**Document approval**

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# Purpose

The purposes of this Standard Operating Procedure (SOP) are to define the methods used to review the Quality Management System that is in operation, to ensure that the provisions of the Quality Management System and its effectiveness are reviewed, to define inputs and outputs for reviewing of current management & operational performance data, and to ensure that continual improvement opportunities of products, processes and the system itself have been addressed.

# Scope

This SOP is valid at {{ CompanyName }} for the whole Organization. The respective training shall be given in accordance with **{{ TrainingCode }} {{ TrainingTitle }}***.*

# Responsibilities

Responsible for the content of this SOP is {{ QualityOrganizationHead }}

|  |  |
| --- | --- |
| **Role** | **Definition/Task** |
| Leadership Team / Senior Management | * Quality Management System (QMS) governance through {{ ManagementReviewTitle }} to ensure its continuing suitability and effectiveness
* performs {{ ManagementReviewTitle }} , assess the conclusions of process performance and product quality and of the QMS
* supports, provides resources for the implementation of decisions made by Senior Management during {{ ManagementReviewTitle }}
* approves report
* monitors outputs and decisions implementation progress of all {{ ManagementReviewTitle }}s
 |
| {{ QualityOrganizationHead }} / Quality Organization | * supports {{ ManagementReviewTitle }} process (preparation, facilitating, reporting and follow-ups monitoring)
* monitors outputs and decisions implementation progress of all {{ ManagementReviewTitle }}s
 |

# Definitions, terms, and abbreviations

|  |  |
| --- | --- |
| **Term/abbreviation** | **Definition at {{ CompanyName }}** |
| {{ ManagementReviewTitle }} | Independent evaluation of the QMS by the Leadership Team / Senior Management at specified intervals to ensure the suitability and effectiveness of the QMS. |
| Senior Management | Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilize resources within the company or site. (Leadership Team, Heads of the Departments. Team Leads, etc.) |

# Workflow

The objectives of the {{ ManagementReviewTitle }} are:

* Quality Management System (QMS)
* Process performance
* Product quality

## Scheduling and preparation of the {{ ManagementReviewTitle }}

The {{ ManagementReviewTitle}} shall be conducted annually by senior management. The {{ QualityOrganizationHead }} plans and communicates each {{ ManagementReviewTitle }} in a timely manner. The {{ QualityOrganizationHead }} may decide with senior management to have a stand-alone {{ ManagementReviewTitle}} or to combine it with other business activities such as strategic planning, business planning, operations meetings, process reviews/councils, customer requirements or functional reviews.

{{ QualityOrganizationHead }} together with Quality Organization prepare a {{ ManagementReviewTitle }} draft report with key quality related data and other inputs.

When preparing a document, a graphical representation of data (trends), actions completion [%] for the planned period, comparison with previous periods, etc. can be used. The last three (3) review periods shall be used (if available) to benchmark the new numbers against.

## Inputs for QMS {{ ManagementReviewTitle }}

{{ QualityOrganizationHead }} together with Quality Organization prepares the draft report for {{ ManagementReviewTitle }} by collecting the following inputs:

* + - Measurement of achievement of QMS objectives of as outlined in the Quality Strategy or {{ QualityPlanTitle }};
		- Assessment of performance indicators that can be used to monitor the effectiveness of processes within QMS, such as:
			* {{ ComplaintsRecallsTitle }},
			* {{ DevMng\_Title }},
			* {{ CAPA\_Title }},
			* {{ ChangeManagementTitle }} processes,
			* Feedback on outsourced activities (performance of external providers),
			* Self-assessment processes including risk assessments, trending, and internal audits,
			* External assessments such as regulatory inspections and findings and customer audits,
			* Adequacy of resources.
		- Status of actions from previous {{ ManagementReviewTitle }};
		- Extent to which quality objectives have been met;
		- Opportunities for improvement QMS;

External changes and challenges (can be facilitated by considering issues arising from legal, regulatory affairs, technological, competitive, market, cultural, social, and economic environments).

### Inputs for {{ ManagementReviewTitle }} of process performance and product quality:

* + - * The results of regulatory inspections and findings, audits and other assessments, and commitments made to regulatory authorities;
		- Any follow-up actions from previous {{ ManagementReviewTitle }};
		- Opportunities for the improvement of process performance and operations quality.
		- Periodic quality reviews, that can include:
			* Measures of customer satisfaction such as complaints and recalls;
			* Conclusions of process performance and operations quality monitoring;
			* The effectiveness of process and operations changes including those arising from corrective action and preventive action;

{{ QualityOrganizationHead }} distributes draft report to Senior Management for reviewing prior appointed meeting date.

## {{ ManagementReviewTitle }}

{{ ManagementReviewTitle }} takes place through a meeting of Senior Management members facilitated by {{ QualityOrganizationHead }}. During the meeting, {{ QualityOrganizationHead }} presents a {{ ManagementReviewTitle }} draft report and related data. After appropriate discussion and assessment, Senior Management members and {{ QualityOrganizationHead }} agreed and approved {{ ManagementReviewTitle }} outcomes (decisions and required actions).

### Outputs of {{ ManagementReviewTitle }}:

* + - * Actions for improvements of QMS, processes, and operations;
			* Allocation or reallocation of resources and personnel training;
			* Proposals for revision of quality policy, quality objectives;
			* Documentation and timely and effective communication of the results of the {{ ManagementReviewTitle }} and actions, including escalation of appropriate issues to Senior Management;
			* Expected period of the next review.

After the {{ ManagementReviewTitle }}, {{ QualityOrganizationHead }} together with Quality Organization update {{ ManagementReviewTitle }} report with all approved outputs. Senior Management review and approve the final {{ ManagementReviewTitle }} Report.

## Monitoring of actions implementation

Quality Organization monitors the implementation of {{ ManagementReviewTitle }} decisions and required actions continuously.

Upon Senior Management’s request, Quality Organization reports on the progress of the implementation.

# Applicable documents

{{ QualityManualCode }} {{ QualityManualTitle }}

{{ QualityPlanCode }} {{ QualityPlanTitle }}

{{ ChangeManagementCode }} {{ ChangeManagementTitle }}

{{ DevMng\_Code }} {{ DevMng\_Title }}

{{ CAPA\_Code }} {{ CAPA\_Title }}

{{ AuditsInspectionsCode }} {{ AuditsInspectionsTitle }}

{{ TrainingCode }} {{ TrainingTitle }}

{{ ComplaintsRecallsCode }} {{ ComplaintsRecallsTitle }}

{{ SuppliersCode }} {{ SuppliersTitle }}

# Appendices

n/a

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Initial SOP introduction | QMS implementation |