SOP Post-Market Surveillance

Summary

This SOP describes how Post-Market Surveillance is performed for products. It ensures that new information about safety and performance is proactively collected and can be used as input for the risk management, clinical evaluation and software development of our products.

General Considerations

This process is followed for each product separately, meaning that for each product, a Post-Market Surveillance Plan and Report are created and continuously updated.

> Note: For class I devices, you could specify a longer update interval, e.g. once every two years. Note: Feel free to assign the responsibility to any other role. It typically makes sense to choose a role that is both close to product development as well as clinical issues.

Responsibility	Document Update Interval
Head of Product	Once per year

> Please also note that according to the Transitional Provisions of Art. 120 MDR, you are required to comply with MDR requirements regarding post-market surveillance (Art. 83 ff.) starting May 2021 even if your product runs on a valid MDD certificate. This basically means to use the new format of a 'Period Safety Update Report' (PSUR).

Process Steps

1. Create Post-Market Surveillance Plan

Based on the clinical evaluation and technical documentation, a new Post-Market Surveillance Plan is created for a product.

Participants
QMO Head of Product

Input	Output
Device Description Clinical Evaluation	Post-Market Surveillance Plan

Input	Output
Risk Management Report	

2. Conduct Post-Market Surveillance

The Post-Market Surveillance is carried out as described in the Post-Market Surveillance Plan in the defined interval.

Ideally, the responsible person continuously collects information of all the categories described below and enters them into our report template.

At minimum, the following information categories have to be taken into consideration:

- **Clinical evaluations and PMCF activities:**: Input from our Post-Market Clinical Follow-Up activities.
- **New research and development in the market:** Information regarding similar medical devices and technologies on the market.
- **Input from recalls and reportable events:** Recalls, incidents and unintended side effects reported by competitors, similar products and procedures or reported for other devices of our company (e.g. check BfArM / FDA databases as further specified in the post-market surveillance plan).
- **New or updated norms and standards, directives, regulation and other laws:** Verification if the list of applicable regulations is up to date.
- **SOUP:** Verification if SOUP list is up to date.
- **Complaints directly reported by customers:** Information gathered through customer feedback and complaints.
- **Other feedback** collected or reported by sales or marketing staff, distributors, or other stakeholders.

For each part of information, it is assessed whether it is applicable to the company's product. Additionally, its severity is rated on the following scale:

- **Severe:** Serious injury or death
- **Moderate:** Non-serious injury
- **Marginal:** Everything else, less than moderate

Depending on the applicability, severity and observed trends of the new information, appropriate actions are initiated. The QMO and Medical Device Safety Officer must be consulted in this step, other roles (e.g. medical staff) should be involved if needed.

Actions may entail:

- **Updating the product risk management file**, for example by adding new risks according to our risk management process, updating occurrence / severity assumptions made for risks we already documented or updating risk mitigation measures in place).

- **Initiating a CAPA**, for example to update processes, training measures or resource allocation.
- **Initiating incident reporting** to authorities or a product recall.
- **Design changes** to the product following the company's change management process.

Participants
QMO
Head of Product

Input	Output
Post-Market Surveillance Plan Post-Market Surveillance Information	Evaluated Information

3. Compile Periodic Safety Update Report

The Product Manager finalizes the Periodic Safety Update Report (PSUR), which is at least reviewed by the Person Responsible for Regulatory Compliance. The report should contain at least the following information:

- main findings of post-market surveillance activities throughout the surveillance interval
- conclusion regarding implications for the risk management and clinical evaluation of the product, in particular the overall residual risk and benefit-risk determination
- the sales volume of the device, e.g. amount of users and, where practicable, the usage frequency of the device.

Participants
PRRC
Head of Product

Input	Output
Collected and evaluated information	Periodic Safety Update Report

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