Prepared By	Reviewed By	Approved By
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1. PURPOSE

To define the procedure for conducting **Management Review** of the Quality Management System (QMS) to ensure its continuing **suitability, adequacy, effectiveness and alignment with applicable regulatory requirements**.

This procedure is established in accordance with **ISO 13485:2016**, applicable requirements of **Indian Medical Devices Rules (MDR) 2017**, **EU MDR 2017/745**, and the organization's QMS procedures.

2. SCOPE

This SOP applies to Management Review activities covering the Quality Management System and applicable processes related to the manufacture, testing, release, storage and distribution of medical devices.

It covers:

- QMS performance and effectiveness
- Quality objectives
- Internal and external audit results
- Customer complaints and feedback
- Non-conformities and CAPA
- Process and product performance
- Supplier performance
- Risk management
- Regulatory and statutory requirements
- Changes affecting the QMS
- Resource requirements
- Opportunities for improvement
- PMS and vigilance information, where applicable

3. REFERENCES

Sr. No.	Reference
1	ISO 13485:2016 – Clause 5.6 Management Review
2	ISO 13485:2016 – Clause 5.6.1 General
3	ISO 13485:2016 – Clause 5.6.2 Review Input
4	ISO 13485:2016 – Clause 5.6.3 Review Output
5	Medical Devices Rules, 2017 – applicable QMS requirements
6	EU MDR 2017/745 – applicable QMS and regulatory requirements
7	Internal QMS procedures and applicable work instructions

4. DEFINITIONS

Management Review: A systematic review conducted by top management at planned intervals to evaluate the suitability, adequacy and effectiveness of the QMS.

Top Management: Person or group of persons who directs and controls the organization at the highest level.

Review Input: Information and data presented to management for evaluation during the Management Review.

Review Output: Decisions, actions and improvements resulting from the Management Review.

CAPA: Corrective and Preventive Action / Corrective Action and Preventive Action, as applicable to the organization's QMS terminology.

PMS: Post-Market Surveillance.

5. RESPONSIBILITIES

5.1 Top Management

Top Management shall:

- Conduct Management Reviews at planned intervals.
- Review the performance and effectiveness of the QMS.
- Review the availability and adequacy of resources.
- Evaluate opportunities for improvement.
- Take decisions and actions related to QMS improvement.
- Ensure applicable regulatory requirements are considered.
- Approve necessary resources and corrective actions.

5.2 QA / QMS Head

QA/QMS Head shall:

- Prepare the Management Review agenda.

- Collect and compile required review inputs.
- Coordinate the Management Review meeting.
- Present QMS performance data.
- Record meeting discussions and decisions.
- Prepare and maintain the Management Review Minutes.
- Track assigned actions until completion.
- Verify closure of actions.

5.3 Department Heads

Department Heads shall:

- Provide required departmental performance data.
- Present relevant problems, risks and improvement opportunities.
- Implement assigned actions within the defined target date.
- Provide objective evidence of completed actions.

5.4 Regulatory / Quality Personnel

Where applicable, responsible personnel shall provide updates regarding:

- Regulatory changes
- Customer complaints
- PMS information
- Vigilance reporting
- Regulatory inspections
- Product safety and performance
- Applicable Indian MDR and EU MDR requirements.

6. MANAGEMENT REVIEW FREQUENCY

Management Review shall be conducted at **planned intervals, at least once per year**, unless a more frequent review is required based on:

- Significant QMS changes
- Major non-conformity
- Serious customer complaint
- Product safety issue

- Regulatory change
- Regulatory inspection finding
- Significant CAPA
- Significant change in organization, process or product
- Significant risk or performance concern

Additional Management Reviews may be conducted whenever required by Top Management.

7. MANAGEMENT REVIEW PROCESS

The Management Review process shall include:

Planning → Collection of Inputs → Meeting → Review & Evaluation → Decisions/Actions → Documentation → Action Follow-up → Effectiveness Verification

7.1 Planning

QA/QMS Head shall:

1. Define the Management Review date.
2. Prepare the agenda.
3. Identify required participants.
4. Collect relevant data and records.
5. Circulate required information to participants, where applicable.

7.2 Participants

Management Review may include:

- Top Management
- QA/QMS Head
- Production Head
- QC Head
- R&D / Engineering Representative
- Regulatory Affairs Representative
- Purchase / Supplier Quality Representative
- Other responsible personnel as required

8. MANAGEMENT REVIEW INPUTS

The following inputs shall be reviewed as applicable:

8.1 Previous Management Review Actions

Status and effectiveness of actions from previous Management Reviews shall be reviewed.

