1. **Purpose**

This document defines the policies and procedures for the measurement, monitoring, and data analysis of manufacturing processes and the quality management system. These policies and procedures include management review, required areas of analysis, and analysis tools.

1. **Scope**

This procedure applies to the processes utilized in the design, manufacturing, and distribution of medical devices and quality management systems.

1. **General** 
   1. **Definitions** – N/A
   2. **Responsibilities**

**Quality Management** – Quality Management is responsible for the monitoring, measurement, and data analysis of the quality management system. Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – Quality personnel shall be trained on this process and records maintained.
  4. **Record Management** – Management Review records shall be maintained by the Quality Department.
  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

1. **Management Review**

The results of the data analysis from the required areas shall be reviewed by management and necessary actions taken to address trends or the suitability and effectiveness of the quality management system. Records of the data analysis shall be submitted and maintained by the Quality Department.

* 1. **Planning and Scheduling**

Management reviews are scheduled at least annually and are intended to provide organization management with an overview of the business and quality system performance. Management shall be scheduled in advance and participant provided with an agenda for the review. The following business functional management (or a representative) are required, occasional absence is acceptable:

* Engineering
* Operations
* Quality and Regulatory
* Sales and Marketing
  1. **Topics for Review**

The following items shall be incorporated into the scope of the management review. Additional items can be added as necessary.

* Meeting minutes from previous management review
* Areas of Analysis list in Section 5.1
* Corrective and Preventive Actions
* Post-Market Surveillance Data and Impacts to Clinical Evaluations
* Audit Results
* Recommendations for Improvement
* Changes to the QMS (Quality Policy, Objectives, Resources, etc)
* Changes to Applicable Regulations (FDA, MDD, CMDCAS, ISO, etc)
  1. **Action Items and Meeting Minutes**

Following the Management Review, a Quality representative shall circulate meeting minutes including agreed upon action items and obtain approval for the functional management that the Quality Management System has been determined to be effective.

1. **Data Analysis Procedure**

The analysis of data is utilized to demonstrate the suitability and effectiveness of the quality management system. If the analysis of data shows the quality management system is not suitable, adequate, or effective; appropriate corrections and corrective actions shall be taken. The results of data analysis are reviewed during the Management Reviews.

* 1. **Required Areas of Analysis**

The following areas require monitoring, measurement, and analysis of data:

* + - Customer Feedback and Customer Satisfaction
    - Conformity to Product Requirements
    - Operations and/or Manufacturing Processes
    - Suppliers

Additional areas may be identified as necessary to ensure conformity and maintain the effectiveness of the quality management system.

* 1. **Analysis Tools**

The tool(s) utilized for monitoring, measurement, and analysis are specific to the process or system being monitored. The following are examples of tools which may be used:

* + - Control Charts
    - Pareto Charts
    - Run Charts
    - Check Sheets
    - Histograms

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0013 |  |  | Initial implementation of the Management Review and Data Analysis Process. |