INSTITUTE
OF PHARMACOVIGILANCE

ISoP

Pharmacovigilance Awareness

A Limited-Time Pilot Program to Shape the Future of PV Certification

Study Guide

Content

About

Pharmacovigilance Awareness for Healthcare Professionals

This certification covers the basic principles of pharmacovigilance, especially its practical use, and is intended for all health care occupations dealing with medicines, such as caregivers, nurses, or pharmacists.

The candidate's knowledge is evaluated via an online AI proctored multiple-choice test, whose content is derived from the competency standard for this role.

Number of questions: 30
Length: 60 minutes
Score needed to pass: 80%
Number of attempts: 3

Certification process

Registration	Prerequisites check	Certification purchase	Taking the test	Certificate issued
The registration is done using the SpeedExam testing platform via this link:https://candidate.speedexam.net/signin.aspx?site=ipv During the registration, you will be asked to provide your name (this will appear on the certificate), a functional email address and select your group – the certification you are interested in.	All mandatory prerequisites are checked prior to the admission to the certification process via CV screening. You might be asked to provide further proofs on an individual basis (e.g., job descriptions, proof of employment, copies of documents, training records or recommendation letters).	Once your registration has been approved, you will be able to access the platform and purchase the desired certification. The payment can be made with credit / debit card or your PayPal account. Upon successful payment, you will receive a confirmation and now have 365 days to take the exam.	The candidate's general and specific knowledge is evaluated via an online, AI proctored multiple-choice test. Unusual behaviour, such as minimizing the browser, taking a screenshot, another face or mobile phone detected, etc. is automatically evaluated and the exam may be terminated in case of severe breach.	Once you have successfully passed all the parts of the examination, a certificate will be issued to you. You can download it as a PDF directly from the testing platform. The validity of the certificate is 3 years and counts from the day the certificate was issued.

Knowledge tested

	General Knowledge	Level
1.	Pharmacovigilance definition, aim, and objectives	●○○ Basic
2.	Pharmacovigilance history	●○○ Basic
3.	Stakeholders in pharmacovigilance	●○○ Basic
4.	Safety monitoring of medicinal products	●○○ Basic
	Role Specific Knowledge	
1.	The safety of medicines in public health programmes	●○○ Basic
2.	Collecting high quality ADR reports	●○○ Basic
3.	Essentials of pharmacovigilance communications	●○○ Basic

Concept of levels

Level	Expected knowledge
N/A	No knowledge required
Basic	Elementary knowledge level of the specific regulation; fundamental understanding of the terms and definitions used, a basic understanding of the concept of the regulation, general overview of what is included in the regulation and what topics it covers, where the regulation can be found and what situations and processes it applies to, passive/delegated usage of the regulation
Intermediate	Very good knowledge level of the specific regulation; unequivocal understanding and usage of the terms and definitions, complex understanding of the concept of the regulation, topics covered by it and its context regarding who/when/where/why/how it applies to, active usage of the regulation when required
Expert	Excellent knowledge of the specific regulation; sterling understanding and usage of the terms, in-depth knowledge of the concept of the regulation, detailed knowledge and comprehensive understanding of the topics covered by the regulation, who/when/where/why/how the regulation and its sections should be implemented and followed, as well as specific outcomes and responsibilities resulting from the regulation regarding all relevant stakeholders, active usage of the regulation on daily basis

Types of questions – definitions

Sample question	Commentary
→ What is the term for a system whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority? a) Record linkage **b) Spontaneous reporting** c) Active surveillance system d) Product stewardship	→ This type of questions asks you to determine the best term for a given definition or vice-versa. All of the questions are multiple-choice with four possible answers and only one of them is always the correct one.

Types of questions
- about facts and principles

Sample question

→ Why are the results from clinical trials incomplete with regard to possible adverse reactions?

a) Clinical trials are based on theoretical research only.
b) Patients from clinical trials are not qualified enough to sufficiently describe the reactions.
c) The number of patients and duration is limited.
d) Clinical trials do not study adverse reactions.

