Standard Operating Procedure

Title: How to Write Standard Operating Procedure (SOP)

Department	Quality Management		Document no	QMS-005	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Document Owner

Quality Assurance Manager

Affected Parties

All manufacturing colleagues

Purpose

This procedure provides a guideline on how to write a Standard Operating Procedure (SOP), including how to format the document.

The "Purpose" of a SOP is to provide detailed instructions on how to carry out a task so that any employee can carry out a task correctly every time. The purpose or objective of a SOP should restate and expand a well-written title.

A well-written SOP will facilitate training. Having complete instructions helps Trainers to ensure that nothing is missed and also provides a reference resource for trainees.

The best SOP is one that accurately transfers the relevant information and facilitates compliance with reading and using the SOP.

Scope

This SOP is for all writers of SOP's. The SOP details how to format a SOP and the guidelines for writing clear and concise documents.

Definition

Standard Operating Procedure (SOP)	Standard Operating Procedures (SOPs) are issued to specifically instruct employees in areas of responsibility, Work Instructions, appropriate specifications and required records.
	SOPs outline procedures, which must be followed to claim compliance with GMP principles or other Statutory rules and regulations.
	Procedures can take the form of a narrative, a flow chart, a process map, computer screen printouts or combination of all or any other suitable form, however must be written in appropriate, effective grammatical style. (e.g. plain English).
Form	A document which is to be printed at the time of use and filled out for the purpose of becoming a record (e.g. Library Log Form), or for the purpose of becoming Visual Display tool.
Template	A form to be used as a template for creating other documentation
Visual Display (VD)	A form requiring no additional data to be added, (i.e. no written record) which provides visual information to instruct in the process, e.g. Out of Order Tag. The information can be in the form of pictures or photographs; flowchart; operating instructions; or a notice.
	The Visual Display form is usually located in a permanent position, however maybe in use for a specific period of time, e.g. for a single batch. Pages from a single Visual Display form must be located together in a specified location. A location form (**Form-410**) must be placed in the Satellite File so the VD can be located if superseded or cancelled.

- Use job titles and/or functions, not people's name.
- **Written using Plain English guidelines** and written using the fewest possible words, phrases and paragraphs. If a procedure has a number of different steps, use bullets to break the procedure into each stage
- **Complete** – include **all** the necessary information to perform the procedure.
- **Objective** – contain facts only. Extra information should be removed and placed into an Appendix or be placed into a Manual.
- **Coherent** – follow a logical thought process and number all steps to complete the procedure,
  if using Hierarchal format, see Hierarchal example below.

  Where possible, use graphics, photographs, icons and flowcharts, as these can be more effective communication than just using text. (Seek advice from DCO regarding insertion of these objects.)

3. Follow the tips below when writing a SOP:

- Have a specific reader in mind. Know the type of person who will be reading the procedure and tailor the writing accordingly.
- Make a rough flowchart, which provides you with a representation of the whole process before you break it up into procedures or steps of a process.
- Start each step of the procedure with an *action* word, e.g. Lift, take, turn on, etc.
- Write the rough draft. Write, with the flowchart in front of you, and write as if you were talking, to maintain your train of thought.
- Use graphics and visuals. These can often be more effective than text.
- Revise the draft.
- Editing guidelines.
  - Is the SOP clear?
  - Is it written in a logical order?
  - Are any new ideas introduced and explained?
  - Are sentences too long and complicated?
  - Are any sections of the SOP vague?

4. Presenting the SOP

Use any of the following four (4) methods in preparing a SOP:

Simple Steps or a Checklist

These are easy to write and work very well when writing short, simple and straightforward tasks.

Example: Making a cup of tea:

1. Collect a cup and saucer
2. Place teabag into cup
3. Boil water in kettle
4. Add water to cup and teabag
5. Allow tea to infuse
6. Remove teabag
7. Add milk and sugar (if desired)

Hierarchical steps

This extension of the simple steps format works well for procedures that require more detail or sub-steps:

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5. SOP Format

5.1. Header

5.1.1. **Subject**: Standard Operating Procedure

5.1.2. **Title**: Typed in sentence case and bold

5.1.3. **Department**: Typed in sentence case and bold

5.1.4. **Document no**: Typed in upper case and bold

5.1.5. **Prepared by**: Author who writes the text

5.1.6. **Checked by**: Authorization of the author's Line Manager who ensured the text is alright.

5.1.7. **Approved by**: Approved by an authorized person from the Quality Assurance.

5.1.8. **Supersedes**: Type the last version number of the document

5.1.9. **Date Issued**: The date from which the document is filed into master database and distributed to satellite files.

5.1.10. **Review Date**: The next review date of the current version.(See SOP A.8.1)

5.2. Footer

5.2.1. **The phrase**: "This is not an approved copy unless stamped in red"

5.2.2. **File Location**: Location of the Database where the soft copy is saved.

5.2.3. **Date Printed**: Type the date when the copy is printed.

5.2.4. **Page Number**: Create automatic page number from the footer.

6. General Document Titles

6.1. Document Owner

Responsible for approving SOP content and ensuring its adherence.

6.2. Affected Departments

List all departments affected by this SOP.

6.3. Purpose

The Purpose of a SOP is to describe the performance of a controlled process and should restate a well-written title.

6.4. Scope

In writing a Scope, ask the question. What the procedure will cover and what is its limitation? Describe the range of applicability of the procedure. Scope may be limited for example, to one department, one process or one task or may applicable to many.

6.5. Definition

Write Definitions for any technical terms and acronyms used in the SOP.

6.6. Related Documentation

Include references to all other relevant documentation, e.g. SOP's, Forms, Visual Display etc.

6.7. EHS Statement