Management Review Policy

Role	Position/Department	Name	Date
Author			DD MMM YYYY
Reviewer			DD MMM YYYY
Approver			DD MMM YYYY

[Company Name], Inc.

1. Purpose

This policy establishes the framework for conducting Management Review at [Company Name], Inc. (hereinafter referred to as "the Company") to ensure that the Quality Management System (QMS) for medical device products remains suitable, adequate, and effective in achieving its intended outcomes. Management Review is a critical element of continual improvement and ensures ongoing compliance with applicable regulatory requirements.

2. Scope

This policy applies to all Management Review activities for the QMS governing medical device products handled by the Company. It encompasses the planning, execution, documentation, and follow-up of Management Review meetings conducted by Top Management.

3. Normative References

This policy is aligned with the following regulatory requirements and standards:

- 21 CFR Part 820 (Quality Management System Regulation - QMSR)
- ISO 13485:2016 (Medical devices - Quality management systems - Requirements for regulatory purposes)
- Applicable FDA guidance documents

4. Definitions

Term	Definition
Management Review	Formal evaluation by top management of the status and adequacy of the quality management system in relation to quality policy and quality objectives. (ISO 13485:2016, 3.11)
Top Management	Person or group of people who directs and controls an organization at the highest level. (ISO 13485:2016, 3.17)
Quality Management System (QMS)	Management system to direct and control an organization with regard to quality. (ISO 13485:2016, 3.14)
Quality Policy	Overall intentions and direction of an organization related to quality as formally expressed by top management. (ISO 13485:2016, 3.13)
Quality Objective	Something sought, or aimed for, related to quality. (ISO 13485:2016, 3.12)
PDCA Cycle	Plan-Do-Check-Act: A four-step management method used for continuous improvement of processes and products.
Continual Improvement	Recurring activity to increase the ability to fulfill requirements. (ISO 13485:2016, 3.2)

5. Policy Statements

5.1 Annual QMS Planning

The Management Representative shall develop an annual QMS plan that includes planned Management Review meetings, internal audits, training programs, quality objectives, and other key QMS activities. Top Management shall approve and periodically update this plan.

5.2 Management Review Meeting Requirements

5.2.1 Frequency

Management Review meetings shall be conducted at least annually. The recommended timing is March of each fiscal year to review the prior year's QMS performance.

5.2.2 Ad-Hoc Meetings

Top Management may convene ad-hoc Management Review meetings when warranted by significant events such as: new product regulatory submissions, major product or process changes, critical quality findings, or recall events.

5.2.3 Meeting Chair

Top Management (President/CEO or designee) is responsible for convening and chairing Management Review meetings.

5.2.4 Attendees

Required attendees shall include: Top Management, Management Representative, Vice President of Quality, Regulatory Affairs Manager, and other personnel as determined by Top Management or the Secretariat.

5.2.5 Quorum Requirements

A meeting shall be considered valid when Top Management, Management Representative, and at least one additional required attendee are present (minimum of 3 persons).

5.2.6 Meeting Coordination

Quality Assurance shall serve as the Secretariat and is responsible for meeting coordination, including scheduling, invitation distribution, input collection, and record keeping.

5.3 Management Review Inputs

Per ISO 13485:2016 Section 5.6.2 and 21 CFR 820.20(c), Management Review inputs shall include but are not limited to:

a) Feedback including complaints;
b) Complaint handling;
c) Reporting to regulatory authorities;
d) Audits (internal, supplier, customer, and third-party);
e) Monitoring and measurement of processes and product;
f) Corrective and preventive actions (CAPA);
g) Follow-up actions from previous management reviews;
h) Changes that could affect the QMS;
i) Recommendations for improvement;
j) New or revised regulatory requirements applicable to the organization.

5.4 Review and Deliberation

During Management Review meetings, the following shall be evaluated:

a) The need for improvements or changes to the QMS;
b) The adequacy of the Quality Policy;
c) The appropriateness of Quality Objectives.

5.5 Management Review Outputs

Per ISO 13485:2016 Section 5.6.3 and 21 CFR 820.20(c), Management Review outputs shall include decisions and actions related to:

a) Improvements needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes;
b) Improvements to product related to customer requirements;
c) Changes needed to respond to applicable new or revised regulatory requirements;
d) Resource needs.

5.6 Record Keeping

Records of Management Review shall be maintained. The Secretariat shall document all inputs, outputs, decisions, and action items in the Management Review Input & Output form (MD-QMS-F102). These records shall be retained per the Document Control procedure.

5.7 Absentee Handling

For required attendees who are unable to attend a Management Review meeting:

a) The Secretariat shall distribute meeting materials to absentees;
b) Absentees shall review the materials and communicate any concerns to the Secretariat;
c) The Secretariat shall take appropriate action to address any concerns raised.

5.8 CAPA Initiation Criteria

CAPA shall be initiated from Management Review when Top Management determines that recurrence prevention or improvement measures are required, or when significant systemic issues are identified that require formal investigation and resolution.

6. References

Reference	Issuing Body	Year
21 CFR Part 820 - Quality Management System Regulation (QMSR)	U.S. FDA	2024
ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes	ISO	2016
Management Review Procedure (MD-QMS-S101)	[Company Name], Inc.	Current
CAPA Policy (MD-QMS-K17)	[Company Name], Inc.	Current

7. Supplementary Provisions

This policy shall be initiated by the Quality Assurance Manager and approved by the Vice President of Quality.