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 2 to 3 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 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 Am2P certificate** for your achieved competencies

How does it cost?

Affordable prices

Students & Professionals	Companies
Annual registration for one short course per person from $230 to $350	**Custom package** Quote on request

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

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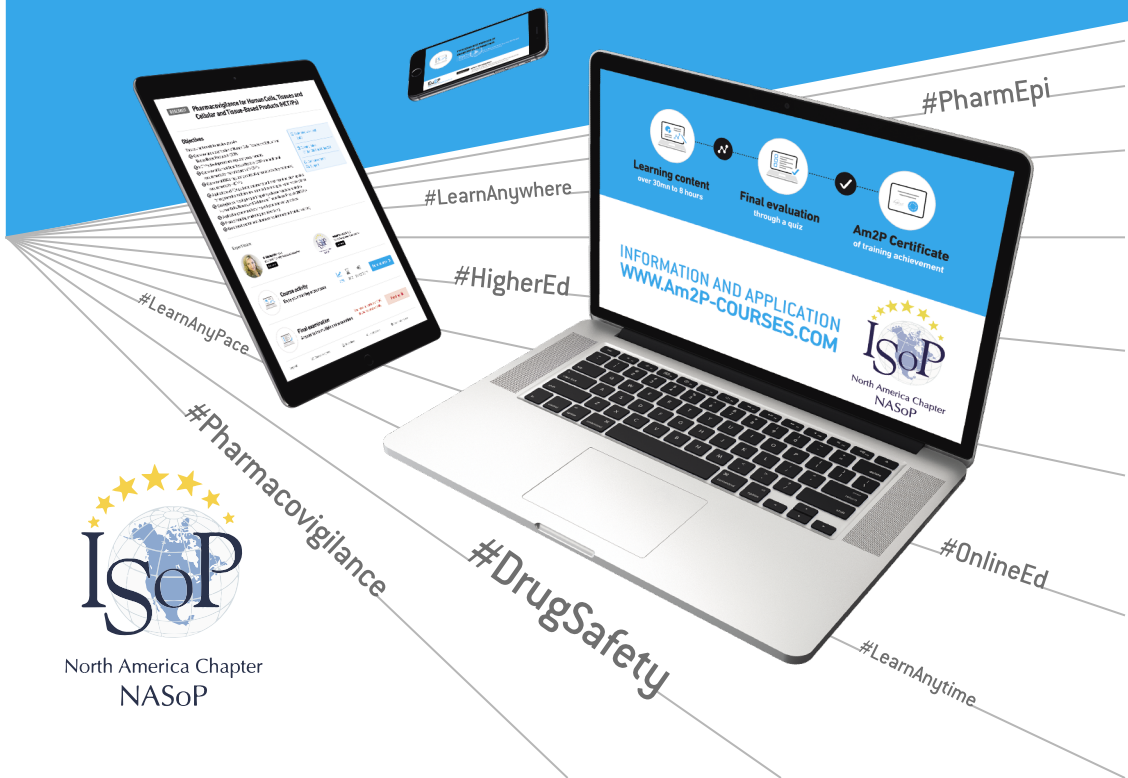
Am2P
AMERICAN PROGRAM IN PHARMACOVIGILANCE

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



ISoP North America Chapter NASoP

Am2P SHORT COURSES CATALOGUE

North America Chapter
NASoP

Basic Pharmacovigilance and Pharmacovigilance Regulations

Pharmacovigilance Regulations

1. US/EU regulations: principles and comparison	3h	$350
2. Overview of the Legal Basis of PV Regulations and the Role of the QPPV	3h	$350

Labeling and Combination Products

3. Principles of Labeling and Description of United States Prescribing Information (USPI)	3h	$350
4. Pharmacovigilance in Combination Products and Regulations	3h	$350

Adverse Drug Reporting

5. From individual cases to the community impact of adverse drug reactions	2h	$230
6. Aggregate reporting in the US	2,5h	$290

Pharmacovigilance for Biologics

Vaccine Pharmacovigilance

1. Vaccines Biologics Regulations	3h	$350

Gene Therapy

2. Gene therapy	3h	$350

Pharmacovigilance for Human Cells, Tissues and Cellular and Tissue-Based Products

3. Pharmacovigilance for HCT/Ps	3h	$350

Targeted therapy

4. Targeted Therapeutics	3h	$350

External databases/RWD/RWE

FDA System

1. FDA Adverse Event Reporting System (FAERS)	2,5h	$290
2. FDA Sentinel System	2,5h	$290

Databases

3. Health care records from large databases as a tool to study the use of medicines	2h	$230
4. Integrating Pharmacovigilance and consumption data analysis - uses, limitations and potentiality	2h	$230

Benefit Risk Assessment

Benefit-risk assessment of medicines

1. Principles and methods of benefit-risk assessment in decision-making of medicines	2h	$230
2. Role of benefit-risk assessment and pharmaco-economics in decision-making of medicines	2,5h	$290

Risk Management

3. Concepts in Risk Management	3h	$350
4. Organization for risk management in the industry	3h	$350
5. Risk Evaluation and Mitigation Strategy (REMS)	2,2h	$260

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