Procedure: Control of Records

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| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

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Clause 4.2.4 of ISO13485 outlines the requirements for records. Section 4 of this procedure describes the general rules for establishing and maintaining records while Section 5 lists the main record categories required. This list only includes records that demonstrate product and process conformity. Financial or personnel records are not relevant and are not included.

# Purpose

This procedure describes what records are required to provide evidence of conformity to requirements and of the effective operation of the quality management system. The procedure will define how they are developed and who is responsible for their collection, storage and retention at [Company].

# Scope

The scope of this procedure includes all records that demonstrate product conformity and quality system effectiveness.

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Engineering Manager |  |
| Quality Manager | Retention of company records. Ensure that relevant Records are controlled, and that they are available to Regulatory and Legal bodies. |
| Regulatory Affairs Manager | Specifying the length of time that regulatory records are retained. |
| Product Development Manager | Specifying the length of time that a product development related record is retained. |
| All staff | Delivery of records to the Quality Manager. |

Add roles and responsibilities that reflect your company structure.

# Procedure

## General

Records are established and maintained to provide evidence that products, processes and the quality system conform to requirements and that the quality system is effective.

This procedure will be followed for the Identification, Storage, Protection, Retrieval, Retention time and Disposition of Records.

Records are organised into the following five categories:

* device history file
* device master record
* device history record
* quality system record
* complaint files

A more detailed breakdown of each category is included in section 5 of this procedure.

## Establishment of records

Edit this section as required to reflect practices in the company.

Personnel performing a task or activity are responsible for recording quality related information in an appropriate format.

Forms are provided for recording the required information. Where the form is more complex, it may be supplemented by an instruction.

Information may also be recorded electronically (e.g. in spreadsheets or databases). Appropriate controls and security must be applied to data stored by electronic means.

Refer also to Procedure QP401: Control of Documents.

## Identification

Records of activities must clearly identify:

* the person performing the activity
* the function of that person
* the product involved
* the activity being undertaken
* the date (and time if appropriate) of the event

## Indexing and storage

Records must be grouped or indexed in a logical fashion to facilitate their retrieval. The storage system, whether it be filing cabinets or electronic files, must be clearly labelled and their contents identified.

Records must be securely stored and maintained (i.e. protected from insects, vermin, moisture, etc.) so that they are kept in a legible condition. They must be readily retrievable at all times by appropriate, key personnel.

Electronic records must be kept securely to maintain their integrity and they must be regularly backed up according to standard procedures.

If appropriate, reference the procedure describing the backup method and schedule.

# Records

Retention periods vary in different regulatory environments. Set retention periods in accordance with regulations applicable to the company. It may also be appropriate to consider legal requirements

If the "lifetime of the device" is referenced, this must be defined in the product specifications.

## Design history

Records in the history file are retained for at least 2 years after the manufacture of the device is discontinued. These records are maintained by the Engineering Manager, where:

* Design project records - design plans and schedules, design input requirements, and design reviews.
* Design verification and validation records - design verification and validation procedures, protocols and reports.
* Device master record
* Records in this file are retained by Quality Assurance for at least 2 years after manufacture of the device is discontinued, where:
* Device specifications - device specifications, packaging and labelling specifications and installation, maintenance and servicing specifications.
* Manufacturing specifications - manufacturing process specifications, quality assurance procedures and specifications.

The scope of these documents, their storage location and retention periods are described in Procedure QP402: Device Master Record.

## Device history file

Add or delete other records that may be relevant to the company (e.g. installation and servicing records).

Records in this file are maintained by Quality Assurance and are retained either for at least 2 years longer than the lifetime of the device, where:

* Purchasing records - purchasing documents for procurement of materials, components, products and services required for the finished product.
* Production records - work orders, traceability records, material certificates, records of process parameters, identification of process operators, SPC control charts, etc.

Edit as appropriate (delete reference to SPC if not relevant).

* Non-Conformance Reports and product rework records - nonconforming product reports, re-inspection and acceptance of reworked product.
* Sterilisation records - logs of control parameters of the sterilisation process for each device or batch of devices.
* Device verification and acceptance records - inspection and test records including the final acceptance inspection.
* Device labelling records - records of labelling and packaging operations and inspections, the date of the individual performing the inspection and the dates performed.

## Complaint files and device recalls

Records in this file are retained by Quality Assurance for at least (insert requirement) year(s).

Check the legal and regulatory requirements applicable to the company.

* Customer complaints log - a summary of all customer complaints, their handling and current status.
* Customer complaints files - files containing details of the complaints, including records of investigations, resolution and communication with the customer and regulatory authorities (where applicable).
* Advisory notices - copies of advisory notices and lists of customers to whom notices were sent.
* Device recall records - meeting minutes, memoranda and other communications and documents used in planning and implementing a device recall.

## Sales records

Sales records are maintained by the Sales department and are retained either for X year(s) or for X year(s) longer than the lifetime of the device, whichever is greater.

Amend retention time as required.

* Sales records - offers, sales orders and other documents established in the course of processing, negotiating and implementing contracts and orders and, in particular, records of contract/order review.

Contract and order review records are a requirement of both ISO 9001 and ISO 13485 (refer ISO 13485 clause 7.2.2) and are implied in 21 CFR Part 820.160(a).

* Device distribution records - these include the name and address of the initial consignee, the identification and quantity of devices shipped, the date shipped and any control number(s).

This is directly from 21 CFR 820.160(b). ISO 13485 requires distribution records only for implantable and active implantable devices.

## Quality system records

The following quality system records are retained according to the following table.

Amend retention periods for each type of record as appropriate for your company.

|  |  |
| --- | --- |
| Quality system record | Description |
| Quality system documentation | QMS documentation includes the quality manual, quality procedures and associated forms. Procedure QP401: Control of Documents describes the distribution, storage and retention of obsolete copies. |
| Internal quality system audit reports | Reports, including audit findings and associated corrective and preventive actions, are retained by Quality Assurance for of X year(s). |
| Management review records | Minutes of management review meetings and other management review documents are retained by Quality Assurance for X year(s). |
| Training records | Training records are retained by Human Resources and the training department for X year(s) after termination of employment. |
| Supplier evaluation and performance records | Documents demonstrating supplier quality capability and quality performance including   * Audits * Reports * Associated correspondence   are retained while the supplier is active and for a further X year(s). |
| Calibration certificates | Measuring and monitoring equipment calibration certificates are retained by Quality Assurance for X year(s). |
| Manufacturing records | All documents associated with the manufacture of product, validation of product, processes, equipment and systems are retained for a period of at least the lifetime of the device manufactured + 2 years. |
| Environmental monitoring records | Logs, charts and other such environmental records are retained by Production for X year(s) or for X year(s) longer than the lifetime of the device, whichever is greater. |
| Cleaning logs, records of filter cleaning, etc. | Retained when conditions such as temperature, humidity, particulates or bioburden are specified. |
| Manufacturing equipment maintenance records | Maintenance plans, logs and reports are maintained by Engineering for X years from date of closure. |
| Non-Conformance reports and rework records | Closed out non-conformance action forms and associated documents prepared to provide evidence are retained for a period of X years from date of closure. |
| Corrective and Preventative Actions | Closed out corrective and preventative action forms and associated documents prepared to provide evidence are retained foe a period of X years. |

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP401 | Control of Documents |
| QP402 | Device Master Record |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
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List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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