Purpose:
To define the process and frequency of activities for gathering production and post-production data as an input into the clinical evaluation process (SYS-041) and risk management process (SYS-010).

Scope:
The scope of this post-market surveillance plan is limited to the [Product Family Name] during the period of [earliest date] to [latest date]. The post-market surveillance system referred to in Article 83 of Regulation (EU) 2017/745 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III. For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II. This plan also addresses the production and post-production activities required as part of the risk management process as defined in ISO 14971:2019, Clause 10.

> Note: If different PMS and Risk Management inputs cover different periods of time, then this should be clarified in the PMS reports (TMP-032) and Risk Management reports (TMP-027). Often a table is ideal to communicate this information. These two report templates may also be combined into a single report.

Responsibilities & Authorities:
The table in the PMS inputs section defines the personnel that are responsible for gathering each type of PMS data for [Product Family Name]. Each person is responsible for gathering the data, summarizing that data, writing a brief discussion of the data analysis and documenting a conclusion that states whether the data warrants updating the PMS report at this time or to continue gathering data until the next cycle is completed. Even if there is no new clinical data gathered during the period, the clinical evaluation report still requires updating the literature search, gathering of complaint data, and If the literature search concludes that there is no new clinical data available, document both the methodology and the results of the search. If there are no new risks identified and the data suggests that no changes to the current risk analysis are needed, then the risk analysis may not need to be updated either, but document the activities that led to that conclusion. The recommended frequency for the next summary of data should be indicated in the conclusion as well.

Technical Documentation on Post-Market Surveillance
The technical documentation on post-market surveillance to be drawn up by the [Company Name] in accordance with Reg. (EU) 2017/745, Articles 83 to 86 shall be presented in a clear, organized, readily searchable and unambiguous manner. The Post-Market Surveillance Plan shall be part of the Technical Documentation.

As required within Annex III, Section 1.1 a) of Reg. (EU) 2017/745 the Post-Market Surveillance Plan shall address the collection and utilization of available information, in particular:

- information concerning serious incidents, including information from Periodic Safety Update Reports (PSUR)s (TMP-033), and field safety corrective actions;
- records referring to non-serious incidents and data on any undesirable side-effects;
- information from trend reporting;
- relevant specialist or technical literature, databases and/or registers;
- information, including feedbacks and complaints, provided by users, distributors and importers; and
- publicly available information about similar medical devices.

As required within Annex III, Section 1.1 b) of Reg. (EU) 2017/745 the Post-Market Surveillance Plan shall cover at least:

- a proactive and systematic process to collect any information referred to above in point (a). The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;
- effective and appropriate methods and processes to assess the collected data;
- suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Reg. (EU) 2017/745, Section 3 of Annex I;
- effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field;
- methods and protocols to manage the events subject to the trend report as provided for in Reg. (EU) 2017/745, Article 88, 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;
- methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
- Reference to procedures to fulfil the [Company Name]'s obligations laid down in Reg. (EU) 2017/745, Articles 83, 84 and 86;
- systematic procedures to identify and initiate appropriate measures including corrective actions;
- effective tools to trace and identify devices for which corrective actions might be necessary; and
- a Post-Market Clinical Follow-up (PMCF) Plan as referred to in Reg. (EU) 2017/745, Part B of Annex XIV, or a justification as to why a PMCF is not applicable (see PMCF Plan Checklist – TMP-008)

As required within Annex III, Section 1.2 of Reg. (EU) 2017/745 the PSUR (TMP-033) referred to in Article 86 and the post-market surveillance report referred to in Article 85 shall also be included.

As required by ISO 14971:2019, Clause 10, [Company Name] shall collect, where applicable:
a) information generated during production and monitoring of the production process;
b) information generated by the user;
c) information generated by those accountable for the installation, use and maintenance of the medical device;
d) information generated by the supply chain;
e) publicly available information; and
f) information related to the generally acknowledged "state of the art."
[Company Name] shall also consider the need to actively collect and review publicly available information about similar medical devices and similar other products on the market.

PMS & Risk Management Inputs:
The following table identifies the PMS Report Inputs for [Product Family Name].

