Prepared By	Reviewed By	Approved By
Gitanjali Pawar	**Pramod Biradar**	**Anuja Ladkat**
(QA Engineer)	**(Manufacturing HOD)**	**(QA HOD / MR)**

1. PURPOSE

To establish a documented and systematic procedure for planning, conducting, reporting, and following up **Internal Audits** to verify that the Quality Management System (QMS), manufacturing processes, product realization activities, records, and applicable regulatory requirements are effectively implemented and maintained.

The procedure ensures compliance with:

- **ISO 13485:2016**
- **Medical Devices Rules, 2017 (Indian MDR)**
- Applicable product-specific standards and regulatory requirements
- Company's approved QMS procedures and documented processes

2. SCOPE

This SOP applies to all departments, processes, activities, sites, functions, and QMS elements related to the manufacture, inspection, testing, storage, release, distribution, and post-market activities of medical devices, as applicable.

The audit shall cover, where applicable:

- Quality Management System
- Document and Record Control
- Management Responsibility
- Risk Management
- Design and Development
- Purchasing and Supplier Control
- Incoming Quality Control
- Production and Process Control
- Process Validation
- Product Inspection and Testing

- Calibration and Maintenance
- Identification and Traceability
- Packaging and Labelling
- Storage and Distribution
- Nonconforming Product Control
- CAPA
- Complaints
- Vigilance / regulatory reporting
- Post-Market Surveillance
- Training and Competency
- Data Integrity and Electronic Records
- Regulatory compliance

3. REFERENCES

Sr. No.	Reference
1	ISO 13485:2016 – Clause 8.2.4 Internal Audit
2	ISO 13485:2016 – Quality Management System requirements
3	Medical Devices Rules, 2017 (India)
4	Applicable Harmonized / Designated / Recognized Standards
5	Company's Quality Manual
6	Applicable SOPs, Work Instructions and Forms
7	Previous Internal Audit Reports and CAPA Records

4. DEFINITIONS

Internal Audit:
A systematic and independent examination performed to determine whether planned arrangements, QMS requirements, procedures, and applicable regulatory requirements are effectively implemented and maintained.

Audit Criteria:
Requirements against which audit evidence is compared.

Audit Evidence:
Records, documents, observations, interviews, data, or other verifiable information used to determine compliance.

Nonconformity (NC):
non-fulfilment of a specified requirement.

Major Nonconformity:
A significant failure that may affect product safety, regulatory compliance, QMS effectiveness, or the organization's ability to consistently meet specified requirements.

Minor Nonconformity:
An isolated or limited failure to meet a requirement that does not represent a significant system failure.

Observation:
A condition noted during the audit that does not constitute a confirmed nonconformity but may require attention.

5. RESPONSIBILITIES

Function	Responsibility
Top Management	Ensure availability of resources and review significant audit results.
Quality Head / QA	Establish audit programme, approve audit plans, assign competent auditors, review reports and monitor closure.
Internal Auditor	Conduct audits objectively and independently, collect evidence and document findings.
Department Head / Process Owner	Provide access to personnel, processes, documents and records and implement corrective actions.
QA	Evaluate findings, verify corrective actions and effectiveness, and close audit findings.
Regulatory / RA Function	Provide applicable regulatory requirements and support assessment of regulatory compliance.

6. PROCEDURE

6.1 Preparation of Internal Audit Programme

1. QA shall prepare an **Annual Internal Audit Programme** covering applicable QMS processes.
2. The audit programme shall consider:
    - Process importance
    - Product risk
    - Regulatory requirements
    - Previous audit results
    - Customer complaints
    - Nonconformities

- CAPA trends
- Process changes
- Organizational changes
- Product changes
- Supplier performance
- Post-market information
- Previous regulatory inspection findings

3. High-risk or problematic processes may be audited more frequently.
4. Additional audits may be conducted when significant quality or regulatory concerns are identified.

6.2 Auditor Selection and Competency

1. Internal auditors shall have appropriate education, training, knowledge, and experience.
2. Auditor competency shall be documented.
3. Auditors shall be independent of the activity being audited wherever practicable.
4. Personnel shall not audit their own work.
5. Auditor training records shall be maintained.

6.3 Audit Planning

Before conducting the audit, QA / Auditor shall define:

- Audit date
- Department / process
- Audit scope
- Audit objectives
- Audit criteria
- Applicable SOPs and standards
- Applicable regulatory requirements
- Auditor / audit team
- Documents and records to be reviewed
- Previous findings
- Sampling approach, where applicable

6.4 Conducting the Audit

The auditor shall:

1. Conduct an opening meeting with the concerned department.
2. Review applicable procedures and regulatory requirements.
3. Verify implementation of approved procedures.
4. Review relevant records and objective evidence.
5. Interview personnel responsible for the process.
6. Observe actual activities where required.
7. Verify traceability of records.
8. Verify control of documents and records.
9. Verify compliance with applicable medical device regulatory requirements.
10. Record findings based on objective evidence.
11. Discuss significant findings with the concerned process owner before closing the audit.

