Vaccine Safety Monitoring and Pharmacovigilance Tools
Advanced Pharmacovigilance Mini E-Workshop
16-18 March 2020

dcvmn
Developing Countries Vaccine Manufacturers Network

Pharmacovigilance Quality Management System (QMS)

Best Practices

Katharina Hartmann

Pharmacovigilance System

Good Pharmacovigilance Practice - GVP Module I

A pharmacovigilance system is defined as a system used by an organization to fulfil its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of medicinal products and detect any change to their benefit-risk balance.

A pharmacovigilance system, like any system, is characterized by its structures, processes and outcomes.

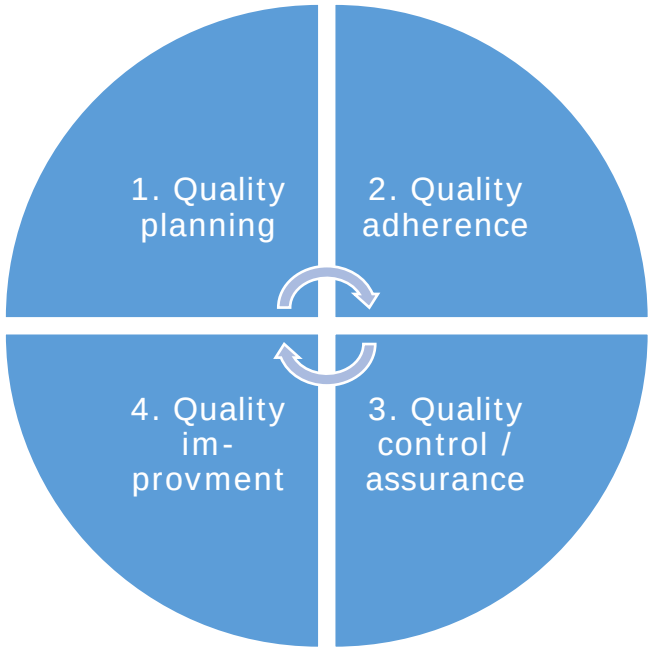
Quality Management System

The Quality System is part of the Pharmacovigilance System and consists of its own structures and processes.

Marketing Authorization Holder (MAH) must have a quality management system in place to support pharmacovigilance activities that have been implemented to meet pharmaco-vigilance legislation guidelines. The Quality System covers the

- Organizational structure
- Responsibilities
- Procedures and processes
- Resources and resource management
- Compliance management
- Record management

Quality Management System
Quality Cycle in GVP



1. Quality planning:

   Establishing structures and planning integrated and consistent processes (e.g., written SOPs)

2. Quality adherence:

   Carrying out tasks and responsibilities in accordance with quality requirements

3. Quality control and assurance:

   At every stage of case / process documentation should be verified for compliance, quality and integrity of data (source data to be recorded and stored)

   Monitoring and evaluating how effectively the structures and processes have been established and how effectively the processes are being carried out (audit system)

