[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR MANAGEMENT REVIEW

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

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Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to ensure a planned, systematic, and periodic review of the Quality Management System (QMS) by [top management] in order to ensure its continuing suitability, adequacy, and effectiveness. [Job title] must ensure that the review results in the evaluation of possibilities for improvement and needs for changes, including Quality Policy and quality objectives.

This Procedure applies to all processes within the QMS.

Users of this document are [members of top and mid-level management] of [organization name].

Commented [AES4]: Adapt to organizational structure.

Commented [AES5]: E.g., Management Representative

Commented [AES6]: E.g., CEO, Management Representative, department managers

Commented [AES7]: Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clause 5.6
- MDR 2017/745, article 10(9) and Annex IX – Chapter I
- Quality Manual

Commented [AES8]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

3. Conducting Management review

[Job title], together with mid-level management and Management Representative, conducts the Management review.

Commented [AES10]: Adapt to the organization's practice.

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3.1. Management review methods

The organization can conduct the Management review in the following ways:

- Meetings with previously defined agenda, proceedings and formally determined actions
- Phone or internet conference
- [illegible]
- [illegible]

3.2. Periodic Management review

[Job title] organizes the meeting with mid-level management and Management Representative. [illegible]

Commented [AES12]: Adapt to organizational structure.

Commented [AES13]: E.g., Management Representative

The objective of the review will be to ensure continued QMS:

1. Suitability – *The quality of having properties that are right for the specific purpose.* [illegible]
2. Adequacy – *Sufficient to satisfy a requirement or meet a need.* [illegible]

3. Effectiveness – *Adequate to accomplish a purpose; producing the intended or expected result.*

3.2.1. Review input

As a minimum, the following information and data are presented during the Management review:

- *Internal and external quality audits*

  The Management Representative presents results of internal and/or external quality system audits.

- *Reporting to regulatory authorities*

- *Customer feedback,* including:

  - Customer satisfaction
  - Customer complaints

- *Process performance and product conformance*

- *Status of corrective/preventive actions*

- *Suppliers' quality performance*

- *New and revised regulatory requirements*

- *Follow-up actions from previous Management reviews*

  The Management Representative reports on the status of action items from previous meetings.

Commented [AES14]: The following inputs for Management

Commented [AES15]: Adapt to the organization's practice.

Commented [AES16]: Adapt to the organization's practice.

Commented [AES17]: Adapt to the organization's practice.

- *Changes that affect the quality system*

  [Job title] highlights any service delivery, process, capacity, or other operational or organizational changes that affect the quality system and proposes specific actions to update or modify the system in response to these changing circumstances. [illegible]

- *Recommendations for improvement*

  [illegible]

- *Quality Policy & Quality Objectives*

  Quality objectives established through the review period are systematically evaluated to assess progress:

  - Objectives that have been achieved may either be upgraded to a higher performance level, or be closed out to free resources for improvement in another area.
  - When objectives are not achieved on time, the review investigates and determines causes for failing to achieve the objectives.
  - [illegible]
  - [illegible]
  - [illegible]
  - [illegible]

  [Job title] reviews the Quality Policy to ensure its continuing relevance. [illegible]

- *Risk Policy*

  [illegible]

- *Data Analysis*

  [illegible]

- *Post-Market Surveillance*

Commented [AES18]: Adapt to the organization's practice.

[illegible]

Commented [AES19]: Adapt to the organization's practice.

[illegible]

Commented [AES20]: Adapt to the organization's practice.

[illegible]

Commented [AES21]: Adapt to the organization's practice.

[illegible]

Commented [AES22]: This is a recommendation; besides this, [illegible]

[illegible]

Commented [AES23]: Adapt to the organization's practice.

[illegible]

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[redacted]

3.2.2. *Additional Management review*

[Job title] conducts an additional Management review in the following situations:

- Major nonconformities in operating and maintaining the QMS
- Sudden disturbance on markets (changes in legal and regulatory requirements, unexpected action of competition, etc.)
- [redacted]

3.3. Review output

Output from the Management review process includes decisions and actions related to the following:

- Improvement needed to maintain the suitability, adequacy, and the effectiveness of the Quality Management System and its processes
- Improvement of product related to customer requirements
- Changes needed to respond to applicable new or revised regulatory requirements
- Resource needs
- [redacted]
- Risk Policy
- Post-market surveillance

[Job title] documents the following in the Management Review Minutes:

- Action items are highlighted to ensure that they are easily identifiable
- Action items include the assignment of responsibility
- [redacted]

[redacted]

4. Managing records kept on the basis of this document

Record name	Code	Storage		[redacted]
		[redacted]	[redacted]	

Commented [AES25]: If the title of the RPRC in your [redacted]

Commented [AES26]: Choose the one that applies.

[redacted]

Post-Market Surveillance Report is used for class I medical devices (class I, class Is, class Ir and class Im), while Periodic Safety Report is used for class IIa, class IIb and class III devices.

Commented [AES27]: Adapt to the organization's needs.

Commented [AES28]: These are recommendations; adapt to [redacted]

Matrix of Key Performance Indicators	PR27.1	[illegible]	[illegible]	[illegible]
Management Review Minutes	PR27.2	[illegible]	[illegible]	[illegible]

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5. Appendices

- Appendix 1 – Matrix of Key Performance Indicators
- [illegible]

[job title]
[name]

_____

[signature]

Commented [AES30]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.