Documentation Practices and Records Control

About This Document

**Purpose**
This procedure describes general documentation practices used to complete documents and records and general policies to control those documents and records.

**Scope**
This procedure applies to all personnel responsible for quality system and business records at __________.

**Affected Departments**
All departments responsible for creating or maintaining Quality System and business documents and records.

**Summary of Governing Regulations**
The following quality systems requirements are addressed by this document:

1. Records shall be legible, readily identifiable and shall be stored to minimize deterioration and damage and prevent loss.

2. All records shall be maintained at applicable manufacturing sites or other locations that are reasonably accessible to applicable employees and representatives from external agencies such as FDA and notified bodies.

3. Records stored in electronically permanent media are considered Electronic Records. Electronic records shall meet the requirements of 21 CFR Part 11.

4. Records shall be retained for a period equivalent to the design and expected life of the device, but in no case less than 2 years from date of release for commercial distribution. See Appendix A for application to specific product records (21 CFR Part 820.180).

5. Records associated with a batch of a OTC drug product must be retained for at least 1 year after the expiration date of the batch (21 CFR Part 211.180).

6. Management reviews, quality audits, and supplier audits, will not be reviewed by FDA. The FDA may, however, request executive management to certify in writing that such activities have been performed and documented and that any required corrective action has been undertaken.

**Document Responsibility**
Who?

*Continued on next page*
About This Document, continued

Definitions

**Controlled Document**
A document that is controlled via the Change Order (CO) process and stored in the Document Control System.

**Document**
Any written, printed, magnetic, or electronic media containing information relating to purchasing, production, inspection, testing, distribution, sale, products or processes, or associated training or auditing. Examples include specifications, protocols, reports, procedures, policies, etc.

**Electronic Records**
Any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

**Expiration Date**
The date established by the manufacturer and printed on the package after which the quality of the product and its related efficacy and safety are not guaranteed and after which the product should not be used. Also called “Life of Device” or “Lifetime of the Medical Device.”

**Independent Electronic Audit Trail**
An audit trail is a secure, computer-generated, time-stamped electronic record or code that independently records the date and time of operator entries and actions that create, modify, or delete electronic records. Audit trails must include functionality whereby record changes do not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

**Raw Data**
Any form, memorandum, note, record or worksheet (including electronic data) that is the result of original observations, testing or other activities

**Record**
A document which furnishes objective evidence of activities performed or results achieved. A quality record provides objective evidence of the extent of the fulfillment of the requirements of quality or the effectiveness of the operation of a quality system element. A record can be written or stored on any data medium.

**Retention Period**
Period of time a particular document must be kept in a manner providing for retrieval and/or review.

<table>
<thead>
<tr>
<th>In This SOP</th>
<th>Topic</th>
<th>See page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Overview</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Documentation Practices</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Record Classification</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Identification and Storage</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Retrieval, Retention, and Destruction</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>Retention Schedule</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Appendix A - Retention Period Rationale</td>
<td></td>
<td>17</td>
</tr>
</tbody>
</table>

*Continued on next page*
Process Overview

Introduction

Documents and records must be legible, clear and provide adequate traceability to the activity or event. Records must be stand-alone and provide an accurate history of the activity or event at the time the activity or event occurred. Records may be in the form of any type of media including electronic, magnetic, microfilm, microfiche, or paper.

Control of documents and records is an essential part of the Quality System and business practices. Business and quality records contain evidence that our products have been designed and manufactured to meet predetermined specifications. Records and documents also demonstrate that quality system elements required by federal and international regulations have been implemented.

The following activities are associated with the control of quality system and business records:

Records Control Process

- Records are completed following good documentation practices
- Documents and records are classified as critical, non-critical or business system.
- Documents and records are identified and stored according to the retention period. Storage conditions assure documents and records are protected against deterioration, damage and unauthorized access.
- Documents and records are retrieved, as appropriate.
- Documents and records are destroyed according to the retention period.
Documentation Practices

