Eu2P

EUROPEAN PROGRAMME IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

BOOST YOUR CAREER IN DRUG SAFETY WITH ONLINE CERTIFICATES

Improve your professional competencies through the Eu2P academic Certificate diploma!

Live lectures

Forums

Tutoring

& Live sessions

Eu2P Certificate

European academic diploma

Certificate course

3 ECTS credits workload

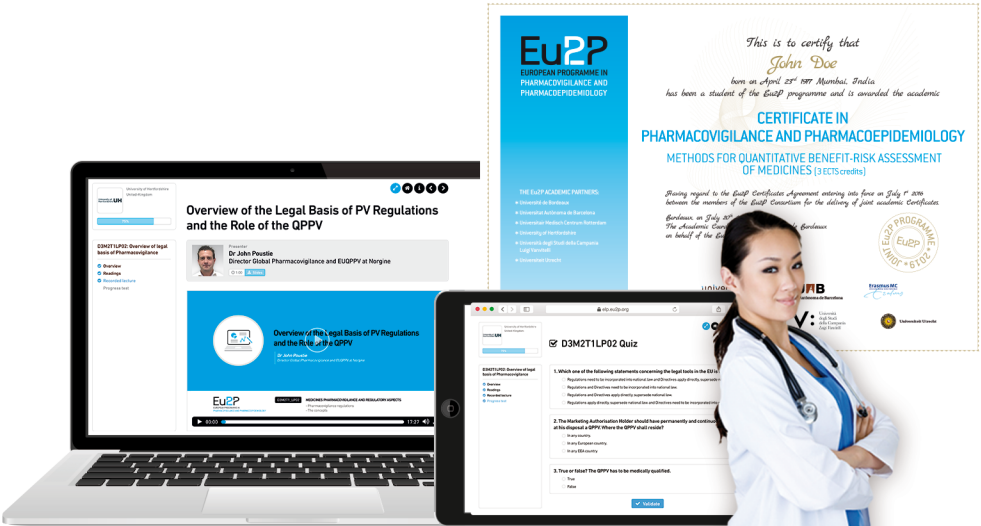
Graded examination

to validate your certificate programme

Continuous assessment

Final examination

3 months



The Eu2P Certificate programme organisation

Get a European academic Certificate

The Eu2P Certificate leads to **academic Awards in pharmacovigilance and pharmacoepidemiology jointly delivered by the European Universities** working together as Eu2P partners.

Standard and extended Eu2P certificates learning achievements are **recognised as respectively 3 and 6 ECTS credits**.

Get a valuable Certificate for job market

Graded expertise level

You can choose between **introductory**, **intermediate** **or** **advanced** **Certificate courses level** fitting your background and needs!

A recognised quality for audit inspections

Eu2P programme ensures and controls up-to-date knowledge, expertise and qualification of medicines-related collaborators, **from individuals to large teams**.

Designed for experts by experts

The Eu2P Certificates have been **built by the academic, regulatory and industrial Eu2P partners**. These certificates are **grounded in real job market** and today's practices.

Eu2P programme is being noticed and **recognised worldwide as an excellent means to get medicines-related jobs**.

Choose a flexible online programme

Awarded for e-learning quality, Eu2P online courses are followed **at home and on job premises** at your convenience. The average course **workload is one day a week over a 3 or 6 months period** (depending on the course ECTS credits).

The Certificate diploma is **awarded after a final assessment session**.

Enjoy affordable prices

Tuition fees are **adjusted to student or professional** status.
Savings on regular fees can be offered under eligibility conditions.

Students	Professionals	Companies
1,500 €	3,000 €	Quote on request

Get savings

Partners' saving

Each **Eu2P partner benefits from a special price** on Eu2P tuition fees for their students or employees!

Savings for Certificate fees	
Student in a Eu2P University	**- 50%**
Employee in a Eu2P agency, company or affiliate	**- 30%**

Reward programme

Gain up-to 20% of savings when studying with Eu2P!

Eu2P gives you reward points each time you register to a Eu2P Certificate: one point amounts to one euro. You can redeem these points and get savings on next course tuition fees!

