Procedure: Management Review

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Table of Contents

[1. Purpose 3](#_Toc406623195)

[2. Scope 3](#_Toc406623196)

[3. Responsibilities 3](#_Toc406623197)

[4. Procedure 3](#_Toc406623198)

[4.1. Frequency and scheduling 3](#_Toc406623199)

[4.2. Attendance 3](#_Toc406623200)

[4.3. Agenda 4](#_Toc406623201)

[4.4. Review input 4](#_Toc406623202)

[4.5. Initiating and implementing quality objectives 5](#_Toc406623203)

[4.6. Reviewing and closing out quality objectives 6](#_Toc406623204)

[4.7. Management review output 7](#_Toc406623205)

[4.8. Record 7](#_Toc406623206)

This procedure is based on ISO 13485 clause 5.6 but also encompasses other references to management review which appear throughout the standard.

# Purpose

This procedure describes the system and assigns responsibilities for scheduling, conducting and recording management reviews of the Quality Management System (QMS).

# Scope

The scope of this procedure includes all activities of the QMS at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Managing Director |  |
| Quality Manager |  |
| Engineering Manager |  |
|  |  |
|  |  |

Amend roles and responsibilities as required for your company structure and processes.

# Procedure

## Frequency and scheduling

ISO 13485 specifies only that management reviews be conducted “at planned intervals”. Reviews should be conducted quite frequently (every 4 or 6 months) when the QMS is young then less often when the system becomes more established. Mature systems may be reviewed every second year and when there are any major changes to the company’s operations or to the QMS.

Performance and the QMS is reviewed by top management every 2 years and whenever there has been a significant change to the company’s operations.

Describe more frequent reviews if this is a new quality management system.

For the first two years of the life of this QMS, management reviews will be conducted every six (6) months. Additional, special reviews will be undertaken if there have been any significant changes to the company’s operations.

## Attendance

Construction of the QMS review team is not specified but should at least include the CEO and the QA Manager. Typically the team would be the same as the company’s executive management team but would usually include the Regulatory, Engineering and Production Managers.

Management reviews are chaired by the CEO and are attended by the managers of Quality Assurance, Marketing/Sales, Engineering, Production, Purchasing and Human Resources.

Name the specific managers (by title). Ensure this list and the titles align with QM Section 5.6.1.3.

Managers unable to attend may send a representative. Absent managers will receive minutes and may submit input to the CEO or QA Manager.

No more than two managers may be absent from the meeting.

The CEO and QA Manager must always attend.

## Agenda

The management review meeting agenda is drafted by the QA Manager and reviewed by the CEO.

The approved agenda is distributed at least one week prior to the meeting.

The agenda must cover all items listed in Section 4.4.

## Review input

The following inputs are derived from ISO 13485 clause 5.6.2 but include other standard requirements (e.g. the training requirements of clause 6.2.2).

The following minimum information and data must be presented for review.

| Review requirements | Description |
| --- | --- |
| Actions from previous meeting | QA reports on the previous meeting’s actions. Incomplete items are carried forward as outstanding actions. |
| Process performance and product conformity | QA presents quality performance data. This includes process and product nonconformities, on-time delivery performance, supplier quality performance and productivity data.  Edit the scope of the performance data and align with QM Section 8.4, Analysis of Data. |
| Internal quality audits | QA presents internal QMS audits including summaries of results, the frequency of audit findings against particular elements of the QMS and discussion of significant findings. |
| Corrective and preventive actions | QA presents key corrective and preventive actions implemented through the period and the status of pending actions. |
| Post-production feedback and customer complaints | QA presents summaries of post-production feedback and customer complaints including analysis of trends for particular categories, as defined in Procedure QP801: Feedback and Customer Satisfaction and Procedure QP809: Customer Complaints. |
| Customer complaints | Customer Service resents summaries of customer complaints as described in Procedure QP809: Customer Complaints. |
| Customer satisfaction | Marketing presents customer satisfaction data and trends as defined in Procedure QP801: Feedback and Customer Satisfaction.  Measurement of customer satisfaction is only a requirement of ISO 9001. Align with procedure QP801. |
| Training | Human Resources reports on the status and effectiveness of training programs including correlation of training with quality and productivity performance trends in corresponding areas.  This item is not mandatory but it supports requirements in Clause 6.2.2(c) of ISO 13485. If this item is omitted, modify this section to align with the Quality Manual Section 6.2, and with procedure QP601. |
| Continual improvement | QA presents data demonstrating progress toward achieving continual improvement goals and reviews current and completed improvement projects.  Continuous improvement is a requirement of ISO 9001 only, Align this section with the Quality Manual Sections 8.5 and procedure QP807. |
| New or revised regulatory requirements | QA (or Regulatory Affairs) informs the team of any new or changed regulations and identifies the implication of them for the facility’s processes and QMS. |
| Changes that could affect the quality system | QA highlights any product, process, capacity or other changes that affect the QMS and proposes actions to update or modify the system in response. |

The management review may also consider the cost of quality versus non-quality, integration of the QMS with other operations and activities and market and customer responses.

