**Document approval**

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| **Effective Date** | **01-09-2023** |

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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 Grau Pharma GmbH for the whole Organization. The respective training shall be given in accordance with **SOP-10 Training Management***.*

# Responsibilities

Responsible for the content of this SOP is Managing Director Tradelaw

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| **Role** | **Definition/Task** |
| Leadership Team / Senior Management | * Quality Management System (QMS) governance through Management Review to ensure its continuing suitability and effectiveness * performs Management Review , 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 Management Review * approves report * monitors outputs and decisions implementation progress of all Management Reviews |
| Managing Director Tradelaw / Quality Organization | * supports Management Review process (preparation, facilitating, reporting and follow-ups monitoring) * monitors outputs and decisions implementation progress of all Management Reviews |

# Definitions, terms, and abbreviations

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| **Term/abbreviation** | **Definition at Grau Pharma GmbH** |
| Management Review | 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 Management Review are:

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

## Scheduling and preparation of the Management Review

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

Managing Director Tradelaw together with Quality Organization prepare a Management Review 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 Management Review

Managing Director Tradelaw together with Quality Organization prepares the draft report for Management Review by collecting the following inputs:

* + - Measurement of achievement of QMS objectives of as outlined in the Quality Strategy or Quality Plan;
    - Assessment of performance indicators that can be used to monitor the effectiveness of processes within QMS, such as:
      * Complaints and Recalls Management,
      * Deviation and Nonconformity Management,
      * CAPA Management,
      * Change Management 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 Management Review;
    - 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 Management Review 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 Management Review;
    - 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;

Managing Director Tradelaw distributes draft report to Senior Management for reviewing prior appointed meeting date.

## Management Review

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

### Outputs of Management Review:

* + - * 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 Management Review and actions, including escalation of appropriate issues to Senior Management;
      * Expected period of the next review.

After the Management Review, Managing Director Tradelaw together with Quality Organization update Management Review report with all approved outputs. Senior Management review and approve the final Management Review Report.

## Monitoring of actions implementation

Quality Organization monitors the implementation of Management Review decisions and required actions continuously.

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

# Applicable documents

MD-01 Quality Manual

SOP-03 Quality Plan

SOP-05 Change Management

SOP-06 Deviation and Nonconformity Management

SOP-07 CAPA Management

SOP-08 Audits Management

SOP-10 Training Management

SOP-11 Complaints and Recalls Management

SOP-12 Suppliers, Customers Management

# 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 |