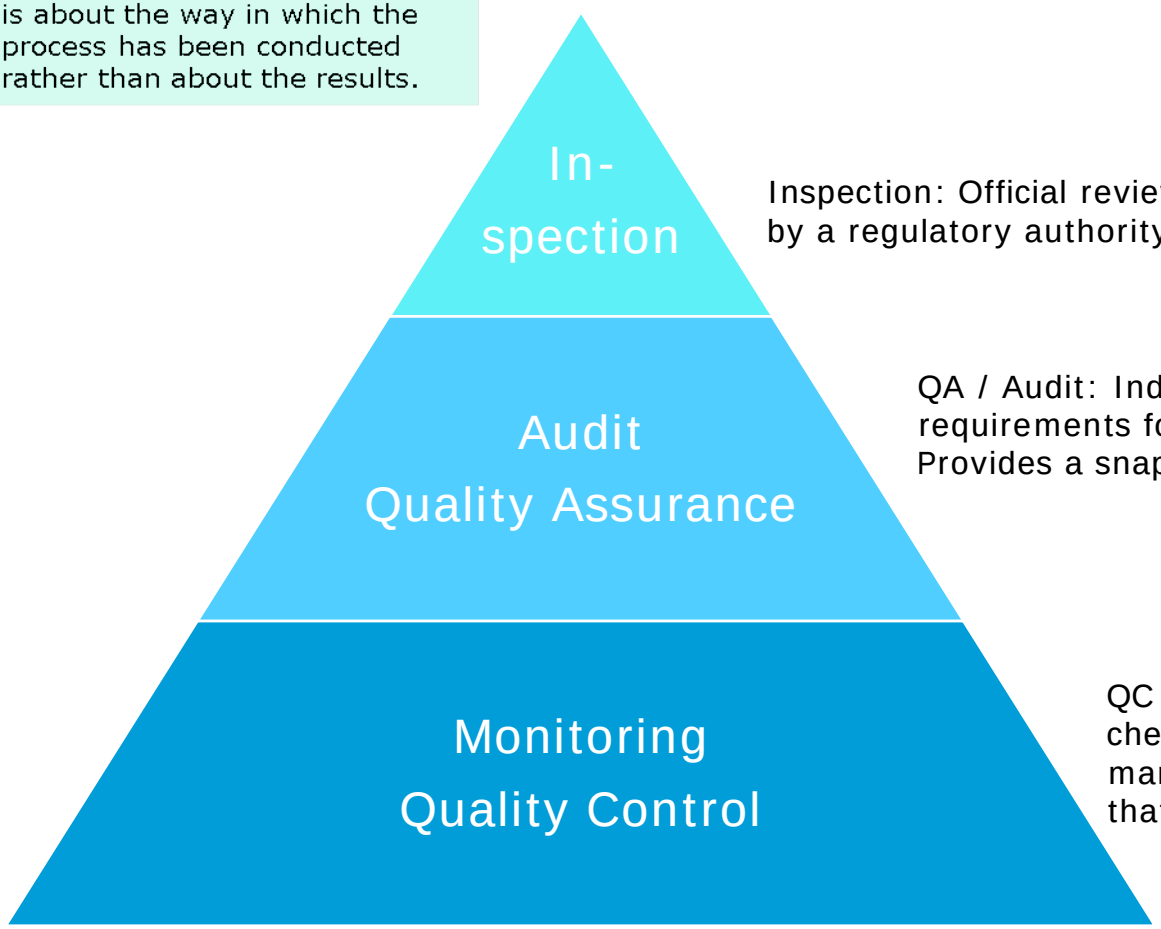
4. Quality improvement:

   Correcting and improving the structures and processes where necessary

Measuring Quality

Checking and measuring quality is about the way in which the process has been conducted rather than about the results.

Senior management should have a formal, overarching responsibility in the measurement of the Quality System and review it on defined periodic basis.



Inspection: Official review of the PV system by a regulatory authority

QA / Audit: Independent assurance that defined requirements for PV processes are followed. Provides a snapshot rather than continuous footage.

QC / monitoring: Pivotal part of QMS to check and ensure by those performing, managing or supervising the PV processes that required standards are met.

Essential features of a Quality Management System

Mission statement of goals and scope

- Definition of applicable laws, regulations, best practices where law is unclear or silent

Procedures (Policies, SOPs, Guidelines, Manuals, Work instructions etc.)

