

[Organization logo]

[Organization name]

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## PROCEDURE FOR MANAGEMENT REVIEW

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## Change history

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

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## 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.

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

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 [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

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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.

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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
- Review across an different units / organizations, with reporting to top management, and conduct that review according to defined plan
- Considering elements that provide a global view of the system, instead of considering each and individual systems

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### 3.2. Periodic Management review

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

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**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.*
2. Adequacy – *Sufficient to satisfy a requirement or meet a need.*

[organization name]

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

The Quality Management System should enable the organization to meet its own needs, those of its customer, and those of other interested parties.

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. This includes summaries of results for the audit, frequency of audit findings against various elements of the quality system, and discussion of particularly important findings.

• Reporting to regulatory authorities

• Customer feedback, including:

- Customer satisfaction
- Customer complaints

– Results of customer satisfaction

XXXXXXXX presents summaries of customer feedback and complaints, including analysis of trends by product category, customer satisfaction data and trends.

• Process performance and product conformance

The Management Representative presents quality performance data, internal and external, and the status of the performance indicators.

• Status of corrective/preventive actions

The Management Representative presents the highest risk or most undesirable actions implemented through the period and the status of pending actions.

• Suppliers' quality performance

XXXXXXXX presents supplier quality performance data, internal and external, and the status of the status indicators and trends.

• New and revised regulatory requirements

XXXXXXXX presents new and revised regulations.

• Follow-up actions from previous Management reviews

The Management Representative reports on the status of action items from previous meetings. Items that are not completed are carried on as pending actions and are included as such in the trends.

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- **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.

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- **Recommendations for improvement**

[Job title] reviews data demonstrating progress toward achieving individual improvement goals, and reviews current and completed improvement projects.

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- **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.

- 1. Depending on the nature of the objective and cause for failure as defined by senior management, you decide to drop the objective, adjust its scope or goal, change responsibilities and/or allocate additional resources, or extend the due date for achieving the objective.
- 2. Key decisions regarding quality objectives are recorded in the minutes of the review.
- 3. New objectives are established where it is necessary to improve performance in order to fulfil the Quality Policy or other organizational goals or objectives.
- 4. New objectives are documented in the minutes of the review.

[Job title] reviews the Quality Policy to ensure its continuing relevance. The Quality Policy is changed when the goals expressed in the Policy have been achieved, or when changes within or outside the organization render the Policy inadequate or inappropriate.

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- **Risk Policy**

[Job title] reviews the Risk Policy to determine if the appropriate levels of controls exist for risk acceptability or need to change in the Policy.

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

- **Data Analysis**

[Job title] collects and analyzes appropriate data to evaluate the effectiveness of the Quality Management System and files a Data Analysis Report.

Commented [AES22]: This is a recommendation; besides this, [Job title] should be prepared to make sure that the data is analyzed and reported.

- **Post-Market Surveillance**

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[organization name]

Review Minutes for the Management Review (MGR) process, also known as the Management Review Minutes (MGRM), and how they are used to track and manage the results of the MGR process.

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### 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.)
- Significant changes in the QMS

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.

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### 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
- Review of the results and actions from the management review
- Review of the results and actions from the management review
- Review of the results and actions from the management review
- Quality Policy
- Quality Objectives
- Risk Policy
- Post-market surveillance

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

[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
- Action items include the assignment of resources for implementation

These minutes serve as a record and generation of the subject, management will determine the continued suitability, adequacy, and effectiveness of the Quality Management System.

## 4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention	Location	

[organization name]

Matrix of Key Performance Indicators	PR27.1	Form	Office of Management Information	Form
Management Review Minutes	PR27.2	Form	Office of Management Information	Form

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## 5. Appendices

- Appendix 1 – Matrix of Key Performance Indicators
- Appendix 2 – Management Review Minutes

[job title]

[name]

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[signature]

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