

Role of QPPV, Staff and Management

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Setting the Scene

Qualified Person responsible for Pharmacovigilance QPPV

- QPPV important natural person for Pharmacovigilance in many jurisdictions
- A QPPV must be designated by the company – requires a PV system in place
- EMA GVP Module I provides extensive description of qualification and roles and responsibilities
- No published consensus on effective implementation – what means “qualified”



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Guideline on good pharmacovigilance practices (GVP)

Module I – Pharmacovigilance systems and their quality systems



I.C.1.1. Responsibilities of the marketing authorisation holder in relation to the qualified person responsible for pharmacovigilance in the EU

I.C.1.2. Qualifications of the qualified person responsible for pharmacovigilance in the EU

I.C.1.3. Role of the qualified person responsible for pharmacovigilance in the EU

Responsibilities of the MAH

GVP Module I

MAH must have an *appropriately qualified* person responsible for PV at its disposal

- Permanently
- Continuously
- Residing and operating in the country of MA (for EU /EEA within an EU country)
- Backup procedures must be in place

MAH to submit name and contact details to NRA (in the EU to MS and EMA)

- Each PV system can have only one QPPV
- In the EU MS can request for a national PV contact person / national QPPV reporting to the QPPV

Duties defined in the job description

Hierarchical relationship defined in Org chart

- Org chart to contain other managerial and supervisory staff

Provide sufficient authority to QPPV

- to influence the performance of the PV Quality System
- to influence the pharmacovigilance activities
- to have access and authority over the PSMF

Ensure structures and processes are in place that QPPV can fulfill the required responsibilities

Responsibilities of the QPPV

GVP Module I

QPPV responsible for establishment and maintenance of the MAH's PV System

- Ensure and verify the information on the PSMF is accurate and up-to-date
- Must have oversight over all relevant aspects of the PV System

Specific responsibilities regarding the medicinal products

- Overview of the products safety profile and emerging safety concerns
- Awareness of MAH's commitments / obligations relating to safety or safe use of the products
- Awareness of risk minimization activities
- Awareness and authority over RMPs
- Awareness of PASS
- Submission (sign off) of all PV-related documents (e.g., PSURs, RMPs)
- Ensure quality, correctness and completeness of PV data submitted
- Ensure prompt response to any request from a NRA for provision of additional information
- Provide relevant information on B/R evaluation to NRAs
- Provide input to preparation of regulatory actions due to emerging safety concerns (e.g., communication to patients and health care providers)
- Act as a single contact point for NRA on a 24h basis
- Contact point for regulatory PV inspections

Qualification of the QPPV

GVP Module I

Adequate theoretical and practical knowledge of the performance of PV activities

- Skills for management of PV Systems
- Expertise or access to expertise in medicine, pharmaceutical science, epidemiology , biostatistics
- QPPV must have university qualifications, knowledge and experience in pharmacovigilance
 - Academic qualifications preferred: MD, PharmD
- In case QPPV does not have basic medical training QPPV must have access to a medically trained person (to be documented)
- Continuous training

QPPV Oversight of the PV System

GVP Module I states: “The QPPV has oversight over the functioning of the system in all relevant aspects, including its quality system...”

GVP Module I states : “The QPPV may delegate specific tasks, under supervision, to appropriately qualified and trained individuals...”

The QPPV is always ultimately accountable

GVP Module II.B.4.8. (PSMF) states: “... the list of tasks that have been delegated by the QPPV shall also be included in the Annexes.”

What does delegation of QPPV tasks mean?

Delegation must be clearly defined and understood

Delegation means empowering and freedom to act

- SOPs and related documents important for capturing the details of delegation
- Instructions need to be explicit

Different levels of delegation

- Delegation of responsibility: Refers to work that is delegated, i.e., the job, the task, the duty
- Delegation of authority: Refers to the power or right to make and implement decisions to come to a successful conclusion / outcome
- Delegation of accountability: For the QPPV not possible as the QPPV is ultimately accountable for success or failure of the delegated responsibility for a job or task

Deputisation

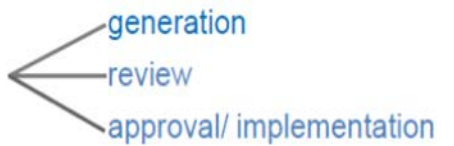

- Special role of delegation is the Deputy QPPV, however not defined in the legislation,
- MAH and QPPV to define what deputisation involves, e.g., act on behalf of the QPPV in special situations
- Clear roles and responsibilities defined in the job description of the Deputy QPPV

What does QPPV System oversight mean?

Have mechanisms in place to ensure QPPV receives all relevant information on:

- emerging safety concerns
- information on benefit-risk evaluation
- ongoing and completed clinical trials and other studies with relevance to safety
- safety information from contractual agreements
- involvement in contractual agreements with business partners if indirect or direct impact on the PV System
- procedures across the company at every level relevant to PV for consistency and compliance
- validation status of the safety database, incl. any failures and respective corrective actions
- significant changes to the safety database

Input and supervision of PV related quality management

- SOP/process definition 
 - generation
 - review
 - approval/ implementation
- PV quality management plan
- Compliance monitoring 
 - metrics, KPIs
 - audits of HQs affiliates, partners, others
 - CAPA monitoring

What should the MAH expect from the QPPV?

