AWARENESS TRAINING · GOOD PRACTICE (GXP)

AI in GMP Manufacturing Training

Self-paced online training (video) · English, with captions

Understand how AI and machine learning can be used in GMP manufacturing under the rules in force today: intended use, risk, data, validation, human review, change control and what regulators have published.

WHO IT IS FOR

Production, QA, QC and engineering staff, validation and IT teams, data scientists working with manufacturing data, and managers deciding whether an AI tool can be used in GMP work at a medicines or active substance site supplying the US or the EU.

WHAT YOU WILL LEARN

- Describe where AI and machine learning are used in GMP manufacturing and quality work
- Explain which rules in force already apply to AI tools in GMP, under Annex 11 and Part 11
- Define an AI tool's intended use and its risk to patients, product and data
- Recognise good practice for training data, test data, acceptance criteria and human review
- Keep an AI tool under control with monitoring, change control and periodic review
- Recognise what the drafts and regulator papers propose, and what is not yet a requirement

PLANNED OUTLINE

1. AI on the shop floor
2. The rules in force
3. Building trust in a model
4. People and control
5. Where the rules are going

PRICE
coming soon

DURATION
coming soon

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