PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Postmarketing Drug Safety Reporting Training (US FDA)

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Report postmarketing adverse drug experiences to US FDA on time and in full: who must report, what counts as serious and unexpected, 15-day Alert reports, ICSRs, periodic reports and PADE inspections.

WHO IT IS FOR

Drug safety and pharmacovigilance staff, case processors and medical reviewers, regulatory affairs and quality teams of NDA, ANDA and BLA holders, label distributors and contract safety providers, and managers responsible for postmarketing compliance in the United States.

WHAT YOU WILL LEARN

- Identify who must report under 21 CFR 314.80, 600.80, 310.305 and section 760
- Classify adverse drug experiences as serious or non-serious and as expected or unexpected
- Build a valid case, follow it up and meet the 15-calendar-day Alert report clock
- Prepare ICSRs and periodic safety reports in the formats FDA accepts
- Set up written procedures, vendor oversight and records that stand up to a PADE inspection
- Recognise the reporting rules for biologics, combination products and nonprescription drugs

MODULES (13)

1. Why postmarketing safety reporting matters
2. The US rules and who must report
3. Adverse drug experience, serious and unexpected
4. Sources of reports and receipt
5. Valid cases, day zero and follow-up
6. 15-day Alert reports
7. Writing and submitting the ICSR
8. Periodic safety reports: PADER and PBRER
9. Other postmarketing reports
10. Biologics, combination and OTC products
11. Procedures, vendors and records
12. PADE inspections and enforcement
13. Putting it together and the exam

PRICE

US$99 per learner

Per learner, by team size

1–10 learners	**US$99**
11–50 learners	**US$79**
51–200 learners	**US$69**

Excluding taxes.

DURATION

About 6 hours in total (3 hours of video)

MODULES

13

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