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

1. PURPOSE

To establish and maintain a systematic process for the identification, preparation, completion, review, storage, protection, retrieval, retention and disposal of quality records generated within the Quality Management System.

This procedure ensures that records are maintained as objective evidence of conformity to specified requirements, QMS processes, product requirements and applicable statutory and regulatory requirements.

2. SCOPE

This SOP applies to all quality, manufacturing, inspection, testing, validation, regulatory and other records generated or maintained within the organisation.

This includes, but is not limited to:

- Quality records
- Batch Manufacturing Records
- Batch Packing Records
- Inspection Records
- Testing Records
- Calibration Records
- Validation Records
- Training Records
- Internal Audit Records
- NCR Records
- CAPA Records
- Complaint Records
- Supplier Quality Records
- Risk Management Records
- Change Control Records
- Device History / Manufacturing Records, where applicable
- Regulatory Records
- Maintenance Records
- Environmental Monitoring Records
- Electronic Records

3. REFERENCES

- ISO 13485:2016 – Quality Management Systems for Medical Devices
- Medical Devices Rules, 2017 (Indian MDR)
- Applicable BIS / IS Standards
- Applicable statutory and regulatory requirements
- Document Control SOP – INV/SOP/QA/02
- CAPA Procedure
- Change Control Procedure
- Internal Audit Procedure
- Training Procedure

4. DEFINITIONS

4.1 Record

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

Documented evidence that an activity has been performed or that a specified result has been achieved.

4.2 Record Control
Systematic control of records with respect to identification, storage, protection, retrieval, retention and disposal.
4.3 Retention Period
The defined period for which a record shall be maintained before authorised disposal.
4.4 Electronic Record
Information generated, received, maintained or stored in electronic form.
4.5 Record Owner
The department or designated person responsible for maintaining a specific record.

5. RESPONSIBILITIES
5.1 Quality Assurance / Document Control
QA shall:
- Establish and maintain the Record Control system.
- Define record identification and retention requirements.
- Maintain the Record Master List.
- Ensure records are legible and retrievable.
- Ensure records are protected from loss, damage and unauthorised access.
- Verify record retention requirements.
- Control disposal of records after the defined retention period.
- Ensure regulatory and customer record requirements are considered.

5.2 Department Head / Record Owner
The Record Owner shall:
- Ensure records are completed correctly.
- Ensure records are available and retrievable.
- Ensure records are stored in designated locations.
- Prevent unauthorised modification or destruction.
- Ensure records are transferred to QA / archive where applicable.

5.3 Employees
Employees generating records shall:
- Enter information accurately and legibly.
- Complete records at the time of performing the activity.
- Follow approved forms and formats.
- Correct errors according to this SOP.
- Protect records from damage or loss.

6. PROCEDURE
6.1 Record Identification
Each record shall be identifiable through appropriate information such as:
- Record / Form Number
- Record Title
- Document Number
- Revision Number
- Date
- Department
- Product Code
- Batch Number
- Lot Number
- Serial Number
- UID, where applicable

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

- Equipment ID, where applicable
- Personnel identification, where applicable

Records shall be traceable to the activity, product, batch, lot or process to which they relate.

6.2 Record Creation

Records shall be generated using approved forms, formats, electronic systems or authorised templates.
Records shall be completed:

- At the time of performing the activity.
- Accurately.
- Completely.
- Legibly.
- In permanent form.
- By authorised / trained personnel.

Blank fields shall be marked **N/A** where applicable.

6.3 Record Review

Where required, records shall be reviewed by authorised personnel to verify:

- Completeness
- Accuracy
- Legibility
- Compliance with specified requirements
- Correct calculations
- Required signatures
- Required dates
- Traceability
- Acceptance criteria

Records requiring approval shall not be considered complete until the required review / approval is performed.

6.4 Correction of Handwritten Records

If an error is identified in a handwritten record:

1. Draw a single line through the incorrect information.
2. Enter the correct information.
3. Initial / sign the correction.
4. Mention the date of correction.
5. Provide the reason for correction where required.

