PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Stability Testing Training (ICH Q1A(R2))

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

Design, run and evaluate stability studies to ICH Q1A(R2), Q1B, Q1D and Q1E: storage conditions, protocols, significant change, shelf life, on-going stability and the US FDA and EU GMP rules.

WHO IT IS FOR

Stability coordinators, QC analysts and laboratory managers, QA and regulatory affairs staff, formulation scientists and anyone who writes stability protocols, evaluates stability data or supports shelf-life claims for drug substances and drug products supplied to the US or the EU.

WHAT YOU WILL LEARN

- Explain what 21 CFR 211.166, 211.137 and EU GMP Chapter 6 require of a stability programme
- Write a stability protocol with the right batches, container closure, tests and time points
- Choose long-term, intermediate and accelerated conditions and judge significant change
- Plan photostability testing and justify bracketing or matrixing designs
- Evaluate stability data and propose a shelf life within the limits ICH Q1E sets
- Run on-going stability, investigate stability failures and keep complete records

PLANNED OUTLINE

1. Why stability testing matters
2. Designing the study
3. Running the study
4. Reduced designs and evaluation
5. Stability after approval
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