PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Computer System Validation (GAMP 5)

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

Validate GxP computerised systems with the risk-based life cycle of the GAMP 5 Guide, Second Edition, from requirements and supplier assessment to testing, release and controlled operation.

WHO IT IS FOR

Validation and quality assurance staff, IT and computerised system owners, laboratory and production system managers, engineering and automation staff, and project managers delivering GxP systems in pharmaceutical, biotech and medical device companies.

WHAT YOU WILL LEARN

- Explain the GAMP 5 key concepts and the risk-based system life cycle
- Classify systems, assess GxP impact and scale validation effort to risk
- Write user requirements and plan validation with supplier involvement
- Plan risk-based testing, including scripted and unscripted approaches
- Release systems and keep them validated through change, incidents and periodic review
- Apply the approach to laboratory, production, cloud and agile-developed systems

MODULES (13)

1. Why validate computerised systems
2. Regulatory expectations and what changed
3. The GAMP 5 key concepts
4. The life cycle, inventory and planning
5. Software categories and scaling effort
6. User requirements and supplier assessment
7. Functional risk assessment
8. Scripted and unscripted testing
9. Traceability, reporting and release
10. Change, incidents and CAPA
11. Periodic review, backup, retirement
12. Cloud, agile, spreadsheets and inspections
13. Putting it together at LMN Biologics

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