PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Qualification and Validation Training (EU GMP Annex 15)

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 5.5 hours in total · English, with captions

Apply EU GMP Annex 15 to facilities, equipment, utilities and processes: planning and the validation master plan, URS to PQ, process validation approaches, ongoing process verification and change control.

WHO IT IS FOR

Validation and qualification staff, quality assurance and Qualified Persons, engineering and production managers, and consultants working for manufacturers that supply medicinal products to the European Union.

WHAT YOU WILL LEARN

- Explain the principles of Annex 15 and how it links to the rest of EU GMP
- Write a validation master plan and risk-based qualification and validation plans
- Carry out qualification from user requirements and design qualification to IQ, OQ and PQ
- Choose and document a process validation approach: traditional, continuous or hybrid
- Run ongoing process verification and link it to the product quality review
- Validate packaging, utilities, transport and test methods, and control changes

MODULES (13)

1. Why qualification and validation matter
2. Annex 15 in EU GMP
3. Planning and the validation master plan
4. Protocols, reports and deviations
5. User requirements, DQ, FAT and SAT
6. IQ, OQ, PQ and requalification
7. Utilities and test methods
8. Process validation: general principles
9. Traditional, continuous and hybrid
10. Ongoing process verification
11. Packaging, transport and cleaning
12. Change control under Annex 15
13. 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

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