Following each presentation, the participating managers discuss the issues, compare their status and performance with preceding periods and identify areas where improvement is required.

## Initiating and implementing quality objectives

ISO 13485, clauses 5.3 and 5.4.1, specifies the requirement to review the company’s quality policy and quality objectives. It is convenient to incorporate this review with the QMS review.

Align this clause with Section 5.4 in the Quality Manual.

Management reviews confirm or reset the company’s quality objectives. The objectives are established to improve performance of the company and its quality system, to meet the quality policy and other goals.

The Quality Objectives Record is beyond the requirements of ISO 13485 and ISO 9001 but provides a way to define and track achievement of quality objectives.

New quality objectives are initiated by the management review using Form FM501-1: Quality Objectives Record. The form is also used to define and track the management projects for implementing the objective. The following information is entered in the top block of the form:

* the quality objective that is to be achieved by the project
* present and targeted levels of performance
* the time frame for achieving the objective
* assignment of a project manager

New quality objectives and the associated Quality Objectives Records are forwarded to the assigned project manager(s) who define the actions required to achieve the objectives. The input at this stage consists of:

* an outline of the program including identification of the major elements
* areas where the project will be implemented
* involvement of other departments, managers and functions
* requirements for personnel, facilities, equipment and other resources (to be documented in the Project Description block)
* monitoring and measurement methods
* means to measure progress toward the objective (to be documented in the Monitoring and Measurement Methods block)

The QA Manager reviews the Quality Objectives Record and, if in agreement, approves implementation. The QA Manager may also determine how many intermediate reviews are required. Intermediate reviews are then documented in the Tracking and Closeout block (Form FM501-1*: Quality Objectives Record* provides space for three intermediate reviews).

The QA Manager may revise the review dates but may not change the objective without full approval of the management review team. Such changes must be recorded in Form FM501-1: Quality Objectives Record.

For simple projects, *FM501-1: Quality Objectives Record* is sufficient to define and track the project. Larger or more complex projects may require a project file to organise associated documents and records. However Form FM501-1*: Quality Objectives Record* is always used as the main initiating, tracking and close-out document.

## Reviewing and closing out quality objectives

Completed projects are reported to the next review team meeting or directly to team members. Achieved objectives may be reset (upgraded to a higher level) to achieve a higher performance. Close-out is recorded in the Closeout by Management Review field at the bottom of Form FM501-1*: Quality Objectives Record*.

If objectives are not achieved, the project is review to determine the cause of the failure. Top management then determine the next action, depending on the nature of the objective and cause(s) of the failure. Decisions regarding quality objectives are recorded in the pertinent Quality Objectives Record.

The company’s Quality Policy is also reviewed to ensure its continuing suitability and relevance. The policy may be changed when the goals expressed in the policy have been achieved or when changes within or outside the company render the policy inadequate or inappropriate.

## Management review output

The review output is specified in ISO 13485 clause 5.6.3.

Management reviews aim to achieve:

* improvement of the quality management system

To comply with ISO 13485 only, change to: "Improvements needed to maintain effectiveness of the QMS ".

* improvement of quality performance

To comply with ISO 13485 only, delete this bullet.

* improvements in products and/or services to better meet customer requirements and give greater customer satisfaction

To comply with ISO 13485 only, delete the last part of this sentence referring to customer satisfaction.

These improvement actions are either defined as corrective and preventive actions (refer to Procedure QP810: Corrective and Preventative Action) or as quality objectives.

Resources needed for implementations of the improvement actions are identified. This will include assignment of responsibility, timeframes and allocation of human, equipment, know-how and other resources.

Management review output is documented in the minutes of the review meeting. Action items are highlighted or are placed under a special heading to ensure that they are readily identifiable.

## Record

Records of management review are important as they form the sole evidence that the review agenda was covered and was concluded with appropriate decisions and actions.

The QA Manager prepares minutes of management review meetings. They are distributed to those attending and any absent managers. The location and retention period for management review records are specified in Procedure QP403: Control of Records.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP403 | Control of Records. |
| QP801 | Feedback and Customer Satisfaction |
| QP809 | Customer Complaints |
| QP810 | Corrective and Preventative Action |
| FM501-1 | Quality Objectives Record |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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