Procedure: Control of Records

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| Quality representative signs to confirm document complies with quality management system | | | |
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# Purpose

This procedure describes what records are required by [Company], how they are developed, and who is responsible for their collection, storage and retention.

# Scope

The scope of this procedure includes all records that demonstrate product and process conformity and QMS (Quality Management System) effectiveness.

Refer to Section 5 for a list of records generated by [Company].

# Responsibilities

Amend as appropriate for your Company.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | Retention of company quality records. |
| Production Manager | Specifying the length of time that a product related record is 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 or their representative. |

# Procedure

## General

This procedure describes and controls the identification, storage, retrieval, protection, retention time and disposition of quality records.

## Establishment of records

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

Forms, laboratory books or other documents are provided for recording the required information. A list of records to be kept is detailed in Section 5.

When entries are made in records, these should be made:

* indelibly in the space provided
* immediately after performing the activities
* identifying the person making the entry.

Corrections to entries should be dated and signed, and the original entry should not be obscured.

Edit this paragraph to ensure that only validated electronic record keeping systems are used to keep primary documentation to comply with Good Automated Manufacturing Practice.

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.

## 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.

## Storage

Records are grouped or indexed in a logical fashion, clearly labelled and contents identified so they are readily retrievable in and readable at all times.

If records are stored in microfiche or similar, appropriate readers must be immediately available.

Records are securely stored and protected from insects, vermin, theft, moisture, etc. so they remain in a clean and legible condition.

Use only validated electronic record keeping systems to keep primary documentation to comply with Good Automated Manufacturing Practice.

Electronic records are securely stored in designated locations which are managed to maintain their integrity.

# Record types and requirements

These sections will be highly specific to your company. Edit as required. Only include records that demonstrate product and process conformity

## Product-specific records

Amend to suit the needs of your company

Records which relate to manufacture of a pharmaceutical raw material, intermediate or product are to be retained for one year after the expiry date of the product.

Laboratory books used to record development and product specific information are to be suitably indexed and retained for five years from the last date of entry.

## Quality records

Amend to suit the needs of your company, specifying appropriate retention periods.

The QMS contains the following quality records.

|  |  |
| --- | --- |
| Record Type | Description |
| Quality system documentation | QMS documentation includes the quality manual, quality procedures and associated forms. Procedure QP401: Document Control describes the distribution, storage and retention of superseded copies. |
| Internal quality system | Reports, including audit findings and associated corrective and preventive actions, are retained for five years from completion of the action. |
| Corrective and preventive action records audit reports | Copies of CARs (Corrective Action Requests) are retained for five years from date of record entry. |
| Management review records | Minutes of management review meetings and other management review documents are retained for five years. |
| Training records | Training records are retained for ten years after termination of employment. |
| Subcontractor evaluation and performance records | Documents demonstrating subcontractor quality capability and quality performance are retained while the subcontractor is active and for a further five years following completion of work. |
| Calibration certificates | Measuring and monitoring equipment calibration certificates are retained for five years. |
| Environmental monitoring records | Logs, charts and other such environmental records are retained by production for five years or for one year longer than the shelf life of the product whichever is greater. |
| Manufacturing equipment maintenance records | Maintenance plans, logs and reports are retained for five years. |
| Cleaning logs, records of filter cleaning, etc., | Are retained when conditions such as temperature, humidity, particulates or bioburden are specified. |

## Complaint files and product recalls

Amend to suit the needs of your company

Records in this file are retained for five years.

|  |  |
| --- | --- |
| Record Type | Description |
| 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. |
| Product recall records | Meeting minutes, memoranda and other communications and documents used in planning and implementing a product recall. |

## Sales records

Amend to suit the needs of your company.

Sales records are maintained by the Sales department and are retained either for seven years (Australian Taxation Office (ATO) regulatory requirement) or for one year longer than the expiry of the product, whichever is greater.

Sales records include offers, quotes, 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.

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 |
| 01 |  |  |  |
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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 | Document Control |

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

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

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.

DOCUMENT END