PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Data Integrity (ALCOA+) and 21 CFR Part 11

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

Keep GxP data attributable, legible, contemporaneous, original, accurate and complete across paper and electronic records, and meet 21 CFR Part 11 for electronic records and electronic signatures.

WHO IT IS FOR

Quality assurance and quality control staff, laboratory analysts and supervisors, production and engineering staff who create GxP records, IT and computerised system owners, and internal auditors in pharmaceutical and medical device companies.

WHAT YOU WILL LEARN

- Explain the ALCOA+ principles and apply them to everyday GxP records
- Apply the data life cycle and data governance to paper, hybrid and electronic records
- Identify the controls 21 CFR Part 11 requires for electronic records and signatures
- Review audit trails and spot common data integrity lapses
- Assess data integrity risks in laboratory and production systems
- Investigate data integrity issues and plan corrective action

MODULES (13)

1. Why data integrity matters
2. Regulators' expectations and data governance
3. ALCOA: the five core principles
4. ALCOA+ on paper, hybrid and electronic
5. The data life cycle, metadata, true copies
6. 21 CFR Part 11: scope and FDA's guidance
7. Part 11 controls for closed and open systems
8. Electronic signatures under Part 11
9. Access control, backup and validation
10. Audit trails and their review
11. Laboratory and production records
12. Data integrity risk and investigations
13. Putting it together at RST 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 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