The original information shall remain readable.
Correction fluid, erasing, overwriting or obliteration shall not be permitted.
Example:
→ **25.8°C / Initial / Date**

6.5 Correction of Electronic Records

Electronic records shall be corrected using authorised system functionality.
Where applicable, the system shall maintain:

- Original entry
- Corrected entry
- Date and time of correction
- User identification
- Reason for change

Unauthorised modification or deletion of electronic records shall not be permitted.

6.6 Record Storage

Records shall be stored in designated locations.

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

Storage conditions shall protect records from:

- Moisture
- Water
- Fire
- Dust
- Excessive humidity
- Physical damage
- Pest damage
- Unauthorised access

Records shall be stored in a manner that allows easy identification and retrieval.

6.7 Electronic Record Storage

Electronic records shall be stored in authorised systems / locations.
Access shall be controlled based on user responsibility.
Where applicable:

- Password protection shall be used.
- User access shall be restricted.
- Data shall be backed up.
- Unauthorised deletion shall be prevented.
- Changes shall be traceable.

6.8 Record Protection

Records shall be protected against:

- Loss
- Damage
- Deterioration
- Unauthorised access
- Unauthorised modification
- Unauthorised destruction

Confidential or sensitive records shall have appropriate access restrictions.

6.9 Record Retrieval

Records shall be indexed to enable timely retrieval.
Retrieval may be based on:

- Record number
- Date
- Batch number
- Lot number
- Product code
- Serial number
- Department
- Customer / complaint number
- Equipment ID
- Employee ID

Records shall be retrievable within a reasonable time when required for:

- Internal audits
- External audits
- Regulatory inspections
- Customer requirements
- CAPA investigations
- Complaint investigations
- Product traceability

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

- Management Review

7. RECORD RETENTION

7.1 General Requirement

Records shall be retained for the period defined in the **Record Retention Matrix**.

Retention periods shall consider:

- Applicable regulatory requirements
- Product lifetime
- Product risk
- Customer requirements
- Contractual requirements
- Applicable standards
- Legal requirements

Where regulatory or customer requirements specify a longer retention period, the longer period shall apply.

7.2 Medical Device Records

Records related to medical devices shall be retained for the period required by applicable regulatory requirements and organisational procedures.

Records supporting product safety, performance, traceability, manufacturing, inspection, testing, validation, complaints and regulatory compliance shall not be disposed of before the applicable retention period expires.

8. RECORD RETENTION MATRIX

The following matrix shall be maintained and controlled by QA.

Sr. No.	Record Name	Record No.	Department	Storage Location	Retention Period	Record Owner	Disposal Method
1	Batch Manufacturing Record		Production		As per applicable regulatory requirement	Production	Secure Disposal
2	Batch Packing Record		Production		As per applicable regulatory requirement	Production	Secure Disposal
3	Inspection Record		QA		As applicable	QA	Shredding
4	Test Report		QA		As applicable	QA	Shredding
5	Calibration Record		QA		As applicable	QA	Shredding
6	Validation Record		QA / Engineering		As applicable	QA	Secure Disposal
7	NCR Record		QA		As applicable	QA	Shredding
8	CAPA Record		QA		As applicable	QA	Secure Disposal
9	Complaint Record		QA / RA		As per regulatory requirement	QA	Secure Disposal
10	Training Record		HR / QA		As applicable	HR / QA	Shredding
11	Internal Audit Record		QA		As applicable	QA	Shredding
12	Risk Management Record		QA / RA		As per regulatory requirement	QA / RA	Secure Disposal
13	Change Control Record		QA		As applicable	QA	Secure Disposal

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

14	Supplier Quality Record		Purchase / QA		As applicable	QA	Secure Disposal

9. RECORD DISPOSAL

Records shall not be destroyed before completion of the approved retention period.

After expiry of the retention period:

1. Record Owner shall identify records eligible for disposal.
2. QA shall verify the retention period.
3. QA / authorised person shall approve disposal.
4. Records shall be disposed of using an appropriate method.
5. Confidential records shall be securely destroyed.
6. Electronic records shall be securely deleted where permitted.
7. Disposal details shall be documented where required.

