PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Responding to FDA 483s and Warning Letters Training

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

Respond to FDA Form 483 observations and warning letters with evidence FDA can evaluate: the response clock, scoping and root cause, CAPA plans, warning letter replies, meetings, import alerts and close-out.

WHO IT IS FOR

Site heads, quality heads, QA and compliance managers, regulatory affairs staff, investigation and CAPA owners, and executives of drug manufacturers, API makers and contract facilities that supply the US market, in the United States and abroad.

WHAT YOU WILL LEARN

- Explain the path from a Form 483 to classification, warning letter, import alert and close-out
- Plan a 483 response within 15 business days, with a team, a clock and an accountable signatory
- Scope each observation, find its root cause and assess the impact on distributed product
- Write a response with CAPA, dates and evidence that FDA can evaluate
- Answer a warning letter and its remediation requests, including data integrity requests
- Keep commitments, prepare for meetings and reinspection, and sustain compliance after close-out

PLANNED OUTLINE

1. After the inspection
2. The 483 response
3. Writing and following through
4. Warning letters
5. Escalation and the way back
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