PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Out-of-Specification (OOS) Investigations Training

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

Investigate out-of-specification laboratory results the way FDA and EU GMP inspectors expect: Phase I laboratory checks, full-scale investigations, retesting and resampling, averaging and outliers, and sound batch decisions.

WHO IT IS FOR

QC analysts, laboratory supervisors and managers, QA reviewers and investigators, production and technical staff who take part in investigations, contract laboratory staff, and Qualified Persons and quality heads who make batch decisions.

WHAT YOU WILL LEARN

- Explain what counts as an OOS result and the US and EU requirements that apply
- Run a Phase I laboratory investigation that tests clear hypotheses before anything is discarded
- Lead a full-scale investigation that reviews production and reaches other affected batches
- Plan retests and resamples in advance, and avoid testing into compliance
- Report results correctly, using averaging and outlier tests only where they apply
- Reach and document batch decisions, field alert reports and effective CAPA

PLANNED OUTLINE

1. Why OOS investigations matter
2. Preventing doubtful results
3. Phase I: the laboratory investigation
4. Phase II: the full-scale investigation
5. Concluding and reporting
6. Running a sound OOS system

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