- Defined
- Documented
- Written

„if not documented – not done"
„compliance must be demonstrated"

Adequate resources

Training

Record management

Documentation of the quality system

Internal audits

Written procedures

- Reflective of requirements in pharmacovigilance legislation and guidance
- Written and reviewed by adequately trained personnel
- Approved by personnel within company who have appropriate authority
- Distributed to and immediately available to appropriate members in the company once the procedure is effective
  - Before coming effective a period of time after approval must be considered for training
- Reviewed on a periodic basis (e.g., annually) to ensure they reflect current practice

Training

Purpose of pharmacovigilance training:

To ensure competency and appropriate qualification of the personnel to achieve the required quality of the PV processes

To provide basic and continuous training to all personnel involved in performing PV activities according to their Job Descriptions

To document the competencies of the personnel by archiving training plans and records

To ensure continuous improvement of relevant skills, scientific progress and professional development of the personnel to enable appropriate understanding of relevant PV requirements and experience for assigned tasks and responsibilities

To check training results for the appropriate level of understanding for the assigned tasks and responsibilities

To ensure adequate training for personnel with no specific PV tasks and responsibilities

Staff training

Initial (basic) training

Specific training on the duties assigned according to Job Description

Continued training / refresher trainings

Monitoring of training, result assessment and documentation

Adequate training for staff with no specific PV tasks

Record Management

All pharmacovigilance information must be recorded to ensure that all information is handled and stored to allow accurate reporting, interpretation and verification of the information.

A record management system for all documents used for pharmacovigilance activities shall ensure retrievability, traceability and traceability of decisions and measures taken to investigate safety concerns, including timelines, dates and the decision-making process.

Record Management System

The record management system should support

- Management of pharmacovigilance data quality:
  - ✓Completeness of the data
  - ✓Accuracy of the data
  - ✓Integrity of the data
- Timely access to all records
- Retention of documents relating to the pharmacovigilance system
- Retention of documents relating to the conduct of pharmacovigilance activities for individual vaccines
- Definition of applicable retention periods
- Specific measures for storage and processing of pharmacovigilance data to ensure data security and confidentiality
- Ensure strict access to documents and database to authorized personnel

Pharmacovigilance System
Description of an appropriate system

Description of the organization and PV activities with documented procedures and defined processes:

- ✓ Responsibilities of the Qualified Person Responsible for Pharmacovigilance
- ✓ Management of Pharmacovigilance Data,
- ✓ Spontaneous Case Processing
- ✓ Reference Safety Information
- ✓ Literature review, incl search strategy
- ✓ Periodic Safety Update Reports / Aggregate reports
- ✓ Signal management / Evaluation of Safety Data
- ✓ Risk Management / Minimization, incl. RMPs
- ✓ Clinical trials / observational studies, if applicable

EU / EEA Member States:
Pharmacovigilance System Master File
PSMF (GVP Module II)

Database

Contractual Agreements for fulfillment of pharmacovigilance obligations

Training

Documentation of the Quality Management System

Documentation of the Quality System

All elements, requirements and provisions adopted for the Quality System should be documented in a systematic manner in form of written and version-controlled policies, procedures, quality plans, quality manuals and quality records.

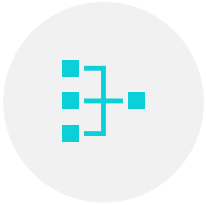
- Documents on organizational structure and assignment of tasks
- Organizational chart defining the hierarchical relationship of managerial and supervisory staff
  - Job descriptions defining the duties of the managerial and supervisory staff
- Training plans and records
- Instructions for the compliance management process
  - Performance indicators where used to continuously monitor performance of the system
- Appropriate instructions on processes to be used in case of urgency or business continuity
  - Instruction on critical processes
- Record management system
- Reports of pharmacovigilance audits

Summary
Principles for Good Pharmacovigilance Practice (GVP)

Upper management should provide leadership in the implementation of the quality system

All persons within the organization should be involved and support the PV system according to their tasks and responsibilities

All persons in the entire organization should engage in continuous improvement



Resources and tasks should be organized as structures and processes to support the proactive, risk-proportionate, continuous and integrated conduct of PV

All available evidence on benefit-risk should be sought and all relevant aspects having an impact on the benefit-risk balance should be considered for decision making

Good cooperation should be fostered between all stakeholders