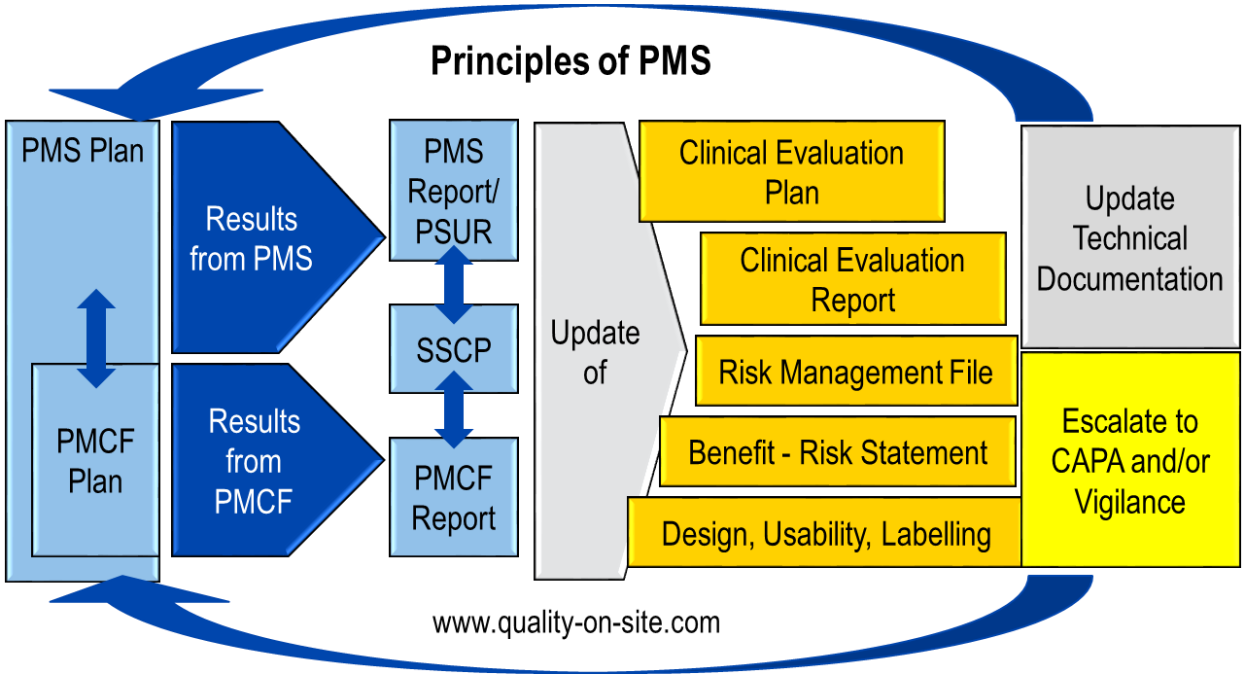
SOP Post Market Surveillance

Background

Medical device regulation (EU) 217/745 (MDR), article 83, requires manufacturers to play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with competent authorities.

To this end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.

The following picture illustrates the principles of the PMS system:



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SOP Post Market Surveillance

Purpose

This SOP is written to describe the process of Post-Market Surveillance (PMS) within xxx. It defines roles & responsibilities within xxx as well as the interfaces needed to other economic operators, notified bodies and competent authorities.

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SOP Post Market Surveillance

1. Definitions

Post Market Surveillance (PMS)

- ‘post-market surveillance’ means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions (see (EU) 2017/745 MDR).

2. Roles and Responsibilities

Within the PMS process, the following key stakeholders are involved.

- Top management: Top management has the overall responsibility for providing an adequate organizational structure including sufficient qualified resources. Top management oversees the effectiveness of the PMS system and has discretion to initiate corrections, corrective and preventive actions as needed as per SOP Management review.
- Person responsible for regulatory compliance (PRRC as per MDR article 15): The PRRC is responsible that the post-market surveillance obligations, including vigilance activities, given in regulations are complied with. The PRRC owns the PMS process and escalates any needs to top management.
- Sales & Distribution: Sales and distribution is responsible to ensure that adequate contracts are in place with relevant economic operators. Distributors of our products are responsible to actively participate in the PMS process. The same applies to importers, authorized representatives or kit packers, if applicable to our products.
- Formal designated complaint unit: The formally designated complaint unit is responsible to collect, document assess any complaints as per SOP Complaint handling. It is their responsibility to forward any information received to the PRRC.

