INSTITUTE
OF PHARMACOVIGILANCE

Pharmacovigilance Awareness

For Healthcare Professionals

Jointly developed by:

The International Society of Pharmacovigilance (ISoP)
Special Interest Group on PV Professional Qualification Framework
&
The Institute of Pharmacovigilance

Competency Standard

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Abbreviations

AI	Artificial intelligence
CV	Curriculum Vitae
HCP	Healthcare Professional
N/A	Not applicable
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

Glossary

Attitude	Competency	Competency standard	Knowledge	Skills
A stable, long-lasting, learnt predisposition to respond to certain things in a certain way.[1]	A generic mix of knowledge, skills, and attitudes with broad application.[2]	An industry-determined specification of competencies required for effective work performance.[3]	An outcome of the assimilation of information through learning. Knowledge is the body of facts, principles, theories, and practices that is related to a field of study or work.[4]	An acquired and practiced ability to carry out a task or job. [2]

[1] EU Commission. Transferability of Skills across Economic Sectors. Luxembourg: Publications Office of the EU; 2011. DOI 10.2767/40404.
[2] Tracey W, Bronstein D. The Human Resources Glossary: The Complete Desk Reference for HR Executives, Managers, and Practitioners. 3rd ed. St. Lucie Press; 2003.
[3] Technical Education and Skills Development Authority. The TVET Glossary of Terms. 4th ed. Manila: Planning Office; 2010. ISBN 978-971-34-0207
[4] European Centre for the Development of Vocational Training. Terminology of European education and training policy. 2nd ed. Luxembourg: Publications Office of the EU; 2008. DOI: 10.2801/15877

Professional Certification

Here is how you can get certified

Prerequisites

All mandatory prerequisites are checked prior to the admission to the certification process via CV screening. The candidate might then 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).

Knowledge

The candidate's general and specific knowledge is evaluated via an online, AI proctored multiple-choice test. The content is derived from reference documents, pharmacovigilance regulations and legally binding documents specified in this guideline.

Terms and conditions

The latest version of Terms and Conditions of GPPC, including detailed requirements for every role and region, can always be found on the Institute of Pharmacovigilance website.

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

Concept of levels – *Example*

Level	Example of knowledge	
N/A	The candidate is not expected to have any knowledge about Pharmacovigilance, its definition, aim, and objectives. The test will not contain any questions reflecting this knowledge.	
Basic	Examples of expected basic knowledge of the candidate might be following what is pharmacovigilance, what is a "pharmacovigilance center", what information does an adverse reaction report contain, etc.	Question: Why are the results from clinical trials incomplete with regard to possible adverse reactions? *Answer: The number of patients and duration is limited.*
Intermediate	This level of knowledge is not required for this role.	
Expert	This level of knowledge is not required for this role.	

Pharmacovigilance: Definition, aim, and objectives

Prerequisites

Mandatory prerequisites

→ Healthcare Professional occupation or student
(e.g., doctor, nurse, pharmacist, other HCPs)

Recommendations

→ Basic working proficiency in English
→ Computer literacy

Knowledge

	General Knowledge	Level
1.	Pharmacovigilance definition, aim, and objectives [5]	●○○ Basic
2.	Pharmacovigilance history [6]	●○○ Basic
3.	Stakeholders in pharmacovigilance [7]	●○○ Basic
4.	WHO UMC: Safety monitoring of medicinal products, Guidelines for setting up and running a Pharmacovigilance centre [5]	●○○ Basic

[5] WHO Uppsala Monitoring Centre. Safety monitoring on medicinal products, Guidelines for setting up and running a Pharmacovigilance Centre. Uppsala: Uppsala Monitoring Centre; 2000. ISBN 91 630 9004 X
[6] M D B Stephens. The dawn of drug safety. Easton, Winchester, Hampshire England: George Mann Publications; 2012. ISBN 97 8 190764009 4
[7] WHO Uppsala Monitoring Centre. The Importance of Pharmacovigilance. WHO; 2002. ISBN 92 4 159015 7

Specific Knowledge

	Chapter I. Regional Regulatory Specific Knowledge	Level
1.	Local regulatory authority guidance for HCPs (if applicable) *Optional; mandatory only for local certificate variants*	●○○ Basic
	Chapter II. Role Specific Knowledge	
1.	WHO UMC: The Safety of Medicines in Public Health Programmes: Pharmacovigilance, an essential tool [8]	●○○ Basic
2.	WHO UMC: Collecting high quality ADR reports (course available for HCPs)	●○○ Basic
3.	WHO UMC: Essentials of pharmacovigilance communications (course available for HCPs)	●○○ Basic

[8] WHO Uppsala Monitoring Centre. The Safety of Medicines in Public Health Programmes: Pharmacovigilance, an essential tool. WHO;2006. ISBN 92 4 159391 1

WHO Pharmacovigilance Core Curriculum for University Teaching

PV Awareness for HCPs closely corresponds with the following summary of the key aspects and content of the WHO Pharmacovigilance Core Curriculum for University Teaching [10]

Knowledge element	Knowledge	Skills	Attitude
Understanding the importance of PV	Drug-induced harm and hospital admission	Recognizing ADRs and their impact on individual patients	Open mindedness of adverse outcomes of drug use in pharmacotherapy
	Historical examples		
Preventing ADRs	General risk factors	Choosing right drug treatment	Safe prescribing / dispensing
	Individual risk factors		
	Treatment guidelines and safety information		
Recognizing ADRs	ADR classification	Clinical and causality reasoning	Awareness of predictable and unexpected ADRs
	Risk factors		
	Confounding factors		
	Epidemiology		

[10] van Eekeren R, Rolfes L, Koster A, Magro L, Parthasarathi G, Al Rammimy H, Schutte T, Tanaka D, van Puijenbroek E, Harmark L. What Future Healthcare Professionals Need to Know About Pharmacovigilance: Introduction of the WHO PV Core Curriculum for University Teaching with Focus on Clinical Aspects. Drug Saf. 2018; 41:1003-1011.

WHO Pharmacovigilance Core Curriculum for University Teaching

Knowledge element	Knowledge	Skills	Attitude
Managing ADRs	ADR classification	Choosing right actions	Optimize risk- benefit balance in an individual patient
	Seriousness	Patient and HCP communication	
	Severity	Recording of ADRs data	
Reporting ADRs	Limitations of premarketing phase	Recognizing ADRs in practice and reporting form completion	Responsibility for sharing (reporting) of ADRs
	Relevance of ADR reporting		
	Documentation of ADRs		

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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