10. RECORD DISPOSAL METHODS

Record Type	Recommended Disposal Method
Paper Records	Shredding
Confidential Paper Records	Secure Shredding
Electronic Records	Controlled / Secure Deletion
Damaged Records	Controlled Destruction
Regulatory Records	Disposal only after applicable retention requirement is fulfilled

11. RECORD TRACEABILITY

Where applicable, records shall maintain traceability to:

- Product
- Batch
- Lot
- Serial Number
- UID
- Raw Material
- Component
- Supplier
- Equipment
- Inspection / Test
- Personnel
- Date and time

This shall support product traceability and investigation of nonconformities, complaints and CAPA.

12. RECORD CONFIDENTIALITY

Records containing confidential, proprietary, personal or regulatory information shall be accessible only to authorised personnel.

Unauthorised copying, alteration, removal or disclosure of records shall not be permitted.

13. RECORD BACKUP

Important electronic records shall be backed up according to the applicable backup system.

Backup shall be protected from:

- Unauthorised access
- Data corruption
- Accidental deletion
- Hardware failure
- Other foreseeable data-loss events

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

14. RECORD AUDIT / VERIFICATION

QA may periodically verify records to ensure:

- Records are complete.
- Records are legible.
- Required approvals are available.
- Retention requirements are followed.
- Records are properly stored.
- Records are retrievable.
- Unauthorised changes have not been made.

Nonconformities identified during record verification shall be handled through the applicable NCR / CAPA process.

15. FORMS / ANNEXURES

Sr. No.	Form No.	Form / Annexure Name
1	INV/SOP/QA/003/F1	Record Master List
2	INV/SOP/QA/003/F2	Record Retention & Disposal Register
3	INV/SOP/QA/003/F3	Record Retrieval / Issue Register

16. RECORDS GENERATED

Record	Form No.	Responsibility	Retention
Record Master List	INV/SOP/QA/03/F1	QA	Current + Obsolete history
Record Retention & Disposal Register	INV/SOP/QA/03/F2	QA	As per QMS requirement
Record Retrieval / Issue Register	INV/SOP/QA/03/F3	QA	As applicable

17. TRAINING

Personnel responsible for generating, reviewing, storing or maintaining records shall be trained on applicable record control requirements.
Training records shall be maintained.

18. COMPLIANCE

This SOP shall be implemented in accordance with:

- ISO 13485:2016
- Medical Devices Rules, 2017
- Applicable BIS / IS Standards
- Applicable statutory and regulatory requirements

19. REVISION HISTORY

Revision No.	Effective Date	Description of Change	Prepared By	Reviewed By	Approved By
01	01.09.26	Initial Release			

NOTE:

1. All records shall be **legible, readily identifiable and retrievable** throughout the defined retention period.
2. Records shall be protected from **loss, damage, deterioration, unauthorised access, alteration and unintended use**.
3. Records shall be completed **at the time of performing the activity** and shall accurately reflect the activity or result obtained.
4. Any correction to a record shall maintain the **original information readable** and shall be traceable to the person making the correction and the date of correction, where applicable.
5. Records shall not be destroyed, altered or disposed of before completion of the applicable **legal, regulatory, customer and QMS retention period**.

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.

6. Where more than one retention requirement is applicable, the **longer applicable retention period shall be followed**.
7. Electronic records shall be protected against **unauthorised modification or deletion** and shall be backed up as applicable.
8. Records related to **medical device manufacturing, inspection, testing, validation, traceability, complaints, CAPA, risk management and regulatory compliance** shall be maintained as required by applicable regulatory requirements.
9. Obsolete or expired records shall be disposed of only after **authorised approval** and through a method that prevents unauthorised disclosure or unintended use.
10. In case of any conflict between internal requirements and applicable **statutory or regulatory requirements**, the applicable statutory or regulatory requirement shall prevail.

This document is the property of INOVO HEALTHCARE PVT LTD. Unauthorized reproduction or distribution is prohibited. Only the latest approved revision shall be used. Obsolete copies shall be withdrawn from all points of use.