Apply on-line

Calendar

On-line application sessions are organised throughout the year according to the Certificates calendar:

Check upcoming Certificates on www.eu2p.org

- A **first** Certificate session runs **from October to December**
- A **second** Certificate session runs **from January to April**
- A **third** Certificate session runs **from April to June**

Admission criteria

The application procedure and the selection process are the same for all candidates, regardless of whether you come from Eu2P partners or not, from European or third countries.

To be eligible, you must:

- **be fluent in English**
- **be familiar with computer use and have Internet access**
- **submit a complete on-line application**, together with all supporting documentation required (diplomas, certificates, letter of motivation...)

Pre-requisites depend on the chosen module: please refer to each Certificate description page on www.eu2p.org.

The Eu2P Certificates

Basics for pharmacovigilance and pharmacoepidemiology

By Université de Bordeaux

D1M1. BASICS IN EPIDEMIOLOGY

75 hours over 3 months
Introductory course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Descriptive epidemiology (person, place and time).
- Observational studies in pharmacoepidemiology.
- Biases in pharmacoepidemiology studies.
- Causality criteria, evidence level and critical reading.

D1M2. BASICS IN STATISTICS APPLIED TO DRUG EVALUATION

75 hours over 3 months
Introductory course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Introduction to statistics and probability.
- Estimates.
- Statistical testing.
- Introduction to multivariable linear regression.

D1M3. VALORISATION AND CRITICAL APPRAISAL IN RESEARCH

150 hours over 6 months
Introductory course level

Student: **2,500 €** / Professional: **5,000 €**
Eu2P Partner: **3,500 €**

- Critical reading of scientific literature: clinical trials and observational studies.
- Principles of the redaction of scientific papers and reports.
- Principles of scientific posters and oral communication.
- Introduction to scientific watch: principles and techniques.
- Presentation of the main institutions in Health Sciences.
- Principles for research funding.

Benefit assessment of medicines

By Universitat Autònoma de Barcelona

D2M1. BASICS IN CLINICAL PHARMACOLOGY

75 hours over 3 months Student: **1,500 €** / Professional: **3,000 €**
Introductory course level Eu2P Partner: **2,100 €**

- Clinical pharmacology: aims and uses in the therapeutics.
- Clinical pharmacology and epidemiological evaluation of medicine effects.
- The randomised clinical trials (RCT) as a method for assess the efficacy of medicines.
- Basics for RCT appraisal: extrapolation of RCTs results to clinical practice.

D2M2. CLINICAL AND PHARMACOLOGICAL PRINCIPLES

75 hours over 3 months Student: **1,500 €** / Professional: **3,000 €**
Intermediate course level Eu2P Partner: **2,100 €**

- Patients' therapeutic needs, medicines and society.
- Patients, physicians, information and prescribing.
- Clinical and pharmacological basis of therapeutics.
- Variability in medicines response.
- Therapeutics and medicines prescribing of medicines for selected health problems.

Benefit assessment of medicines

By Universitat Autònoma de Barcelona

D2M3. METHODS IN CLINICAL RESEARCH, PHARMACOEPIDEMIOLOGY AND IN THE ASSESSMENT OF THE EFFICACY OF MEDICINES

75 hours over 3 months
Intermediate course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Scientific methods and causality.
- Statistical and methodological issues for the design and analysis of clinical trials.
- Ethical issues in the development of clinical research and clinical trials.
- Systematic review and meta-analysis of randomised clinical trials.
- Other methods for the evaluation of the effectiveness of medicines and therapeutic interventions.

D2M4. CRITICAL APPRAISAL OF CLINICAL TRIALS: EVIDENCE-BASED MEDICINE AND ITS UNCERTAINTIES

75 hours over 3 months
Advanced course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Randomised clinical trials limitations.
- Evidence-based medicine and its limitations.
- Critical appraisal of randomised clinical trials limitations.
- Critical appraisal of a meta-analysis of randomised clinical trials.
- From therapeutic uncertainty to a research protocol.

Medicines pharmacovigilance and regulatory aspects

By University of Hertfordshire

D3M1. PRINCIPLES OF PHARMACOVIGILANCE

75 hours over 3 months
Introductory course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Introduction to Pharmacovigilance principles.
- Safety evaluation during a products lifecycle.
- Labelling and risk management.

D3M2. PHARMACOVIGILANCE REGULATIONS

75 hours over 3 months
Intermediate course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Pharmacovigilance regulations: concept.
- The working Pharmacovigilance regulations.
- Other related Pharmacovigilance regulations and guidelines.
- Pharmacovigilance regulations.