General Documentation Requirements

- Documentation requirements for lab notebooks must follow SOPxxx.
- Documentation for logbooks and worksheets must follow SOPxxx.
- Use only the current revision of a document.
- Record all entries directly on quality records or laboratory notebooks.
- Entries on quality records must be in black or blue indelible (non-erasable) ink as per applicable document.
- All entries must be in English.
- Ensure that all entries are legible, clear and concise.
- Entries to working records should be completed at the time the activity is performed and should be completed in the space provided.
- All entries must be traceable to the person who recorded the entry (for example, by initialing/dating adjacent to the entry, or by signing/dating the form, etc.).
- When recording handwritten, raw data, all available fields must be completed or clearly indicated with an N/A that they will not be used.
  - If not readily apparent, the reason for not using available fields must be documented, signed and dated.
- If original data is transferred from a controlled record to another controlled record, traceability from the new document to the original must be documented by retaining the source record and either attaching it or cross-referencing it on the new record.
  - Transferred data shall be reviewed by a second person.
  - If not readily apparent, the reason for transferring data must be documented, signed and dated.
- Arrows may ONLY be used when documenting scientific formulations and calculations.
- Footnotes are allowed when appropriate (for example, if multiple lines or areas in the same document require N/A’s for the same reason and the reason is not readily apparent).
  - The explanation and signature (or initials/date), if required, should appear in one location. It is not necessary to sign/initial/date next to every footnote if they are made on the same day and by the same person.
- Attachments that are not contained in notebooks/logbooks should be page numbered and traceable to the records they support. (i.e. Part number, lot number, document number).
- Original records shall be under Xxxxxxxx control when transported between facilities.
- Records shall not be destroyed until after the retention period specified in this procedure.

Practices NOT Allowed

- Dating to a previous or future date.
- Use of post-it notes or other loose “scrap” paper to capture or record quality data or information.
- Transferring of information from non-official documents (such as post-it notes or plain copier paper) to controlled documents (such as lab notebooks).
- Writing over, retracing or obscuring data.
- Ditto marks (“”).
- Use of arrows for repeating information.
- Use of pencil
- Use of markers, fountain pens, flair pens, gel pens, pens that have water soluble ink (such as felt-tip pens), or any other ink that smudges.
- Use of correction tape or correction fluid (such as liquid paper, white-out, etc.).
- Signing someone else’s name or initials.
- Signing for review/acceptance of a document that you have not read.
- Waiting until the end of the day or shift to record in-process or production data.
- Destruction of records prior to end of retention period or in a manner other than specified in this procedure.
Signatures

The governing procedure or the document itself will indicate what the actual signature means. Signatures in documents should fall into one of the following categories:

- **Performed by** – Signature of the person executing a procedure, operation, calculation, etc. that is being documented.
- **Approved by** – Signature of the Supervisor or designated person responsible for the operations and content of the document or report being evaluated, certifying that disposition entered is correct.
- **Reviewed by** – Signature of the person that reviewed the document, certifying the accuracy of calculations, that data and documented information is complete and free of errors according to the good documentation practices specified in this procedure and with other applicable procedures.
- **Verified by** – Signature of the person that visually verifies the performance of the activity and assures that it has been carried out according to the procedures. In this case, the person should be present during the operation, unless evidence can be provided that the activity actually took place.
- **Attended** - signature indicates that the signee was present at the event, meeting, discussion, etc.

Signatures are required for all information added to a document. For corrections to information on a document, see requirements for “Initials”.

A delegation of approval authority is acceptable to assign a designee; evidence of this authority must be included with the record being signed.

Each individual making an entry must sign in a way that clearly identifies the person responsible.

Handwritten signatures must consist of first initial/name and full last name.

All Signatures must be dated.

Signing someone else’s name, employee number or using someone else’s stamp is considered forgery and is strictly forbidden. This action may be grounds for disciplinary action.

Initials

- Initials (along with the date) may be used in place of signatures provided that the:
  - Document or record contain at least one complete signature of the person initialing, and
  - The initials are identifiable with the signature by initialing adjacent to the complete signature.

- Initials may be used instead of signatures to verify cross outs and the corrected information.
- Initials may be used instead of signatures to verify N/A’s (in this case, initials would not require an adjacent complete signature).
- The practice for initials is first, middle (optional) and last initial. The initials should be legible.
- Initials shall not be used to indicate approval.
Documentation Practices, continued

**Dating**

- A date must accompany every signature or set of initials on a document.
- Dates recorded using American date style shall specify the month, day, and year (e.g. 1/15/00, 1-15-00, 1•15•00 which means January 15, 2000).
- Dates recorded using International date style shall specify the day, month, and year. The name of the month shall be spelled out (e.g. 15-January-00 or 15-Jan-00).
- Always use the current date. If a date is required for work performed on a previous day, date the entry with the current date and provide an explanation regarding why the entry was made after the work was performed.

