ISoP Global Competency Standard

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

Jointly developed by:

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

INSTITUTE OF PHARMACOVIGILANCE

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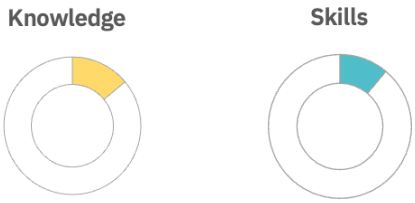
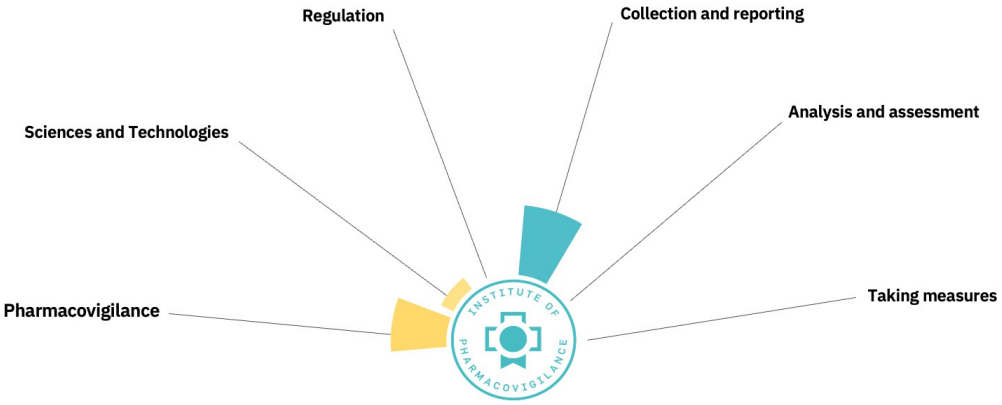
This competency standard covers the basic principles of pharmacovigilance, especially its practical use, and is intended for all professionals who might encounter pharmacovigilance during their work.





Typical profile

→ **Mandatory requirements as per applicable regulation**

→ No specific background prerequisites

More about this role

Complete information about the role, including typical job description and responsibilities can be found in the PV Career Framework prepared by members of ISoP Special Interest Group on PV Professional Qualification Framework and Institute of Pharmacovigilance.
This document is available at:
https://pharmacovigilance.institute

Knowledge

	Pharmacovigilance	Level	
1.	Pharmacovigilance aim, scope, and history	●○○	Basic
2.	PV glossary and definitions	●○○	Basic
3.	Ethics and leadership in pharmacovigilance	●○○	Basic
4.	Societal burden of adverse reactions to medicines	●○○	Basic
5.	The global PV-relevant regulatory landscape (including data privacy)	●○○	Basic
6.	Architecture of pharmacovigilance system (industry, regulators, other)	●○○	Basic

	Sciences and Technologies	Level	
1.	Mechanisms underlying adverse reaction to medicines	○○○	N/A
2.	Information Technologies systems applied to pharmacovigilance	○○○	N/A
3.	Collection, processing, and medical evaluation of safety data	●○○	Basic
4.	Detection and management of safety signals. Benefit vs Risk evaluation	○○○	N/A
5.	Risk management planning and risk minimisation methods	○○○	N/A
6.	Safety decision making (including labelling variation)	○○○	N/A
7.	Pharmacoepidemiology and safety data generation	○○○	N/A
8.	Generation, distribution, and evaluation of safety regulatory documents	○○○	N/A
9.	Quality Management of PV-Relevant processes (QC, QM, QA, A&I)	○○○	N/A
10.	Product quality safety management	○○○	N/A

	Local regulation	Level	
1.	Local applicable regulations	○○○	N/A

○○○ N/A – No knowledge required
●○○ Basic – Fundamental understanding of terms and concepts, general overview
●●○ Intermediate – Complex understanding of terms and concepts
●●● Expert – In-depth understanding, detailed knowledge of specific outcomes and responsibilities

Skills

	Collection and reporting	Level	
1.	Collecting spontaneous adverse drug reaction reports	●○○	Basic
2.	Collecting reports using active surveillance	○○○	N/A
3.	Reporting of suspected adverse reaction	●○○	Basic

	Analysis and assessment	Level	
1.	Data management in pharmacovigilance	○○○	N/A
2.	Signal management in pharmacovigilance	○○○	N/A
3.	Interaction between PV and product quality defect systems	○○○	N/A
4.	Benefit-Risk evaluation of authorized medicinal products	○○○	N/A
5.	Periodic Benefit-Risk Evaluation reporting	○○○	N/A
6.	Risk management of medicinal products	○○○	N/A

	Taking measures	Level	
1.	Safety Variations	○○○	N/A
2.	Safety Communication to competent authorities	○○○	N/A
3.	Safety Communication to healthcare professionals and patients	○○○	N/A
4.	Management of post-authorisation pharmacovigilance commitments	○○○	N/A

	General skills	Level
-	-	-

○○○ N/A – Skill not required
●○○ Basic – Passive/delegated usage
●●○ Intermediate – Active usage when required, often in collaboration with other specialists
●●● Expert – Active usage on daily basis, usually responsible person, or leader of activities

Attitude

	Cognitive competencies	
-	-	-

	Intrapersonal competencies	
-	-	-

	Interpersonal competencies	
-	-	-

Developed and delivered by: INSTITUTE OF PHARMACOVIGILANCE

GLOBAL PHARMACOVIGILANCE PROFESSIONAL CERTIFICATION

ISoP and IPV aim at the GPPC becoming the new global pharmacovigilance qualification assessment standard for competency to perform specific pharmacovigilance roles. This guideline relates to **a Limited-Time Pilot Program to Shape the Future of PV Certification**

Knowledge

Identified knowledge is evaluated via an online, AI-proctored multiple-choice test, which can be taken from anywhere.

Local regulation

**Optional part*

This online test covers applicable PV-relevant regulatory frameworks knowledge for specific countries or regions.

Where to start?

To understand what exactly is required to pass the certification, we have put together a Study guide, in which you will find suggested reading along with examples of questions. You can find this document on our website and there is also a short demo version of the online test available for purchase.

Skills

This certification does not test your skills.

Attitude

This certification does not test your skills.

UPGRADE YOUR CAREER AT PHARMACOVIGILANCE.INSTITUTE

International Society of Pharmacovigilance is an international non- profit scientific organisation, which aims to foster Pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, in all countries.

INSTITUTE OF PHARMACOVIGILANCE

Institute of Pharmacovigilance is a not-for-profit, non-governmental organisation with a clear goal – to elevate the pharmacovigilance profession by competency and seniority certification.

We always welcome your comments and input; if you have any, please send us an email to info@pharmacovigilance.institute