PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Process Validation and Equipment Qualification (US FDA)

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

Validate drug manufacturing processes the way US FDA expects: process design, equipment and utility qualification, process performance qualification and continued process verification under 21 CFR Part 211.

WHO IT IS FOR

Validation, quality assurance and quality control staff, production and engineering managers, technical services and technology transfer teams, and consultants working with drug products made for the US market.

WHAT YOU WILL LEARN

- Explain the CGMP requirements for process validation and FDA's three-stage life cycle
- Turn development knowledge into a documented process design and control strategy
- Plan and carry out the qualification of facilities, utilities and equipment
- Write a process performance qualification protocol and report with a sound sampling plan
- Set up continued process verification with statistical trending and annual review
- Assess changes and keep processes and equipment in a validated state

MODULES (12)

1. Why process validation matters
2. The CGMP basis in Part 211
3. The life cycle and variation
4. Stage 1: process design
5. Facility and equipment requirements
6. Qualifying equipment
7. Utilities, automation and methods
8. Process performance qualification
9. Running PPQ and the report
10. Continued process verification
11. Change, maintenance, requalification
12. Putting it together at JKL Pharma

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