ISoP Global Competency Standard

for Qualified Person in Pharmacovigilance (QPPV)

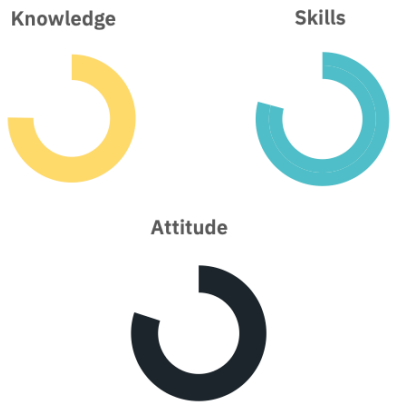
Jointly developed by:

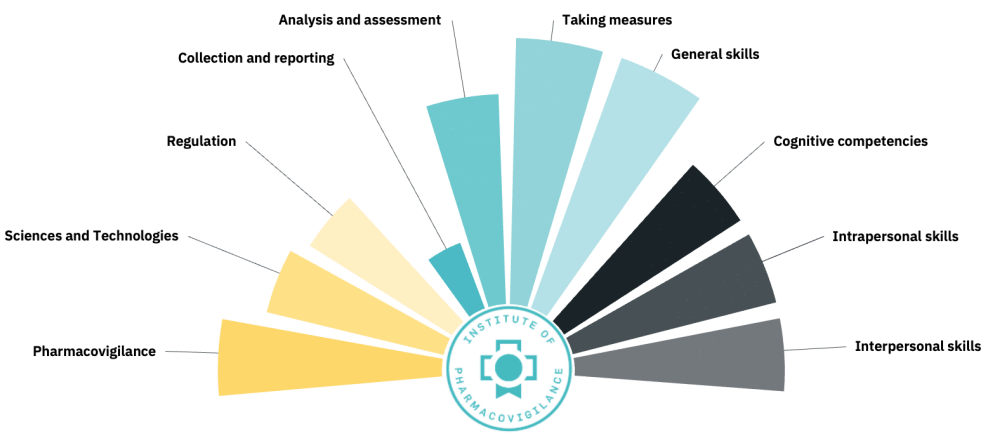
International Society of Pharmacovigilance (ISoP)
ISoP Special Interest Group on PV Professional Qualification Framework
Institute of Pharmacovigilance (IPV)

INSTITUTE OF PHARMACOVIGILANCE

Qualified Person Responsible for Pharmacovigilance (QPPV)

A QPPV establishes and maintains a pharmacovigilance system, provides Health Authorities with information relevant to product safety and is delegated by the MAH to be personally responsible for the safety of human pharmaceutical products marketed by a company in a given country or region.





Typical profile

- → **Mandatory requirements as per applicable regulation**
- → Minimum of 5 years of experience in critical areas of PV
- → Minimum undergraduate degree in Life sciences
- → Medical degree in human medicine strongly recommended
- → Exposure to competent authority inspection
- → MedDRA Coder certification
- → Proficiency in English, computer literacy

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	●●●	Expert
2.	PV glossary and definitions	●●●	Expert
3.	Ethics and leadership in pharmacovigilance	●●●	Expert
4.	Societal burden of adverse reactions to medicines	●●○	Intermediate
5.	The global PV-relevant regulatory landscape (including data privacy)	●●○	Intermediate
6.	Architecture of pharmacovigilance system (industry, regulators, other)	●●○	Intermediate
7.	Industry-specific knowledge	●●●	Expert

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

	Local regulation	Level	
1.	Local applicable regulations	●●○	Intermediate

○○○ 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	●○○	Basic
3.	Reporting of suspected adverse reaction	●○○	Basic

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

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

	General skills	Level	
1.	Business continuity of pharmacovigilance systems	●●●	Expert
2.	Good Documentation Practices	●●●	Expert
3.	Good Clinical Practices	●●●	Expert
4.	Data Privacy Protection	●●●	Expert

○○○ 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

	Cognitive competencies	
1.	Strategic thinking	
2.	Analysis and use of information	
3.	Decision making	

	Intrapersonal competencies	
1.	Ethical	
2.	Independent	
3.	Professional	
4.	Performance oriented	

	Interpersonal competencies	
1.	Leadership	
2.	Influencing	
3.	Communication	

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 and elevating the standard of knowledge of pharmacovigilance profession as well as providing benchmarks for individual roles.

PV knowledge

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

QPPV knowledge

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

Where to start?

To understand what exactly is required to pass the certification, we have prepared 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.

Regulation

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

Oral exam

Assessed via Examination Board interview evaluating overall PV competence and decision-making in practical scenarios.

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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.

ISoP

INSTITUTE OF PHARMACOVIGILANCE

Institute of Pharmacovigilance is a not-for-profit, non-governmental organisation with a clear goal – to elevate the pharmacovigilance industry 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