PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Aseptic Processing Training (US FDA)

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Make sterile drugs by aseptic processing to US FDA requirements, from 21 CFR Part 211 and FDA's 2004 guidance to ISO 5 design, people, media fills, sterilisation, monitoring and investigations.

WHO IT IS FOR

Aseptic operators and supervisors, sterility assurance and microbiology staff, QA and QC staff, validation and engineering teams, and managers of sterile drug and biologics sites that supply the US market.

WHAT YOU WILL LEARN

- Explain the 21 CFR Part 211 requirements and the FDA guidance that apply to aseptic processing
- Describe ISO 5 critical areas, supporting clean areas, airflow, pressure and HEPA filtration
- Apply personnel qualification, gowning and aseptic technique to everyday operations
- Plan and interpret process simulations (media fills) that reflect real operations
- Control sterilisation, filtration, endotoxin and time limits, and monitor the environment
- Investigate sterility and monitoring failures and prepare for FDA inspection findings

MODULES (13)

1. Why aseptic processing matters
2. The US rules for aseptic processing
3. The critical area and supporting clean areas
4. Airflow, pressure and HEPA filters
5. Design, isolators and blow-fill-seal
6. People: training and gowning
7. Components, closures and endotoxin
8. Filtration and sterilisation
9. Media fills: designing the simulation
10. Media fills: reading the results
11. Environmental monitoring
12. Sterility testing and investigations
13. 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

13

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