Post Market Surveillance (PMS) Plan

Device Name/ Model Name

Document Authorisation

Task	Name	Signature	Date
Document Prepared By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Reviewed By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY
Document Approved By	Enter the In-charge Person's Name	Insert Signature	DD-MM-YYYY

Revision History

Version	Release Date	Change History
Version Number	DD-MM-YYYY	Changes made on the particular release date mentioned in previous column.

Table of Contents

1. Introduction

This section introduces the document, including a brief overview of the Post-Market Surveillance (PMS) requirements as per the EU MDR. Explain that this plan is established to ensure the ongoing monitoring of device performance, identification of adverse events, and alignment with regulatory requirements.

2. Purpose and Scope

Define the purpose of the PMS Plan, stating its role in maintaining and improving the safety, performance, and compliance of the device(s) in the EU market. Mention that the scope includes all activities related to PMS for the device in the European Union.

3. Device Description

Provide a brief description of the medical device, including:

- Device name
- Device model/version number(s)
- Intended purpose
- Classification as per EU MDR
- Overview of key components and technology

4. Objectives of PMS Activities

List the specific objectives of the PMS Plan, such as:

- Monitoring device safety and performance post-market
- Identifying potential safety signals or risks
- Detecting and addressing non-conformities
- Ensuring continued compliance with the General Safety and Performance Requirements (GSPR)

5. Data Collection and Analysis

5.1. Sources of Data

Identify the sources of data used in PMS activities, such as:

- Customer complaints and feedback
- Vigilance data and incident reports
- Literature and scientific publications
- Data from competitors' devices
- Data from distributors, sales, and technical service reports

5.2. Frequency of Data collection

Outline the frequency for data collection activities (e.g., monthly, quarterly). Specify intervals for evaluating and analyzing data to detect potential trends.

6. Risk Management

Explain how PMS data will feed into the device's risk management process, including:

- Assessment of residual risks
- Updates to the risk management file
- Trigger points for initiating corrective or preventive actions (CAPA)

7. PMS Responsibilities and Resources

Define the roles and responsibilities of individuals or teams involved in PMS activities, including:

- Designation of the responsible person for PMS (in-house or external if required)
- Allocation of resources (personnel, data collection tools)
- Training and expertise requirements

8. Reporting and Review Process

Describe the process and timeline for compiling PMS findings into reports, such as:

- Periodic Safety Update Reports (PSURs)
- PMS report submissions (for Class I devices)
- Process for internal reviews and management approvals

9. PMS Plan Updates and Review

Outline the frequency of PMS Plan reviews and updates (e.g., annually, biannually) to ensure ongoing compliance and relevance. Specify the process for making amendments in response to significant changes in risk profile, device modifications, or new regulatory requirements.