# The Am2P Certificate programme

## Get an academic Certificate

- The Am2P Certificate leads to **academic Awards in pharmacovigilance and pharmacoepidemiology jointly delivered by the European Universities** working together as Eu2P partners.
- Standard Am2P certificates learning achievements are **recognised as 3 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

- Am2P 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 Am2P Certificates have been **built by the academic, regulatory and industrial Consortium partners**. These certificates are **grounded in real job market** and today's practices.
- Am2P 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**, Am2P 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 months period** (depending on the course ECTS credits).
- The Certificate diploma is **awarded after a final assessment session**.

## Enjoy affordable prices

| Students | Professionals | Am2P Partner |
|---|---|---|
| $1,750 | $3,500 | $2,450 |

**Am2P 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**: am2p.office@am2p-courses.com

## Powered by

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# Am2P
AMERICAN PROGRAM IN PHARMACOVIGILANCE

# BOOST YOUR US CAREER IN DRUG SAFETY WITH ONLINE CERTIFICATES


ISoP North America Chapter NASoP

# Am2P CERTIFICATES CATALOGUE

North America Chapter
NASoP

Check upcoming certificates on www.am2p-courses.com

## Basic Pharmacovigilance and Pharmacovigilance Regulations

Over 3 months / $1,750 / $3,500 / $2,450

**OBJECTIVES**

- The requirements for Pharmacovigilance in the United States as compared to the ones in the European Union, for Pre-approval and Post-approval and the imminent changes in the European Union and in the United States.
- The legal framework that governs pharmacovigilance and the central role of the QPPV in pharmacovigilance practice.
- The safety communication processes and the safety risk management approach, including the safety label change process.
- The principles of prescription drug labeling in the United States, the FDA requirements for prescribed drug labels and the United States Prescribing Information (USPI).
- The analysis of the safety profile of any medicine which should weight up the consequences of a given adverse drug reaction to individual patients exposed to the medicine, as well as the impact on the community.

**MODULE PARTS**

1. Pharmacovigilance Regulations
2. Labeling and Combination Products
3. Adverse Drug Reporting

## Pharmacovigilance for biologics

Over 3 months / $1,750 / $3,500 / $2,450

**OBJECTIVES**

- An overview of the concepts and principles of vaccines pharmacovigilance in USA.
- A review of the current pharmacovigilance requirements for Gene Therapy including clinical development and long-term follow-up, pharmacovigilance complexities with regard to different type of Gene Therapy as described within FDA guidance, EU perspective for development of ATMP and high level understanding of ethical consideration.
- An overview and classification of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) followed by HCT/Ps development and regulatory requirements.
- Understand the current therapeutic landscape of cancer therapy, learn about the history of targeted therapeutics, and their classification, understand how targeted therapeutics differ in their adverse event profile and reporting, appreciate specific regulatory differences in the US FDA regarding targeted therapeutics, understand the future directions of targeted therapies and understand the current therapeutic landscape of cancer therapy.

**MODULE PARTS**

1. Vaccine Pharmacovigilance
2. Gene Therapy
3. Pharmacovigilance for Human Cells, Tissues and Cellular and Tissue-Based Products
4. Targeted therapy

## External databases RWD - RWE

Over 3 months / 1,500 € / 3,000 € / 2,100 €

**OBJECTIVES**

- Have an overview of the FAERS database, particularly the FDA Adverse Event Reporting System (FAERS), Access to the system, Uses of FAERS, Interpretation of statistical safety signals, Strengths of the FAERS Database and Limitations of the FAERS Database.
- Have an overview of the FDA Sentinel System, particularly on the current FDA Sentinel Monitoring System and the future FDA strategies to enhance Sentinel over the next 5 years.
- Discuss new data sources for information on medicines consumption, describe some of these new data sources through a reflection based on a couple of practical examples and critically assess some advantages and biases of these kind of studies.
- Highlight the importance of how patients actually use medicines in the appearance of adverse drug reactions, discuss some examples showing the potentiality of analysing the characteristics of use of medicines, help you to identify potential sources of information on medicines use and discuss strengths, limitations and biases of different sources of information describing medicines use.

**MODULE PARTS**

1. FDA System
2. Databases

## Benefit-Risk Assessment

Over 3 months / $1,750 / $3,500 / $2,450

**OBJECTIVES**

- The different qualitative frameworks and basic quantitative methods for Benefit-Risk assessment, including their potentials and limitations.
- Insight in the changing health care environment and gives an overview of the different stakeholders that are involved in pharmacotherapeutic decision-making. Specific attention is given to the drivers and background of the different stakeholders and the rationale of benefit/risk and pharmacoeconomic evaluations in decision-making.
- An overview and to define the concepts necessary to built a risk management plan for medicinal product.
- Define the general principles needed to build a process for developing Risk Management Plans for a medicinal product by the Industry. This course is based on the experience of a large international pharmaceutical company.
- An introduction to REMS principles, content, implementation, reporting and assessment, When a REMS is required and the Differences between REMS and RMP.

**MODULE PARTS**

1. Benefit-risk assessment of medicines
2. Risk Management

● Introductory course level ● Intermediate course level