PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Nitrosamine Impurities: Risk Assessment and Control Training

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

Assess and control nitrosamine impurities in medicines: root causes, the three-step approach, confirmatory testing, acceptable intake limits, NDSRIs, specifications and changes, as US FDA and the EU expect today.

WHO IT IS FOR

QA, QC and analytical staff, regulatory affairs and CMC teams, API and finished-product manufacturing and development scientists, supplier quality staff, and managers of companies that make or hold authorisations for medicines supplied to the US or the EU.

WHAT YOU WILL LEARN

- Explain why nitrosamines are a cohort of concern and how acceptable intake limits are set
- Identify nitrosamine root causes in API synthesis, excipients, water, equipment and packaging
- Run a documented risk assessment for an active substance and a finished product
- Plan confirmatory testing with suitably sensitive methods and interpret the results
- Set specifications and a control strategy, including for NDSRIs and multiple nitrosamines
- Handle changes, reporting and supply risks under US FDA and EU expectations

PLANNED OUTLINE

1. Why nitrosamines matter
2. Where nitrosamines come from
3. Acceptable intake limits
4. Risk assessment and testing
5. Control and mitigation
6. Regulatory actions and the lifecycle

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