PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

Pharmacovigilance Training (EU GVP)

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 5.5 hours in total · English, with captions

Run pharmacovigilance as EU law and the EMA's Good Pharmacovigilance Practices require: the QPPV and master file, adverse reaction reports to EudraVigilance, signals, PSURs, risk management, audits and inspections.

WHO IT IS FOR

Pharmacovigilance and drug safety staff, QPPVs and their deputies, local safety contacts, regulatory affairs and quality teams of marketing authorisation holders in the EU, and service providers and non-EU companies that hold or support EU marketing authorisations.

WHAT YOU WILL LEARN

- Explain the EU pharmacovigilance framework, the GVP modules and who does what
- Set out the duties of the QPPV and maintain a pharmacovigilance system master file
- Collect, validate and submit adverse reaction reports to EudraVigilance on time
- Take part in signal management and prepare PSURs to the EU reference dates
- Maintain a risk management plan and apply risk minimisation measures
- Plan pharmacovigilance audits and prepare for competent authority inspections

MODULES (13)

1. Why pharmacovigilance matters
2. The EU framework and who does what
3. The system and its quality system
4. The QPPV and the master file
5. Collecting adverse reaction reports
6. Valid ICSRs and EudraVigilance
7. Signal management
8. Periodic safety update reports
9. Risk management plans
10. Risk minimisation and communication
11. Post-authorisation safety studies
12. Audits and inspections
13. Putting it together

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 5.5 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