**Documenting Changes**

**Corrections**

- Incorrect entries may not be canceled, erased, obscured, or altered in any form that makes them illegible.
- All handwritten changes must be legible.
- When making corrections, apply a single horizontal line through the error.
- Enter the correct information next to or as close as possible to the original entry followed by initials and date of correction.

**Additions**

- Enter the information next to or as close as possible to the original entry followed by initials and date of entry.

A brief explanation indicating reason for changes must be provided when:

- The reason for the change is not readily apparent
- The change affects the acceptance of processes or product, for example:
  - Corrections: changes to quantities, temperature, parameters, humidity, time, duration, laboratory results, or any other changes that may put in doubt the acceptance of a product or process.
  - Additions: late recording, entering data that was originally “N/A”ed, or any other changes that may put in doubt the acceptance of a product or process.

Entries made by someone other than the person making the original entry are permitted when all of the following are true:

- The individual that made the original entry is not available.
- The addition/correction/omission is obvious.
- The change must be substantiated by documented objective evidence.
- The information must be retrieved and verified from other documented sources.

Where an entry was made AFTER the document has been signed (reviewed/approved/verified/etc.), the signature must be signed/dated again or initialed/dated again.
**Failed Data and Voids**

- All failed data and aborted tests must be retained, along with an explanation for the failure/abort, signature or initials, and date.
- Records that need to be voided should be defaced with a diagonal line through at least the first page of the record and identified with the word “VOID.”
- The person voiding the record shall ensure the following:
  - Written explanation for voiding the record when the reason is not apparent
  - Signature/date when the void was made
  - The original (voided) document should be kept with the document that replaces it, or must save the original document and the new document must cross-reference the original
- DO NOT discard raw data unless it is permitted by this document.

**Copies and Facsimiles**

Typically, original records will be used and retained; however, use of non-thermal facsimile or photocopied records where the recipient of such a document believes that it is a true and accurate copy of the original document is acceptable (for example, when receiving a faxed approval from another location or from a known external source).

- When distinction between an original record and a copy is desired (for example, some types of hand-written raw data), the first page of the copied record must be stamped “copy” or be clearly marked as a copy and must be signed/dated or initialed/dated.

Xxxxxxxx recognizes the acceptability of electronic storage and archiving of paper records. Upon completion of the archiving these electronic records become the “record of record” and any paper can thus be discarded. The electronic records thus created must comply with the requirements of electronic record retention and must be shown to comply with appropriate procedures.

When records are to be created on paper media and transferred to electronic media for storage the following requirements must be met:

- A method of verification of the legibility of the electronic record must be determined
- A record of the transfer and verification must be maintained

Some examples of acceptable methods of compliance include:

- Individual verification by the person creating the electronic copy and documenting this activity (This can be used for individual or small quantities of records such as on-line data sheets)
- Development and validation of a system that allows for large volume electronic copying (scanning) that has been shown to provide a high degree of certainty of the legibility of the electronic record. Such systems must have a documented validation as well as a plan for periodic verification of the system’s capability of maintaining this level of accuracy. The person performing such activity must be documented and associated to the records.

**Record Classification**
**Introduction**

Records are classified as critical, non-critical, or business system records. Critical and non-critical records may be further classified as protected health information (PHI), as appropriate. Record classification determines the requirements necessary to properly store and retain the records.

---

**Classification**

Record classification is based on the following criteria:

**Critical Records**

Critical Records are records required to maintain the viability of our products for sales and distribution, including potential recall, even after a disaster. These include the Batch and/or Lot History Records, Investigations and Nonconforming Material Reports, Training Records, Product Shipment and Distribution Records and Contract Review Records. Critical records are identified as such in this document and must be maintained in duplicate at a secondary location separate from the original records.

**Non-Critical Record**

Records required by the regulations and essential to the business but could be replaced if lost. It would create a significant inconvenience, time delay, or cost to the company.

**Business Record**

Those records maintained to expedite and/or enhance the conduct of our business. They are not considered part of the records required to demonstrate compliance with our quality system.

**Protected Health Information (PHI)**

Protected Health Information includes information transmitted in any form or medium that:

- Is created or received by a Covered Entity
- Relates to an individual’s physical or mental health, the provision of health care to an individual, or the payment for the provision of health care to an individual, and
- Identifies the individual or which provides a reasonable basis to believe the information could be used to identify the individual.

