**Document approval**

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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 NBE-Therapeutics for all Organization. The respective training shall be given in accordance with **SOP-10SOP-10TrainingTitle>***.*

# Responsibilities

Responsible for the content of this SOP is Quality Management Director.

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

# Definitions, terms and abbreviations

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| --- | --- |
| **Term/abbreviation** | **Definition at NBE-Therapeutics** |
| 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

Management Review shall be done by Senior Management annually. Quality Management Director plans and communicates in a timely manner each Management Review. Management Reviewwith Senior Management may decide to have stand-alone Management Review or combine it with other business activities, e.g., strategic planning, business planning, operations meetings, process reviews/councils, customer requirements or functional reviews.

Quality Management Director 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

Quality Management Director 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 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 audit,
			* 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 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 Annual Product Quality Reviews.

Quality Management Director 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 Quality Management Director. During the meeting, Quality Management Director presents an Management Review draft report and related data. After appropriate discussion and assessment, Senior Management members and Quality Management Director agree and approve MR outcomes (decisions and required actions).

### Outputs of Management Review:

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

After the Management Review, Quality Management Director together with Quality Organization update Management Review report with all approved outputs. Senior Management review and approve 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 progress of the implementation.

# Applicable documents

MD-(New) Quality Manual (New)

SOP-03 Quality Plan

SOP-05 Change Management

SOP-06 Deviation Management

SOP-07 CAPA Management

SOP-08 Audits and Inspections Management

SOP-10 Training Management

SOP-11 Annual Product Quality Review

SOP-12 Complaints and Recalls Management

SOP-14 Outsourced activities Management

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 |