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

BASICS FOR PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

1.	Principles in Epidemiology	5 h	500€
2.	Epidemiología para los no epidemiólogos (in spanish)	5 h	500€
3.	Basis in statistics	5 h	500€

MEDICINES PHARMACOVIGILANCE AND REGULATORY ASPECTS

Regulations outlines

1.	Pre-marketing pharmacovigilance legislation	2 h	200€
2.	Post-marketing pharmacovigilance legislation	2 h	200€
3.	EudraVigilance & EVMPD	1,5 h	150€
4.	Development Safety Update Report (DSUR)	1 h	100€
5.	International Harmonisation Initiatives	0,5 h	
6.	Guidelines for Good Pharmacoepidemiology Practices	6 h	500€
7.	Vaccines biologics regulations	1 h	100€
8.	Materiovigilance regulations	1 h	100€
9.	Contractual Agreements in PV	1,5 h	150€

International regulations

10.	US regulations	2 h	200€
11.	Japanese regulations	2 h	200€
12.	French regulations (in French)	2 h	200€
13.	Canadian regulations	2 h	200€

European Union regulations

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

Pharmacovigilance in practice

25.	Signal detection	1,5 h	150€
26.	Management and reporting of Adverse Drug Reactions (ADR)	4 h	400€
27.	Gestión y Notificación de RAM (in spanish)	4 h	400€
28.	Risk Management Plans (RMP) and European Union regulatory perspective	2 h	200€
29.	Principles of labeling and Summary of Product Characteristics (SmPC)	3 h	300€
30.	Role of the Qualified Person responsible for Pharmacovigilance (QPPV)	3 h	300€

MEDICINES BENEFIT ASSESSMENT

1.	Heterogeneity of treatment effect in clinical trials	2 h	200€
2.	Selecting outcomes: Surrogate endpoints	2 h	200€
3.	Fundamentals of the adaptative clinical trials	2 h	200€
4.	Fundamentals of the network meta-analysis	2 h	200€
5.	Composite outcomes in clinical trials	2 h	200€
6.	Early stopping rules in clinical trials	2 h	200€
7.	Non inferiority approach in clinical trials	2 h	200€
8.	Recruitement strategies in clinical trials	2 h	200€

MEDICINES RISK IDENTIFICATION AND QUANTIFICATION

1.	Introduction to risk management plan (RPM)	1 h	100€
2.	Concepts in risk management	3 h	300€
3.	Pharmacovigilance plan versus risk minimisation plans	3 h	300€
4.	Organisation for risk management in the industry	3 h	300€
5.	Methods and new initiatives for signals detection	6 h	500€

MEDICINES BENEFIT-RISK ASSESSMENT

1.	Role of benefit-risk assessment & pharmacoeconomics in decision-making of medicines	1 h	100€
2.	Principles and methods of benefit-risk assessment in decision-making of medicines	2 h	200€
3.	Drug life cycle as a tool in drug policy analysis	1 h	
4.	Main challenges of health economics and outcomes research	2 h	200€

MEDICINES AND PUBLIC HEALTH

1.	Health care records from large databases as a tool to study the use of medicines	2 h	200€
2.	Integrating Pharmacovigilance & consumption data analysis - uses, limitations & potentiality	2 h	200€
3.	From individual cases to the community impact of adverse drug reactions: measuring tools	2 h	200€
4.	From individual cases to the community impact of adverse drug reactions: limitations	2 h	200€
5.	Drug interaction risks: the value of concomitant medication	2 h	200€
6.	Drug misuses risks: the effects of inappropriate use of the target medicine	2 h	200€

MEDICINES RISK COMMUNICATION

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

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