How does it work?

Course format and duration

- Short courses are divided in several learning activities such as recorded lecture, reading, quiz, and forum that altogether **run over 30 minutes to 6 hours**. The learning activities **can be followed according to your wish**. You can start a learning activity then stop and start another one, then come back later to the one you have firstly opened.
- **Once open, your training remains accessible until completion, and within one year**.

Attendance and progress report

- **The Eu2P central office can quantify and analyse** your own training attendance, workload and quiz progress per learning activity and per short course.

Evaluation and award

- When **your training progress reaches 100%**, you **perform an online graded evaluation** on your whole training content.
- This evaluation consists in a **quiz covering all your learning activities**.
- The training **evaluation is successful if you reach at least a 80% good score**.
- You **then receive an official Eu2P certificate** for your achieved competencies.

How does it cost?

Affordable prices

Students & Professionals	Companies
Annual registration for one short course per person from 100 € to 500 €	**Custom package** Quote on request

Eu2P supports worldwide pharmaceutical companies for their in-house training plans and provides quotes tailored to their needs in terms of content, duration and number of collaborators.

For more information, contact **Dr Karine Palin**: eu2p.office@eu2p.org

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Eu2P
EUROPEAN PROGRAMME IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

GAIN FAST AND SOLID EXPERTISE IN DRUG SAFETY WITH ONLINE SHORT COURSES

Eu2P short courses catalogue

Pharmacovigilance and regulatory aspects

Pharmacovigilance in practice

1.	Signal detection	1,5 h	150€
2.	Management and reporting of Adverse Drug Reactions (ADR)	4 h	400€
3.	Principles of labeling	3 h	300€
4.	Risk Management Plans (RMP) and European Union regulatory perspective	2 h	200€
5.	Role of the Qualified Person responsible for Pharmacovigilance (QPPV)	3 h	300€

Regulations outlines

6.	Contractual agreements in pharmacovigilance	1,5 h	150€
7.	Pre-marketing pharmacovigilance legislation	2 h	200€
8.	Post-marketing pharmacovigilance legislation	2 h	200€
9.	Development Safety Update Report (DSUR)	1 h	100€
10.	Vaccines biologics regulations	1 h	100€
11.	Materiovigilance regulations	1 h	100€
12.	Guidelines for Good Pharmacoepidemiology Practices	6 h	500€
13.	Eudravigilance, clinical trial and post-authorisation modules	1 h	
14.	International Harmonisation Initiatives	0,5 h	

European Union regulations

15.	GVP Module I - Pharmacovigilance system and their quality system	2 h	200€
16.	GVP Module II - Pharmacovigilance System Master File (PSMF)	2 h	200€
17.	GVP Module III - Pharmacovigilance Inspections	1 h	100€
18.	GVP Module IV - Pharmacovigilance Audits	1 h	100€
19.	GVP Module V - Risk Management System	2 h	200€
20.	GVP Module VI - Management and Reporting of Adverse Reactions to Medicinal Products	4 h	400€
21.	GVP Module VII - Periodic Safety Update Report (PSUR)	3 h	300€
22.	GVP Module VIII - Post-Authorisation Safety Studies (PASS)	2 h	200€
23.	GVP Module IX - Signal Management	1 h	100€
24.	GVP Module XVI - Risk Minimisation Measures	2 h	200€

International regulations

25.	US regulations	2 h	200€
26.	Canadian regulations	2 h	200€
27.	Japanese regulations	2 h	200€

Risk identification and quantification

1.	Concepts in risk management	3 h	300€
2.	Pharmacovigilance plan versus risk minimisation plans	3 h	300€
3.	Organisation for risk management in the industry	3 h	300€
4.	Methods and new initiatives for signals detection	6 h	500€

Benefit-risk assessment

1.	Role of benefit-risk assessment & pharmacoeconomics in decision-making of medicines	2 h	200€
2.	Principles and methods of benefit-risk assessment in decision-making of medicines	2 h	200€
3.	Main challenges of health economics and outcomes research	2 h	200€
4.	Drug life cycle as a tool in drug policy analysis	1 h	

Risk communication

1.	How to measure the effectiveness of risk communication?	2 h	200€
2.	How can risk communication be minimized?	1 h	100€
3.	Communicating emerging safety risks of marketed medicines	1 h	100€
4.	Basis of risk communication with special focus on risk communication on medicines	2 h	200€
5.	Understand communication challenges facing the regulatory agencies	2 h	200€
6.	Concept of risk communication throughout modern time	2 h	200€
7.	Risk perception. How to deal with it in risk communication?	2 h	200€
8.	A case study: the pandemic influenza vaccine	2 h	200€

Medicines benefit assessment

1.	Heterogeneity of treatment effect in clinical trials	2 h	200€
2.	Selecting outcomes: Surrogate endpoints	2 h	200€

Medicines and public health

1.	Integrating Pharmacovigilance & consumption data analysis - uses, limitations & potentiality	2 h	200€
2.	From individual cases to the community impact of adverse drug reactions: measuring tools	2 h	200€
3.	From individual cases to the community impact of adverse drug reactions: limitations	2 h	200€
4.	Health care records from large databases as a tool to study the use of medicines	2 h	200€

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