Company reliance on QPPV

- QPPV is the company's expert in relation to all aspects of PV

Part of the management team – internal safety advisor

- Develop “global” PV understanding – QPPV is expected to be the expert
- Be available 24/7 to quickly respond to a broad range of complex questions
- Broad multifunctional role that spreads across licensed products and clinical trials

Strong educational role

- QPPV is expected to keep the company informed on local / global PV legislation
- Contribute to new business processes

Keep current with legislation and safety initiatives

- Provide guidance to maintain company compliance

What should a QPPV expect from the MAH?

QPPV as a high rank position within the company to have authority to act

Regular meetings with company's Senior Management, incl presentations

Ensure QPPV function has resources and organizational support necessary to implement and maintain a compliant PV system

Support QPPV by demonstrating trust and confidence

Training QPPV to develop necessary skills in leadership and delegation

Provide educational opportunities to QPPV to continuously seek best practices to improve efficiency of operation of the PV System

Practicalities

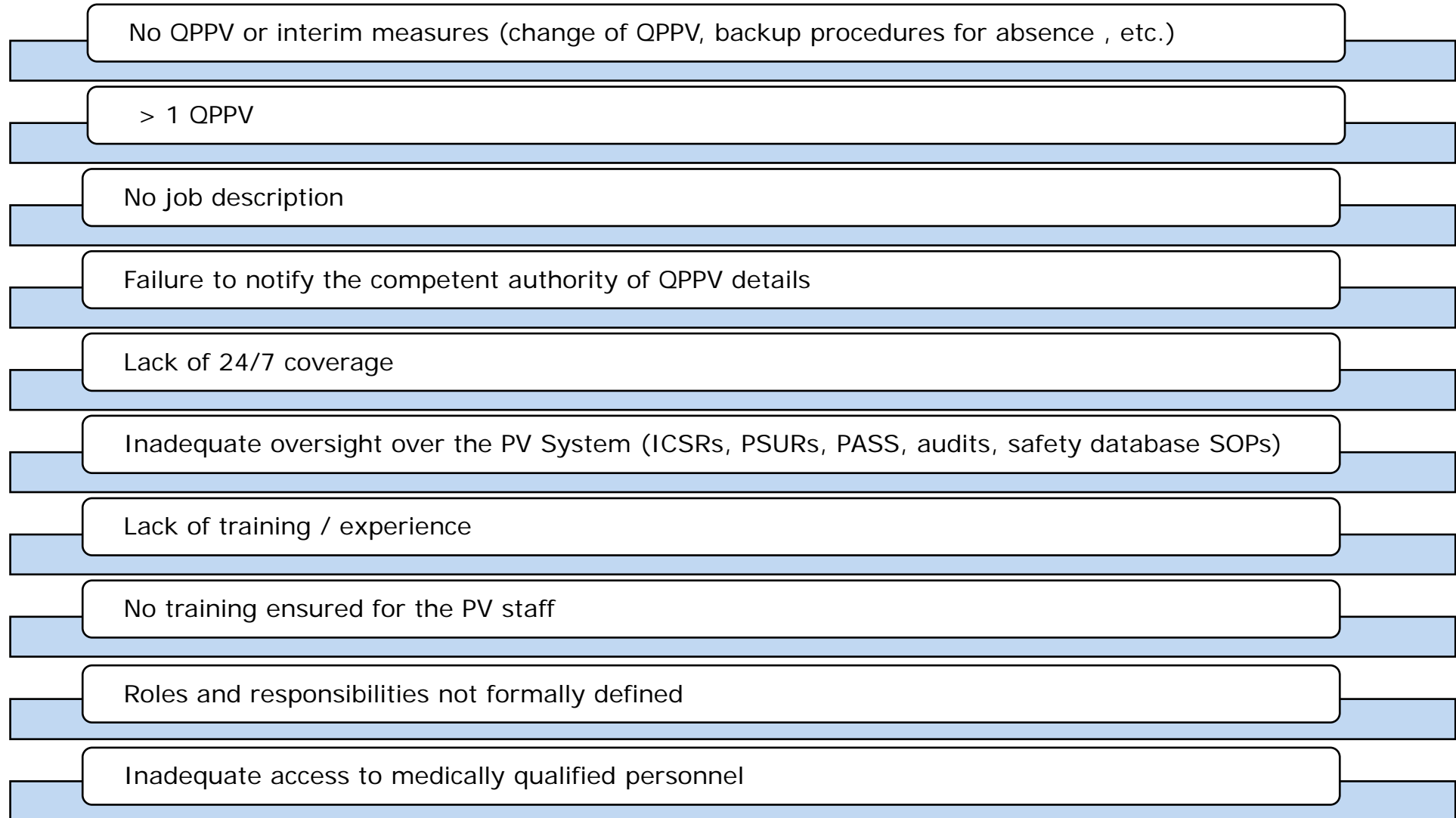
QPPV is a responsible and difficult position – communication and managerial skills are crucial