8.2 Internal and External Audit Results

Review shall include:

- Internal audit findings
- External audit findings
- Regulatory inspection findings
- Customer or certification audit findings
- Status of corrective actions

8.3 Customer Feedback and Complaints

Review shall include:

- Customer complaints
- Customer feedback
- Complaint trends
- Product return information
- Complaint investigation status
- Serious incidents, where applicable

8.4 Process Performance

Management shall review applicable process performance indicators such as:

- Production output
- Rejection rate
- Rework rate
- Process deviations
- IPQC/FQC results
- On-time production performance
- Process capability, where applicable

8.5 Product Performance

Review may include:

- Product quality
- Product failures
- Product non-conformities
- Product testing results
- Product returns
- Field performance
- Safety and performance information

8.6 CAPA

Review shall include:

- Open CAPAs
- Closed CAPAs
- Overdue CAPAs
- Root causes
- Effectiveness verification
- Recurring problems

8.7 Supplier Performance

Review shall include:

- Supplier quality
- Incoming rejection
- Supplier complaints
- Supplier corrective actions
- Approved supplier status
- Supplier performance trends

8.8 Quality Objectives

Management shall review:

- Quality objectives
- Achievement against targets
- KPI trends

- Reasons for missed targets
- Actions required for improvement

8.9 Risk Management

Management shall review significant risk-related information, including:

- Changes in identified risks
- New risks
- Risk control effectiveness
- Post-production / post-market information affecting risk
- Significant product or process changes

8.10 Regulatory Requirements

Applicable regulatory changes shall be reviewed, including:

- Indian MDR 2017 requirements
- EU MDR 2017/745 requirements, where applicable
- Applicable standards
- Regulatory notifications
- Licensing requirements
- Registration requirements
- Vigilance requirements

8.11 PMS and Vigilance

Where applicable, review shall include:

- PMS data
- Trend information
- Serious incidents
- Field safety corrective actions
- Vigilance reports
- Safety-related customer feedback

8.12 Changes Affecting the QMS

Management shall review significant changes such as:

- New products
- New processes
- New equipment
- New facilities
- Organizational changes
- Regulatory changes
- Supplier changes
- Software / IT changes
- Changes in applicable standards

8.13 Resource Requirements

Management shall evaluate adequacy of:

- Manpower
- Infrastructure
- Equipment
- Testing facilities
- Training
- Working environment
- Financial resources
- IT systems
- External service providers

8.14 Opportunities for Improvement

Management shall identify opportunities related to:

- Product quality
- Process improvement
- Cost reduction without compromising quality
- Customer satisfaction
- QMS effectiveness
- Regulatory compliance

- Risk reduction

9. MANAGEMENT REVIEW OUTPUTS

Management Review outputs shall include decisions and actions related to:

1. Improvement of the QMS and its processes.
2. Improvement of products related to customer requirements.
3. Changes required to the QMS.
4. Resource requirements.
5. Actions related to regulatory compliance.
6. Actions related to product safety and performance.
7. CAPA or improvement activities.
8. Changes to quality objectives.
9. Additional monitoring or follow-up activities.

All assigned actions shall have:

- Action description
- Responsible person
- Target completion date
- Status
- Evidence of completion
- Effectiveness verification, where applicable

10. MANAGEMENT REVIEW RECORD

The following records shall be maintained:

- Management Review Agenda
- Management Review Attendance Record
- Management Review Minutes
- Management Review Input Data
- Action Plan
- Previous Review Action Status
- Supporting records/evidence

- Closure and effectiveness verification records

11. ACTION FOLLOW-UP

QA/QMS Head shall monitor all actions arising from Management Review.

The status shall be classified as:

- **Open**
- **In Progress**
- **Completed**
- **Overdue**
- **Closed after Effectiveness Verification**, where applicable

Overdue actions shall be escalated to the concerned Department Head and Top Management.

12. EFFECTIVENESS VERIFICATION

Where an action requires effectiveness verification, QA/QMS shall verify whether the action has achieved the intended result.

Verification may include:

- Record review
- Process observation
- KPI/trend review
- Internal audit
- CAPA effectiveness review
- Complaint trend review
- Reassessment of risk

If the action is found ineffective, further action shall be initiated.

13. RECORD CONTROL

All Management Review records shall be:

- Legible
- Accurate
- Complete
- Traceable
- Protected from unauthorized modification

- Readily retrievable
- Retained as per the organization's Record Control SOP and applicable regulatory requirements.

14. DOCUMENTED INFORMATION / RECORDS

Sr. No.	Record Name	Record No.	Responsibility
1	Management Review Agenda	INV/SOP/QA/06/F1	QA/QMS
2	Management Review Attendance Record	INV/SOP/QA/06/F2	QA/QMS
3	Management Review Minutes	INV/SOP/QA/06/F3	QA/QMS
4	Management Review Action Plan	INV/SOP/QA/06/F4	QA/QMS
5	Management Review Effectiveness Verification Record	INV/SOP/QA/06/F5	QA/QMS

15. FLOW CHART

Management Review Planning
↓
Collection of Review Inputs
↓
Preparation of Agenda & Data
↓
Management Review Meeting
↓
Review of QMS Performance & Regulatory Compliance
↓
Identification of Issues / Risks / Opportunities
↓
Management Decisions & Action Plan
↓
Assignment of Responsibility & Target Dates
↓
Implementation & Monitoring
↓
Effectiveness Verification, where applicable
↓
Closure & Record Retention

16. ANNEXURES

Sr. No.	Annexure / Form	Document No.
1	Management Review Attendance Record	INV/SOP/QA/06/F1
2	Management Review Minutes	INV/SOP/QA/06/F2
3	Management Review Action Plan	INV/SOP/QA/06/F3
4	Management Review Effectiveness Verification Record	INV/SOP/QA/06/F4

17. REVISION HISTORY

Revision No.	Effective Date	Description of Change	Prepared By	Approved By
00		Initial Issue		