Item #	Description of Input	Responsible Person	Frequency of Review
1	Information from R&D (may include contract design firm)	Design Team Leaders	At design phase reviews
2	Service data as per SYS-013 (individual service records and statistical analysis in accordance with 21 CFR 820.200 & ISO 13485:2016, Clause 7.5.4)	Service Manager	Monthly
3	Complaint data as per SYS-018 (individual complaint records and trend analysis of complaints as per 21 CFR 820.198 & ISO 13485:2016, Clause 8.2.2)	Complaint Handling Unit	Monthly
4	Customer Feedback Surveys as per SYS-019 including: • information generated by the user • information generated by those accountable for the installation, use and maintenance of the medical device	Customer Service	Quarterly

5	Adverse Event Databases (e.g., MAUDE)	Regulatory Affairs	Quarterly
6	Clinical Literature Review as per SYS-041 (i.e., periodic execution of literature search protocol) • information related to the generally acknowledged “state of the art” • information about similar medical devices and similar other products on the market.	Clinical Affairs	Quarterly
7	New & Revised Regulatory Requirements, External Standards, Common Specifications, and Guidance Documents	Regulatory Affairs	Management Review Output
8	Drug-related information (if applicable)	Clinical Affairs	Quarterly
9	Own-Brand Labeled PMS (if applicable)	Quality Assurance	Quarterly
10	Salesforce, Distributor, Tradeshow Feedback, and other publicly available information	Sales	Quarterly
11	Information generated during production and monitoring of the production process	Production	Monthly
12	Information generated by the supply chain	Supply Chain	Monthly

Data Summary:
Each person responsible for gathering PMS data shall summarize the data on the frequency identified in the table above. If there is no new data to report, this should be stated in the summary. If there is a large amount of similar data, it is acceptable to present a statistical analysis of that data (refer to SYS-022, Statistical Techniques).

Review of Information:
[Company Name] shall review the information collected for possible relevance to safety, especially whether:
— previously unrecognized hazards or hazardous situations are present;
— an estimated risk arising from a hazardous situation is no longer acceptable;
— the overall residual risk is no longer acceptable in relation to the benefits of the intended use; or
— the generally acknowledged “state of the art” has changed.
The results of the review shall be recorded in the risk management file, by updating the risk management report (TMP-027).

Compliance is checked by inspection of the risk management file.

Discussion of Data:
If the data gathered is similar to previous data gathered, then this should be stated in the discussion. If there is new data, the severity of harm caused by device malfunction changes or if the frequency of incidents change this should be stated in the discussion. A separate discussion of data from each input source is recommended. In the periodic PMS report, it should be stated which input sources identified significant new data or changes in the data trends.

Actions:
If the collected information is determined to be relevant to safety, the following actions apply.
1) Concerning the particular medical device,
— the [Company Name] shall review the risk management file and determine if reassessment of risks and/or assessment of new risks is necessary;
— if a residual risk is no longer acceptable, the impact on previously implemented risk control measures shall be evaluated and should be considered as an input for modification of the medical device;
— the [Company Name] should consider the need for actions regarding medical devices on the market; and
— any decisions and actions shall be recorded in the risk management file.
2) Concerning the risk management process,
— the [Company Name] shall evaluate the impact on previously implemented risk management activities; and
— the results of this evaluation shall be considered as an input for the review of the suitability of the risk management process by top management.

Conclusions:
The conclusion of each summary report from each PMS input should state if a PMS report is recommended based upon the inputs or if it is acceptable to continue to gather data without generating a periodic PMS report. Any new risks, changes to risks or changes to frequency of occurrences should be noted and should trigger either an update to the clinical evaluation report, the risk analysis or both. The recommended time for conducting the next review of PMS data from each source should be specified in the conclusions.

Training of personnel:
All personnel that are involved in the review of PMS data shall be trained on the following procedures:

- SYS-010, Risk Management
- SYS-019, Post-Market Surveillance
- SYS-041, Clinical Evaluation Procedure

Documents & Records:

The PMS plan for each product family shall be assigned a controlled document number and changes to the plan shall be documented as a controlled revision in accordance with SYS-001, Control of Documents. The summary reports for each PMS data source and the periodic summary reports of PMS data shall be controlled quality system records that reference the PMS plan, the PMS data source, the period of time over which the data was collected and the persons that performed the data analysis. All PMS records shall be stored as electronic records and organized by record type (e.g., review of monthly complaint data). The following network server location contains the PMS records: https://yourserver/PMSrecords/.