PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Sterile Manufacturing Training (EU GMP Annex 1)

Self-paced online training (video) · 14 modules · about 3.5 hours of video, plus practice exercises · about 6.5 hours in total · English, with captions

Apply the 2022 EU GMP Annex 1 to sterile manufacturing, from the contamination control strategy and cleanroom grades to barrier technology, personnel, sterilisation, monitoring and aseptic process simulation.

WHO IT IS FOR

Sterile production operators and supervisors, sterility assurance and microbiology staff, QA, QC and validation staff, engineers, Qualified Persons and managers of sites that make sterile medicines for the EU market.

WHAT YOU WILL LEARN

- Explain the principles, scope and structure of the revised Annex 1 and its dates
- Build and review a contamination control strategy across the site
- Apply cleanroom grades, airflow, barrier technology and qualification requirements
- Apply Annex 1 requirements for personnel, gowning, utilities and sterilisation
- Set up environmental and process monitoring and run aseptic process simulations
- Prepare a sterile site for an EU GMP inspection against Annex 1

MODULES (14)

1. Why sterile manufacturing matters
2. Annex 1 at a glance
3. The contamination control strategy
4. Premises, grades and airflow
5. RABS and isolators
6. Qualification and disinfection
7. Equipment and utilities
8. Personnel and gowning
9. Production routes
10. Sterilisation and filtration
11. Closing, inspection, technologies
12. Environmental monitoring
13. Aseptic process simulation
14. QC, release, 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 6.5 hours in total (3½ 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