**Document approval**

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|  | **Name** | **Date** | **Signature** |
| **Author’s designation**  **<QualityDesignee2>** |  |  |  |
| **Reviewer’s designation**  **<QualityDesignee1>** |  |  |  |
| **Approver’s designation**  **<QualityOrganizationHead>** |  |  |  |

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# Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the methods used to review the Quality Management System that is in operation, and related inputs and outputs for reviewing of current management & operational performance data.

# Scope

This SOP is valid at <CompanyName> for all 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>

<ManagementReviewTitle> shall be done by Senior Management annually. <QualityOrganizationHead> plans and communicates in a timely manner each <ManagementReviewTitle>. <QualityOrganizationHead> with Senior Management may decide to have stand-alone <ManagementReviewTitle> or combine it with other business activities, e.g., 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:
      * <ComplRecl\_DocName>,
      * <DevMng\_DocName>,
      * <CAPAMng\_DocName>,
      * <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 audit,
      * 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 improvement process performance and product quality.
      * Periodic quality reviews, that can include:
        + Measures of customer satisfaction such as product quality complaints and recalls;
        + Conclusions of process performance and product quality monitoring;
        + The effectiveness of process and product changes including those arising from corrective action and preventive action;

All product related data summarized in <APQRsTitle>s.

<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 an <ManagementReviewTitle> draft report and related data. After appropriate discussion and assessment, Senior Management members and <QualityOrganizationHead> agree and approve <ManagementReviewTitle> outcomes (decisions and required actions).

### Outputs of <ManagementReviewTitle>:

* + - * Actions for improvements of QMS, processes, products;
      * 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 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 progress of the implementation.

# Applicable documents

<QualityManualCode> <QualityManualTitle>

<QualityPlanCode> <QualityPlanTitle>

<ChangeManagementCode> <ChangeManagementTitle>

<DevMng\_DocCode> <DevMng\_DocName>

<CAPAMng\_DocCode> <CAPAMng\_DocName>

<AuditsInspectionsCode> <AuditsInspectionsTitle>

<TrainingCode> <TrainingTitle>

<APQRsCode> <APQRsTitle>

<ComplRecl\_DocCode> <ComplRecl\_DocName>

<OutsourceCode> <OutsourceTitle>

EudraLex Volume 4EU GMP Chapter 1 Pharmaceutical Quality System EMA/CHMP/ICH/214732/2007 ICH guideline Q10 on pharmaceutical quality system ISO 9001:2015 Quality management systems – Requirements

# Appendices

n/a

# Document revision history

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