Examples of PHI records include Patient Consent Forms and Customer Complaint files. Refer to Appendix A for additional information regarding PHI records.

---

**Types of Records**

The Record Retention Schedule separates records into four types, as follows:

1. **Product Master Record** - A compilation of records containing the procedures and specifications for a finished product or any of its components.

2. **Quality System Record** - Those records that demonstrate the effective operation of our overall quality system.

3. **Business Records** - Those records maintained to expedite and/or enhance the conduct of our business. These are not records required to demonstrate compliance with our quality system.
Identification and Storage

Introduction
Records must be stored and maintained in an environment which minimizes deterioration and damage throughout the specified record retention period. Additionally, records must be identified in a manner that prevents inadvertent mix-up or loss and facilitates retrieval for subsequent review purposes.

Identification and Storage Requirements
Area Management is responsible for:
- Identifying and maintaining records in accordance with the specific quality system requirements that govern their area.
- Establishing methods for orderly processing, filing, identifying, storing, and maintaining records in a central location.
- Authorizing methods for duplicating and maintaining critical records at a secondary location. **Note:** Provisions for storage at a remote location are acceptable if systems are in place so that these records, or copies, can be accessed within one or two days.
- Ensuring that records are labeled or otherwise identified and that files are configured to expedite requests for record duplication and review.
- Implementing appropriate security measures to prevent unauthorized changes, removal or access to records.
- Verifying that the types of records maintained by the area are correctly indicated or covered by the Retention Schedule listed in this procedure.
- Approved records management companies may be used for off-site storage.

Electronic Records
Electronic records require special handling as required by 21 CFR Part 11. The retention period defined within this document applies to all document types (paper or electronic). Electronic records created, modified, maintained or transmitted in support of the Quality System must employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot repudiate the signed record as not genuine. Such procedures and controls shall include the following:

a) validation of systems for their intended use to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.
b) the ability to generate accurate and complete copies that preserve the content and meaning of records in both human readable and electronic form suitable for inspection, review and copying by the agency.
c) protection of records to enable their accurate and ready retrieval throughout the records retention period.
d) limiting system access to authorized individuals.
e) use of a documented and justified risk assessment to determine the extent of the application of secure, computer generated time stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. This must preserve the ability of the records to meet all predicate rule requirements. Such audit trail documentation shall be retained for a period of time at least as long as that required for the subject electronic record and shall be available for agency review and copying.
# Record Retrieval, Retention, and Destruction

## Record and Document Retrieval
Records must be readily accessible to personnel requiring the information necessary to perform their jobs. It is the user's responsibility to ensure the information or records are appropriate for the use intended and to control or destroy copies when the records are no longer needed or current.

Documents may be obtained through the Document Control System or by requesting it from the department listed under the *Location of Records* in the Retention Schedule.

The area responsible for managing the records determines provisions for document checkout and duplication for record review purposes.

## Record and Document Retention
Record retention periods as specified in this procedure reflect the minimum length of time that a record must be maintained and accessible. Area management may choose, upon consultation with Xxxxxxx’s Legal department, to maintain records beyond the record retention periods established by this SOP. Record retention periods are determined from the time the document is no longer the governing document. For example, the current revision of a document shall retain its change control history until superseded by the next revision. At that time, the superseded record is governed by the record retention requirements.

Records or documents associated with the manufacture of product cannot be destroyed if they are still in-use.

Records or documents in association with legal consideration such as lawsuits must be retained until destruction is authorized by the Legal Department, this time period may be beyond the retention period established in the record retention schedule.

## Record and Document Destruction
At the end of the defined retention period, records should be destroyed in a confidential manner such as shredding or by electronic means so that the record’s content cannot be reproduced. Documents shall be destroyed within 3 months of the retention period.
Retention Schedule

In the tables that follow, the retention period and location of records is defined.

Notes:
- Where documentation/records, designated as “Product Dependent”, apply to more than one product with differing retention periods, the longer retention period shall be used. See Records Management Process above for determination of when retention time starts.

<table>
<thead>
<tr>
<th>Records Type</th>
<th>Critical Records?</th>
<th>Record Retention Period</th>
<th>Department Responsible for Final Disposition of Records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>