QPPV must be knowledgeable and able to discuss, e.g., during inspections, safety concerns / crisis

QPPV function can be outsourced, e.g., to consultant or CRO

- Mainly small companies or generic companies may outsource the function
- Delegation must be rigidly and carefully documented and signed off by all parties

Frequent QPPV Inspection findings by EMA



Pharmacovigilance activities

Medical Safety activities in pre- and post-licensure

Management of all safety matters

benefit / risk assessments, decisions, escalation and communication of safety information:

Medical assessment of individual safety information (e.g., AEFIs/ICSRs, SAEs, AESIs/IMEs,)

Safety surveillance: signal detection, labeling for RSI, DCSI, CCSI, SPC

Regulatory safety compliance

Risk management (including EU-RMPs / DRMPs and REMS)

Review / sign off the Safety Sections of all Clinical Trial Documents (e.g., IB, synopsis, clinical trial protocol, CRF, ICF, SAP, CSR)

Aggregate reports (e.g., DSURs, PSURs / PBRERs, monthly reports)

Handling of Urgent Safety Measures

Oversight over all vaccine safety matters

Escalation of safety issues to Senior Management (e.g., Safety Board)

Safety-related communication (internal & external stakeholders)

Pharmacovigilance activities

Operational and QA activities

Management of operational / QA (compliance) pharmacovigilance activities:	Case handling process
	Safety Database
	Regulatory safety compliance
	Regulatory Intelligence
	Compliance management
	PV training: internal / cross functional
	Record management
	Monitoring performance and effectiveness
	Safety Data Exchange Agreements with third parties
	Audit / Inspection readiness
	Business continuation
	Crisis management / Preparedness planning

Training of personnel for pharmacovigilance

All personnel involved in performing PV activities must receive initial and continued training

- Training relates to the roles and responsibilities as per Job Description

Record keeping of training

- Training plans, training documents to maintain and develop personnel competencies must be retrievable and traceable (record management)
- Training records are subject to monitoring / inspection

Training to support continuous improvement of relevant skills and ensure appropriate qualifications

All company members must be trained on what to do when they become aware of a safety concern

Training must be checked (e.g., by tests)

- To ensure training results in appropriate level of understanding / conduct of PV activities

Adequate training to staff with no direct involvement in PV tasks but activities may impact PV

- Such activities include Clinical trials, Product complaints, Medical information, Sales / Marketing, Regulatory affairs, Legal affairs, Audits

Training on business continuity

PV Training practicalities

Have training SOPs in place (training methodology, training records)

Compile a training grid for PV staff training and PV awareness training

Have training slide sets for the different PV SOPs / processes

Have training slide sets for new PV staff relating to the respective roles and responsibilities

Have a training plan for new PV staff

Have training slide set for company new-comer training on PV

Have training slides for company PV refresher training

Have PV training slide sets for specific company functions (e.g., RA, Clin Dev, Marketing, Medinfo, etc.)

PV Training Practicalities

After this training, you will be able to:

- Identify and understand the importance of reporting adverse events, special situations, and product complaints.
- Describe the process to follow when you become aware of an adverse event, special situation, or product complaint.
- Understand your obligations to report.



All COMPANY employees, contractors, vendors, and suppliers (e.g. CROs and call centers), working on behalf of COMPANY must know what is required of them if they are notified of an adverse event, special situation, or a product complaint related to a COMPANY product.

For all vendors and suppliers, this must be detailed in an agreement and training of the appropriate persons must be completed before the start of the program.

Pharmacovigilance and product complaint training is mandatory and required to be repeated on an annual basis.

On the date of contact with the reporter, attempt to obtain the following information:

- Patient identifiers**
 - Initials, date of birth, gender, age or age group.
 - Collecting safety information in the pediatric or elderly population is particularly important, so when collecting safety information, attempt to obtain either the patient's age or age group (e.g., infant, child, adolescent, adult, elderly).
- Adverse Event, Special Situation, or Product Complaint**
 - Brief description of event, situation, or complaint, as depicted by the reporter.
- Reporter**
 - Name and contact details of initial reporter if consent is given.
- COMPANY product name of suspect product**
 - Include Batch/Lot number & Expiry Date if known.
 - Include details of drug combinations, if applicable.
 - Dose/strength.
 - If Product Complaint, report Packing configuration/size if known.

Even if you don't have all the details, report the information you do have.

Know and recognize what qualifies as an **AE, Special Situation, and Product Complaint**, so that when you become aware of one, you do the following:



This must be forwarded to COMPANY PV immediately, preferably within 24 hours, and no later than by next business day.



THANK YOU

Questions ?