Sterling ACADEMY

Build the competence. Prove it with confidence.

COURSE BROCHURE

SPECIALIST TRAINING · GOOD PRACTICE (GXP)

US FDA cGMP Implementation Training for Pharmaceuticals (21 CFR Parts 210 and 211)

Self-paced online training (video) · 40 modules · about 5 hours of video · about 8 hours in total · English, with captions

Implement US FDA current good manufacturing practice across a pharmaceutical site, from the quality system and validation to the laboratory, data integrity and inspection readiness.

WHO IT IS FOR

Quality, production, engineering, laboratory and regulatory leaders at pharmaceutical sites in the United States and sites that supply the US market

WHAT YOU WILL LEARN

- Explain who must follow 21 CFR Parts 210 and 211 and how FDA guidance and ICH Q7, Q9 and Q10 support them
- Set up the quality unit, quality system and quality risk management
- Plan qualification, cleaning validation and process validation
- Run laboratory controls, OOS investigations and data integrity controls
- Prepare a site for an FDA inspection and a credible 483 response

MODULES (40)

1. Why US cGMP pays
2. The law and who must follow it
3. A map of Part 211 and its key terms
4. The pharmaceutical quality system
5. Quality risk management
6. The quality unit in practice
7. People: qualifications, training and...
8. Writing SOPs that work
9. Buildings and facilities
10. Equipment: design, cleaning, maint...
11. Equipment qualification: IQ, OQ, PQ
12. Cleaning validation
13. Components, containers and closu...
14. Supplier qualification
15. Production controls: charge-in, yiel...
16. In-process controls, microbes and...
17. The master production record
18. The batch record and its review
19. Process validation: design and qual...
20. Continued process verification
21. Packaging and labelling control
22. Warehousing and distribution recor...
23. Laboratory controls
24. Stability and expiry dating
25. Reserve samples and special testing
26. OOS investigation, part 1: the labor...
27. OOS investigation, part 2: full inves...
28. Data integrity and ALCOA+
29. Part 11 and computerised systems
30. Audit trails, shared logins and testi...
31. Deviations, root cause and CAPA
32. Change control
33. Complaints, returns and salvage
34. The annual product review
35. Recall readiness
36. Active ingredient makers: ICH Q7
37. Getting ready for an FDA inspection
38. After the inspection: 483s, warning...
39. The implementation roadmap
40. Your part, and the course close

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 8 hours in total (5 hours of video)

MODULES

40

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