1. **Purpose**

This document defines the policies and procedures for post-market surveillance activities to gain information regarding the quality, safety, and performance of products released for commercial distribution.

1. **Scope**

This document applies to medical devices that have been released for commercial distribution. Products that have not been released for distribution are exempt from this procedure.

1. **General** 
   1. **Definitions**

* **Surveillance:** The collection of processes and activities used to monitor the safety and effectiveness of medical devices, including the evaluation of this information.
* **Post-Market Surveillance:**  The pro-active collection of information on quality, safety or performance of medical devices after they have been placed on the market.
* **Post-Market Clinical Follow-Up (PMCF):**  Part of the Post-Market Surveillance involving monitoring of clinical data to supplement or verify the assumptions made in connection with the clinical evaluation.
* **Vigilance:**  Systematic procedures for dealing with reporting to authorities, issuing of safety messages and enforcement of safety related corrective actions for delivered products.
* **Clinical Data:** Safety and/or performance information that are generated from the clinical use of a medical device.
* **Clinical Evaluation:**  The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.
  1. **Responsibilities**

**Quality Management** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and maintaining records.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirements** – Quality personnel shall be trained to this procedure and the training documented.
  4. **Record Management** – Post Market Surveillance records are maintaining within Management Review and Design Control records.
  5. **Reference Documents and Materials**

**21 CFR 820** FDA Quality System Regulations

**ISO 13485** – Medical Device Quality Management Systems

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**MEDDEV 2.12-2:** Guidelines on Post Market Clinical Follow Up

**NB-MED/2.12/Rec1**: Post-Marketing Surveillance (PMS)

**GHTF SG5 (PD) N4R7**: Post-Market Clinical Follow-Up Studies

**GHTF/SG2/N47R4:** Review of Current Requirements on Post Market Surveillance

1. **Post-Market Surveillance Procedure**

The inputs identified below define Post-Market Surveillance as performed to support international vigilance requirements. Post-Market Surveillance data is assessed as part of the Design Control Process and Management Review.

* 1. The company will identify applicable information from the sources below in order to be able to gather relevant information regarding quality, safety and performance of medical devices which have been placed on the market. Surveillance is an ongoing process of reviews throughout the life of the device. Information Sources include, but are not limited to:
     + Production Activities
     + Product quality and product reliability from the field
     + Relevant CAPA’s
     + Customer Complaints and MDR’s
     + Quality Audits (Product Audits)
     + Information and reports from sales agents and distributors (e.g. customer satisfaction)
     + Reports from medical meetings and trade shows
     + Available scientific publications related to products
     + Review of adverse event / vigilance information provided by various regulatory agency websites, publications, etc. of both manufactured products and similar products from competitors
  2. When establishing and documenting Post Market Surveillance, the company considers:
     + Whether the design of the device, the material, the principles of operation, the technology, or the medical indication is new
     + The extent of available scientific knowledge (e.g. on long term effects)
     + The state of the art and market experience with similar products and technology
     + Sensitive target population
     + Well known risk from the literature and/or of similar marketed devices, and
     + Identification of an acceptable risk during pre-clinical evaluation, which should be monitored in a longer term and/or through a larger population
  3. The results of the Post-Market Surveillance information gathered will be reviewed to determine whether a corrective and preventive action needs to be taken in product design, manufacturing, labeling and/or training, etc., and to evaluate and determine whether regulatory action such as Medical Device Vigilance Reporting (EU), advisory notices, recalls and other actions are needed. This information shall be evaluated against the risk management file to determine if additional actions are necessary.
  4. The review of Post-Market Surveillance summaries, data, information, and all actions taken, including the determination that no actions are required, will be documented as part of the Post-Market Surveillance effort and reviewed during the Management Review Process. The review of the Post-Market Surveillance shall include a documented assessment of the impacts and updates to any relevant Clinical Evaluations.

Post Market Clinical Follow Up (PMCF) Studies may be required as defined below. The determination on when a required PMCF is performed is decided by appropriate management.

| **PMCF** | **Product Specifics** | **Required Actions** |
| --- | --- | --- |
| Not Required | Products for which the medium/long term clinical performance and safety is well established, or from fully transferable experience with equivalent devices | * Systematic review of all customer feedback and adverse events data. * Monitoring of sources of information known by the manufacturer, including published literature. * Monitoring of post market performance, taking into account relevant data publicly available with similar devices. |
| Required | Devices where identification of possible emerging risks and the evaluation of long term safety and performance are critical | * Plans should establish protocols for performing a PMCF of all or a justifiable subset of patients already enrolled in pre-marketing Clinical Investigations; or on specific sub-groups and/or prospective study or registry of a sample of products. * PMCF report to be provided to the relevant Notified Body for review and to competent authority if requested.   Note: The manufacturer must justify the design, nature, and duration of post-marketing follow-up, in consideration with any published standards |

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0024 |  |  | Initial release of the post market surveillance process |