AWARENESS TRAINING · GOOD PRACTICE (GXP)

Product Quality Review (APQR/PQR) Training

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

Prepare an annual product quality review that meets FDA and EU GMP expectations: what it must cover, how to collect and trend the data, draw conclusions and turn them into actions that improve the product.

WHO IT IS FOR

QA and QC staff who compile or review product quality reviews, production and technical services staff who supply the data, regulatory affairs staff, Qualified Persons and site managers who approve the conclusions.

WHAT YOU WILL LEARN

- Explain what FDA's annual product review and the EU product quality review require
- Plan the scope, period, sources and owners of a product quality review
- Collect and trend batch, test, deviation, change, stability and complaint data
- Draw clear conclusions and decide on CAPA, revalidation and specification changes
- Handle grouping, contract manufacturers and responsibilities between parties
- Present the review to management and keep it ready for inspection

PLANNED OUTLINE

1. Why the review matters
2. Planning the review
3. Reviewing the data
4. Changes, stability and the market
5. Conclusions and actions
6. Putting it together

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