or outside it, and their contract partners.

WHAT YOU WILL LEARN

- Explain the EU GMP framework, from the Directive to EudraLex Volume 4 and EU inspections
- Describe the pharmaceutical quality system, quality risk management and the product quality review
- Apply the EU GMP requirements for personnel, premises, equipment and documentation
- Apply the requirements for production, cross-contamination control, suppliers and quality control
- Manage outsourced activities, complaints, quality defects, recalls and self-inspections
- Explain Qualified Person certification and batch release, including for imported products

MODULES (14)

1. Welcome: why EU GMP matters
2. The EU GMP framework
3. The pharmaceutical quality system
4. Product quality review and improvement
5. Personnel: training and hygiene
6. Premises and equipment
7. Documentation and data integrity
8. Materials, suppliers and cross-contamination
9. Processing, packaging and returns
10. Quality control
11. Outsourcing and self-inspection
12. Complaints, defects and recalls
13. QP certification and the annexes
14. Putting it together: an EU inspection

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