Procedure: Information and Records

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This procedure describes how information is recorded in a GMP manner and how changes are made (if required).

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for recording information and completing records at [Company].

# Scope

The scope of this procedure includes records of:

* materials receipt of dispatch
* manufacturing processes
* in-process testing
* laboratory testing
* batch release, etc.

Edit the scope as appropriate to the company.

# Responsibilities

It is the responsibility of all personnel involved that the specified records or results are obtained and recorded clearly and accurately.

# Procedure

## Manufacturing records

When recording information it is critical that it is identified and recorded directly, promptly, accurately, legibly and indelibly by the person obtaining the data. Personnel must ensure the following when recording data:

* data is recorded onto the appropriate form (i.e. not on a scrap of paper and then transcribed into the required form later)
* data is recorded promptly at the time the activity took place
* data is recorded accurately and legibly
* data is recorded using indelible ink (i.e. not pencil)
* data is signed or initialled (as indicated on the form) so that the person performing the activity is identified
* data is dated to record when the procedure was performed
* dates are entered in the format 18 Jun 2008 (i.e. to avoid possible confusion with US date format, the date should be numeric; the month a 3 letter abbreviation; the year a 4 digit number)

## Laboratory records

All laboratory information, data or results related to testing should be recorded either in a bound note book with sequentially numbered pages or in a designated form specific for the test being carried out.

Data from any investigations carried out (including equipment or method validation) should be recorded in the bound, numbered note book.

All records and any changes to information should be clear and accurate, as described in Section 3.1 above.

## Correcting errors

Should a correction or alteration to a data form be required (i.e. the wrong time or date was entered, or a number was not legible) the entry is scored out using a single line (so that it does not obscure the previous entry) and the alteration entered.

All changes are identified by date and signature of the person making the change, and if necessary a reason for the change included.

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 | |
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| Doc. No. | Document Title |
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List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
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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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