6.5 Regulatory Compliance Verification

During the audit, the auditor shall verify applicable requirements related to:

ISO 13485:2016

- QMS processes
- Document and record control
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement
- Internal audit
- CAPA
- Nonconforming product

Indian MDR 2017

- Applicable manufacturing licence / registration requirements
- Device classification and applicable requirements

- Manufacturing and quality system controls
- Device records and traceability
- Labelling and packaging requirements
- Complaint handling
- Adverse event / regulatory reporting, as applicable
- Applicable inspection and regulatory requirements

6.6 Audit Findings

Findings shall be documented with sufficient objective evidence to demonstrate the requirement and the observed condition.

Each finding shall include:

- Requirement / reference
- Objective evidence
- Description of nonconformity
- Classification
- Responsible department
- Corrective action requirement
- Target completion date

6.7 Classification of Findings

Classification	Description
Major NC	Significant system failure, regulatory noncompliance, or condition that may adversely affect product quality, safety, or QMS effectiveness.
Minor NC	Isolated or limited failure to meet a specified requirement.
Observation	Potential weakness or improvement opportunity without confirmed nonconformity.

The classification shall be based on the significance and risk of the finding.

6.8 Internal Audit Report

After completion of the audit, the auditor shall prepare an **Internal Audit Report** containing:

- Audit number
- Audit date
- Department / process

- Audit scope
- Audit criteria
- Auditor name
- Documents reviewed
- Objective evidence
- Findings
- NC classification
- Corrective action requirement
- Target date
- Audit conclusion

The report shall be reviewed by QA / Quality Head.

6.9 Corrective Action

For each applicable nonconformity:

1. The process owner shall implement immediate correction where required.
2. Root cause shall be determined.
3. Corrective action shall be defined.
4. Action responsibility shall be assigned.
5. Target completion date shall be established.
6. Supporting evidence shall be submitted to QA.
7. CAPA shall be initiated where required based on risk and significance.

6.10 Verification of Corrective Action

QA / designated auditor shall verify:

- Whether the action was implemented.
- Whether objective evidence is available.
- Whether the identified root cause was addressed.
- Whether recurrence has been prevented.
- Whether the action is effective.

If satisfactory, the finding shall be closed.

If not satisfactory, the finding shall remain open and additional action shall be required.

6.11 Audit Effectiveness

The effectiveness of corrective actions shall be verified based on the nature and risk of the finding.

Effectiveness may be verified through:

- Review of subsequent records
- Follow-up audit
- Process observation
- Trend analysis
- Review of repeat findings
- Review of complaints / NCs
- Review of CAPA effectiveness

6.12 Management Review Input

Significant internal audit results shall be provided as input to **Management Review**, including:

- Audit status
- Major and minor NCs
- Recurring findings
- Overdue actions
- CAPA status
- Audit trends
- Effectiveness of corrective actions
- Regulatory compliance concerns

6.13 INTERNAL AUDIT FLOW

Annual Audit Programme

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Risk-Based Audit Planning

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Select Competent & Independent Auditor

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Prepare Audit Plan / Checklist

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Conduct Audit

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Collect Objective Evidence

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Record Findings

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Classify NC / Observation

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Issue Audit Report

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Correction / Corrective Action / CAPA

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Verification of Implementation

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Effectiveness Verification

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Close Audit Finding

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Management Review / QMS Monitoring

7. RECORDS

Sr. No.	Record	Responsible Department
1	Annual Internal Audit Programme	QA
2	Internal Audit Plan	QA
3	Internal Audit Checklist	QA / Auditor
4	Internal Audit Report	QA / Auditor
5	Audit Finding / NC Record	QA
6	Corrective Action / CAPA Record	Concerned Department / QA
7	Corrective Action Evidence	Concerned Department
8	Audit Closure Record	QA
9	Auditor Training / Competency Record	QA / HR
10	Audit Trend / Summary	QA

8. RECORD CONTROL

All internal audit records shall be:

- Legible
- Identifiable
- Traceable
- Protected from unauthorized alteration
- Readily retrievable
- Retained for the defined retention period

- Controlled according to the applicable Document and Record Control procedure

Electronic audit records shall be protected against unauthorized access, modification, or deletion.

10. AUDIT FREQUENCY

Internal audits shall be conducted according to the approved annual audit programme.

The frequency shall be determined using a **risk-based approach** and may be increased based on:

- Major nonconformities
- Repeated findings
- CAPA trends
- Customer complaints
- Regulatory changes
- Product/process changes
- Significant quality issues
- Previous audit performance

11. TRAINING

Personnel involved in internal auditing shall receive appropriate training covering:

- Internal audit methodology
- ISO 13485 requirements
- Applicable Indian MDR requirements
- QMS procedures
- Risk-based auditing
- Nonconformity classification
- CAPA and root cause analysis
- Audit evidence and reporting
- Data integrity and documentation practices

Training and competency records shall be maintained.

12. ANNEXURES / FORMS

Annexure	Title
Annexure I	Annual Internal Audit Programme
Annexure II	Internal Audit Plan

Annexure III	Internal Audit Checklist
Annexure IV	Internal Audit Report