

## 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

 <b>Students &amp; Professionals</b>	 <b>Companies</b>
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](mailto:eu2p.office@eu2p.org)

### Powered by



# 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 & EVMPD	1,5 h	150€
14. International Harmonisation Initiatives	0,5 h	

### European Union regulations

15. GVP Module I - Pharmacovigilance V Quality Management System	4 h	400€
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)	4 h	400€
23. GVP Module IX - Signal Management	1 h	100€
24. GVP Module XVI - Risk Minimisation Measures	3 h	300€
25. Validation of Computerized systems	1 h	

### International regulations

26. US regulations	2 h	200€
27. Canadian regulations	2 h	200€
28. 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	1 h	100€
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€
3. Fundamentals of the adaptative clinical trials	2 h	200€
4. Fundamentals of the network meta-analysis	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€
5. Risk Management Plans: the value of concomitant medication	2 h	200€



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