STANDARD OPERATING PROCEDURE

Management Review SOP

Document no.	SOP-QA-005
Revision	1.0
Owner	Quality Manager
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To make sure top management periodically reviews the performance of the quality management system, decides on needed changes, resources and improvement actions, and that decisions are tracked to completion.

2. Scope

Applies to planning, gathering inputs for, running and following up on scheduled management review meetings. Execution of individual CAPAs and audits is covered by their own SOPs; this SOP covers reviewing their combined results.

Definitions

Management review	A scheduled meeting where top management evaluates quality system performance and decides on changes.
Input	A standard agenda item, such as audit results or complaint trends, that feeds the review.
Action item	A decision from the review assigned to a named owner with a due date.
Quality objective	A measurable target the organization has set for quality performance.

3. Responsibilities

Quality Manager	Schedules the review, compiles inputs, and tracks action items to completion.
Executive Sponsor	Leads decision-making on changes, resources and improvement priorities.
Process Owner	Presents performance data for their area against quality objectives.
Document Controller	Records minutes, distributes them, and archives review inputs.

RACI matrix

Activity	Quality Manager	Executive Sponsor	Process Owner	Document Controller
Schedule the review and compile inputs	R/A	I	C	I
Present performance against objectives	C	I	R/A	-
Decide on changes and resources	C	R/A	C	-

Activity	Quality Manager	Executive Sponsor	Process Owner	Document Controller
Record and distribute minutes and actions	C	I	I	R/A
Track action items to completion	R/A	I	C	I

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- Management review agenda and input template
- Meeting minutes template
- Action item tracker
- Quality objective performance data

5. Procedure

Step	Task	Owner	Done
5.1	**Schedule the review meeting** The Quality Manager schedules the management review meeting according to the defined review cycle and invites the required attendees.	Quality Manager	☐
5.2	**Compile the inputs** The Quality Manager compiles the standard inputs, including audit results, CAPA status, complaint trends, quality objective performance, and the status of prior action items. **Checkpoint:** Every standard input area appears in the compiled package; none are skipped for the sake of time.	Quality Manager	☐
5.3	**Distribute the pre-read** The Quality Manager distributes the compiled input package to attendees ahead of the meeting so they arrive prepared.	Quality Manager	☐
5.4	**Present each input area** The Process Owner presents performance in their area against the relevant quality objectives during the meeting.	Process Owner	☐
5.5	**Discuss risks and opportunities** The Executive Sponsor leads a discussion of risks, resource needs and opportunities for improvement raised by the inputs.	Executive Sponsor	☐
5.6	**Decide on changes** The Executive Sponsor decides on needed changes to the quality management system, processes or resources based on the discussion. **Checkpoint:** Each decision made in the meeting has a named owner and a due date before the meeting ends.	Executive Sponsor	☐
5.7	**Record decisions and action items** The Document Controller records the decisions, action items and owners from the meeting in the minutes.	Document Controller	☐
5.8	**Distribute approved minutes** The Document Controller distributes the approved minutes and action items to attendees and relevant process owners.	Document Controller	☐

Step	Task	Owner	Done
5.9	**Track action items** The Quality Manager tracks each action item to completion between review cycles using the action item tracker. **Warning:** An action item without a tracked due date tends to never get closed.	Quality Manager	☐
5.10	**Escalate overdue items** The Quality Manager escalates any overdue action item to the Executive Sponsor for a decision on how to proceed.	Quality Manager	☐
5.11	**Report prior action status** The Quality Manager reports the status of prior action items as a standard input to the next management review meeting.	Quality Manager	☐
5.12	**Archive review records** The Document Controller archives the management review minutes and supporting inputs in the document management system.	Document Controller	☐

6. Quality checks

- Every scheduled input area appears on the agenda for each review meeting.
- Decisions and action items are recorded with a named owner and due date.
- Overdue action items are escalated to the Executive Sponsor.
- Prior action item status is reported as an input to the next review.

7. Records

- Management review agenda and pre-read package
- Meeting minutes with decisions and action items
- Action item tracker
- Archived review inputs

8. KPIs

- Percentage of management reviews held on schedule
- Percentage of action items closed on time
- Number of overdue action items at any given time
- Trend in quality objective performance across reviews

9. Common mistakes

- Skipping a standard input area because there's nothing urgent to report.
- Recording a decision without a named owner or due date.
- Not following up on action items between meetings.
- Letting the review become a status readout with no actual decisions made.

10. Revision history

Revision	Date	Description	Reviewed by
1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

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