D3M3. PHARMACOVIGILANCE REGULATORY PROCESSES

75 hours over 3 months
Intermediate course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Case reporting.
- Periodic reporting.
- Product Labelling and Risk Management Plans.
- Contractual arrangements.

Medicines risk identification and quantification

By Erasmus UMC Rotterdam

D4M1. PRINCIPLES OF IDENTIFYING AND RECOGNIZING ADVERSE EVENTS AND SAFETY SIGNALS

75 hours over 3 months | Student: **1,500 €** / Professional: **3,000 €**
Intermediate course level | Eu2P Partner: **2,100 €**

- Definition of adverse drug reactions - type of ADRs.
- Detection and recognition of adverse events in clinical trials.
- Adverse event coding principles and differences.
- Spontaneous reporting databases.
- Principles of signal detection on electronic health care databases.
- Risk management plans.

D4M3. IDENTIFYING SUSCEPTIBILITY FOR ADVERSE DRUG REACTIONS

75 hours over 3 months | Student: **1,500 €** / Professional: **3,000 €**
Advanced course level | Eu2P Partner: **2,100 €**

- Introduction, risk factors and effect modification.
- Variability in drug response and principles of pharmacogenetics/pharmacogenomics.
- Assessment of pharmacogenetic influence through candidate genes and genome-wide association studies (GWAS).
- Ongoing initiatives and biological interpretation.
- Successes and failures in pharmacogenetic studies.

Medicines risk identification and quantification

By UMC Utrecht

D4M2. SUBSTANTIATION AND QUANTIFICATION OF RISKS

150 hours over 6 months
Intermediate course level

Student: **2,500 €** / Professional: **5,000 €**
Eu2P Partner: **3,500 €**

- Introduction: from case based reasoning to population based reasoning, examples: H1N1 vaccination, Yellow fever vaccine.
- Designing a study: study designs, basic epidemiological measures, data sources, workflow to quantify risks, case and exposure identification, codes of conduct, writing a protocol.
- Designing a study II: Causality from different perspectives, Causal diagrams, and Building a Statistical Analysis Plan.
- Raw Data to Metrics: Elementary and advanced analysis methods with an introduction to data analysis in R.
- Communication of results: communication with academia, regulators, pharmaceutical industry, writing a pharmacoepidemiological paper.

By Harvard Medical School

D4M4. EFFECTIVENESS RESEARCH WITH LONGITUDINAL DATABASES

75 hours over 3 months
Intermediate course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Introduction to Effectiveness Research with Longitudinal Healthcare Databases.
- Topics in Design and Analysis of Longitudinal Healthcare Database Studies.

Medicines benefit-risk assessment

By University of Utrecht

D5M1. INTRODUCTION TO BENEFIT-RISK ASSESSMENT AND PHARMACOECONOMICS IN DECISION MAKING

75 hours over 3 months Student: **1,500 €** / Professional: **3,000 €**
Introductory course level Eu2P Partner: **2,100 €**

- Introduction.
- Benefits.
- Risk/Harms.
- Principles and methods of comparative benefit-risk assessment.
- Principles of Pharmacoeconomics.

D5M2. PRINCIPLES OF PHARMACOECONOMICS AND VALUATION OF HEALTH STATES

75 hours over 3 months Student: **1,500 €** / Professional: **3,000 €**
Intermediate course level Eu2P Partner: **2,100 €**

- Introduction.
- Costs.
- Effects.
- Pharmacoeconomic analysis.
- How to perform a good pharmacoeconomic evaluation.

Medicines benefit-risk assessment

By University of Utrecht

D5M3. FUNDAMENTALS OF QUANTITATIVE BENEFIT-RISK ASSESSMENT METHODS IN DECISION MAKING ON MEDICINES

75 hours over 3 months
Intermediate course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Introduction to benefit-risk analysis methods.
- Benefit/Risk assessment during life cycle of medicines.
- Measures based on statistics/simulation.
- Health outcomes models.

D5M4. ADVANCED QUANTITATIVE BENEFIT-RISK ASSESSMENT METHODS IN DECISION MAKING ON MEDICINES

75 hours over 3 months
Advanced course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Multi-criteria decision analysis.
- Conjoint analysis.
- Personalised benefit-risk assessment.