3. Interfaces

This section gives an overview of the interfaces needed between key stakeholders of PMS

3.1. Economic operators

Several distributors, importers, authorized representatives or kit packers may be applicable to our products. In order to ensure timely and complete information exchange between xxx and those economic operators, sales and distribution will establish and maintain adequate contracts between the organizations. These contracts are to be made as per the details given in SOP Sales and Distribution including

- Information loops if there is reason to believe that a device is not in conformity with the requirements;
- Reporting requirements to competent authorities if there is reason to believe that the device presents a serious risk or is a falsified device;
- Mechanisms to co-operate with each other to ensure that the necessary corrective actions to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken.
- Communication of complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, to xxxx and, where applicable, our authorised representative, and the importer.
- The need to keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep xxxx and, where available, our authorised representative and the importer informed of such monitoring and provide them with any information upon their request.
- The commitment to, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

3.2. Notified Body and Competent Authorities

The exchange of information between xxx and notified bodies and competent authorities is described in SOP Complaint Handling, WI Vigilance and Work Instruction EUDAMED, including

- Reporting of serious incidents, trend reporting and field safety corrective actions and notices,
- Uploading periodical safety update reports (PSUR) and the summaries of safety and clinical performance (SSCP)

3.3. Internal communication

The PRRC will be responsible ensuring that the PMS system is well integrated in all quality system processes within xxx in order to collect any information needed and to escalate and inform about any corrections and corrective actions needed.

4. PMS plan

The PRRC is responsible to establish a PMS plan for each type of device. The PMS plan will address the collection and utilization of available information from the following processes:

- SOP complaint handling and WI Vigilance
  - serious incidents
  - field safety corrective actions
  - non-serious incidents
  - undesirable side-effects
  - trend reporting
- SOP Clinical Evaluation
  - relevant specialist or technical literature
  - databases and/or registers
  - publicly available information about similar medical devices
  - PMCF
- SOP Sales and Distribution
  - information, including feedbacks and complaints, provided by users, distributors and importers

Within the PMS plan the tools for collection and analysis will be described, including

- sources of data,
- frequency of proactive collection per individual data source like, for example,
  - complaint and vigilance data monthly,
  - literature quarterly,
  - registries twice a year,
  - market analysis annually, and
  - PMCF annually,
- methods of data analysis and comparison between the device and similar products available on the market,
- methods and tools to analyse market-related experience collected in the field,
- methods and protocols to manage the events subject to the trend report as per SOP Complaint handling, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period,

- suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit- risk analysis and of the risk management as described in SOP Risk management,
- systematic procedures to identify and initiate appropriate measures including corrective actions as per WI Vigilance,
- effective tools to trace and identify devices for which corrective actions might be necessary as per SOP CAPA, and
- a PMCF plan (Template PMCF) or a justification as to why a PMCF is not applicable.

Template PMS plan is to be used. The PMS Plan will be maintained throughout the entire lifetime of the device.

5. PMS report

5.1. Timelines and contents

The data collected within the PMS will be reported summarising the results and conclusions of the analyses of the post-market surveillance data together with a rationale and description of any preventive and corrective actions taken. The report will be documented as

- PMS report for class I devices.
  - The report shall be updated when necessary and made available to the competent authority upon request.
  - Template PMS report is to be used.
- PSUR (periodic safety update report) for class IIa, class IIb and class III devices. The PSUR will include
  - the conclusions of the benefit-risk determination
  - the main findings of the PMCF
  - the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.
  - The PSUR will be updated at least
    - annually for class III and IIb devices
    - at least every two years for IIa devices
  - Template PSUR is to be used.

5.2. Distribution

PMS report and PSUR will be part of the technical documentation as described in SOP Technical documentation.

For class III devices or implantable devices, the PSUR will be submitted as per WI Eudamed to the notified body. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. The PSUR will be made available to competent authorities by the notified body.

For class the other devices the PSUR is available to the notified body and to competent authorities upon request.

6. Outputs from PMS

The data gathered within PMS will be used

- to update the benefit-risk determination and to improve the risk management as per SOP Risk Management,
- to update the design and manufacturing information, the instructions for use and the labelling as per SOP Design Control,
- to update the clinical evaluation as per SOP Clinical Evaluation,
- to update the summary of safety and clinical performance as per WI SSCP,
- for the identification of needs for preventive, corrective or field safety corrective action as per SOP CAPA and WI Vigilance,
- for the identification of options to improve the usability, performance and safety of the device as per SOP Design Control, and
- to detect and report trends in accordance as per SOP Complaint handling.

It is the responsibility of the PRRC to communicate relevant information to the relevant functions above. When relevant, the information will be used within the PMS system to contribute to the PMS of other devices.

Any update of PMS report or PSUR will discuss the need for an update of the relevant PMS plan and other plans and/or reports for the same device, like

- PMCF plan and/or report,
- Risk management and/or report,
- Clinical evaluation and/or report.

The technical documentation shall be updated as per SOP Technical documentation accordingly.

7. References

- SOP Risk Management
- SOP Clinical Evaluation
- SOP CAPA (Corrective and Preventive Actions)
- SOP Complaint Handling
- SOP Design Control
- SOP Management Review
- SOP Sales and Distribution
- SOP Technical Documentation
- WI EUDAMED
- WI SSCP (Summary of Safety and Clinical Performance)
- WI Vigilance
- Template PMS Plan xxx
- Template PMS Report
- Template PSUR
- Template PMCF Plan