Commentary

→ This type of questions asks you for a specific fact or principle applied in pharmacovigilance. The information can be found in one of the reference documents, usually fairly explicitly.

All of the questions are multiple-choice with four possible answers and only one of them is always the correct one.

The questions might also be in negative with NOT capitalized.

Our tips

Check the settings

All the examinations are proctored, which means that a video and audio recording will be made of you and your computer. It is highly recommended you check your system compatibility at the testing platform in advance. During the exam, it is necessary to be in a quiet environment and alone, so try to minimize the risk of any interruptions which might disturb the exam.

Read carefully

Make sure you read all the questions carefully and thoroughly – sometimes overlooking even one word can change the whole meaning. Same applies to the answers. While there is always one correct answer, this one might be similar to another option. Pay special attention to negatively-worded questions.

Manage your time

There is always a set time limit for you to complete the whole examination, so keep an eye on the timer, which will be visible during the examination. The examinations are designed to provide sufficient time to comfortably answer all the questions, but always consider your usual pace. Before the test, you will know how many questions from which category to expect, so use this to prepare even better.

Navigating the test

During the test, you will be able to skip and go back to questions, even between the individual test sections. You will always be able to see answered, unanswered and flagged questions, which allows you to advance through the test as you wish. It might be a good idea to keep the unsure answers marked for another revision later.

Do not stress out

In case you feel too stressed about the exam, we recommend you postpone taking it and dedicate a little more time to the preparation. Afterall, the examination is available 24/7 and up to 365 days from the date of purchase. You also have more than one attempt. If anything goes wrong during the exam, do not hesitate to reach out to us for support.

Reference documents

	General Knowledge	Link
1.	Pharmacovigilance definition, aim, and objectives WHO Uppsala Monitoring Centre. Safety Monitoring of Medicinal Products, Guidelines for setting up and running a Pharmacovigilance Centre. Uppsala: Uppsala Monitoring Centre; 2000. ISBN 91 630 9004 X	https://who-umc.org/
2.	Pharmacovigilance history M D B Stephens. The dawn of drug safety : the discovery, reporting and management of adverse drug reactions prior to Thalidomide. Easton, Winchester, Hampshire England: George Mann Publications; 2012. ISBN 97 8 1907640094	https://who-umc.org/
3.	Stakeholders in pharmacovigilance WHO Uppsala Monitoring Centre. The Importance of Pharmacovigilance. WHO; 2002. ISBN 92 4 159015 7	https://apps.who.int/
4.	Safety monitoring of medicinal products WHO Uppsala Monitoring Centre. Safety Monitoring of Medicinal Products, Guidelines for setting up and running a Pharmacovigilance Centre. Uppsala: Uppsala Monitoring Centre; 2000. ISBN: 91 630 9004 X	https://who-umc.org/
	Role Specific Knowledge	
1.	The Safety of Medicines in Public Health Programmes WHO Uppsala Monitoring Centre. The Safety of Medicines in Public Health Programmes: Pharmacovigilance, an essential tool. WHO;2006. ISBN 92 4 159391 1	https://who-umc.org/
2.	Collecting high quality ADR reports WHO UMC: Collecting high quality ADR reports (online course available for HCPs)	https://learning.who-umc.org/
3.	Essentials of pharmacovigilance communications WHO UMC: Essentials of pharmacovigilance communications (online course available for HCPs)	https://learning.who-umc.org/

INSTITUTE
OF PHARMACOVIGILANCE

Institute of Pharmacovigilance

info@pharmacovigilance.institute

GET CERTIFIED NOW!

We always welcome your comments and input; if you have any, please send us an email.

Thank you for your contribution to the pharmacovigilance profession!

Team of authors

A Limited-Time Pilot Program to Shape the Future of PV Certification