Medicines and public health

By Universitat Autònoma de Barcelona

D6M1. BASICS IN PHARMACOEPIDEMIOLOGY

75 hours over 3 months
Introductory course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Patients, medicines and prescribing in society. Life cycle of medicines.
- The knowledge-building process of the effects and adverse effects of medicines during their development and clinical use.
- Overview of studies to detect and to evaluate the risk associated with therapeutic interventions. Scope, uses and limitations.
- The need to monitor the medicines prescribing process.
- Introduction to the study of the use of medicines in clinical practice.

D6M2. DRUG UTILISATION STUDIES: INTRODUCTION AND QUANTITATIVE METHODS

75 hours over 3 months
Intermediate course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Measurement of drug use.
- Overview of drug utilisation studies (DUS).
- Quantitative measures of drug utilisation.
- Design of quantitative DUS.
- How to read papers on quantitative DUS.

Medicines and public health

By Universitat Autònoma de Barcelona

D6M3. DRUG UTILISATION STUDIES: QUALITATIVE METHODS

75 hours over 3 months | Student: **1,500 €** / Professional: **3,000 €**
Intermediate course level | Eu2P Partner: **2,100 €**

- Sources of data and standards to compare with.
- Methods to identify how medicines are used in the community (1) - prescription vs. indication and indication vs. prescription.
- Methods to identify how medicines are used in the community (2) - cohort and case-controls studies as a source of drug utilisation data.
- Design of qualitative DUS: Objectives, methods and discussion of proposals.
- How to read papers on qualitative DUS. Limitations of DUS.

D6M4. THE PUBLIC HEALTH IMPACT OF ADVERSE DRUG REACTIONS

75 hours over 3 months | Student: **1,500 €** / Professional: **3,000 €**
Advanced course level | Eu2P Partner: **2,100 €**

- Data generalization: from particular cases to population impact-1.
  The interpretation of the results of clinical trials and meta-analyses from the public health point of view.
- Data generalization: from particular cases to population impact-2. Examples of the value of observational studies and meta-analyses of observational studies in the evaluation of the public health impact of medicines use.
- Public health impact - Case: Hormone replacement therapy.
- Public health impact: Beyond case - Control studies.
- The importance of the denominator: case-population studies. The future of pharmacovigilance.

Medicines risk communication

By Università degli Studi della Campania Luigi Vanvitelli

D7M1. BASICS IN MEDICINES RISK COMMUNICATION

75 hours over 3 months
Introductory course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Which knowledge and skills are useful for communication?
- Concrete examples of communication: what do we retain?
- Why communicate? Nature and importance of communication. Personal and social dimension of communication.
- Face to face between doctor and patient. How to find the right word?

D7M2. INFORMATION AND COMMUNICATION ABOUT BENEFIT-RISK OF MEDICINES. BASIC PRINCIPLES.

75 hours over 3 months
Introductory course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Principal actors in communication on medicines risk, of traditional and new forms of communication, of routes of communication and their evolution through time.
- Basis of risk communication process.
- Regulatory responsibilities and requirements concerning medicines risk communication.
- Communication of actual and alleged risks associated to medicines: 3 different scenarios.

Medicines risk communication

By Université de Bordeaux

D7M3. KEY ROLES AND STAKEHOLDERS IN MEDICINES RISK COMMUNICATION: DUTIES AND CHALLENGES

75 hours over 3 months
Advanced course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Hepatitis B vaccine in France, pandemic influenza vaccines, HRT and cancer. What can we learn? What could have been done?
- Communication aspects based on drug withdrawals: e.g. rofecoxib, rosiglitazone, benfluorex. What can we learn? What could have been done?
- How to measure the effectiveness of risk communication.
- Active participation.

D7M4. CASE STUDIES IN MEDICINES RISK COMMUNICATION

75 hours over 3 months
Advanced course level

Student: **1,500 €** / Professional: **3,000 €**
Eu2P Partner: **2,100 €**

- Hepatitis B vaccine in France, pandemic influenza vaccines, HRT and cancer. What can we learn? What could have been done?
- Communication aspects based on drug withdrawals: e.g. rofecoxib, rosiglitazone, benfluorex. What can we learn? What could have been done?
- How to measure the effectiveness of risk communication.
- Active participation.

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