International Journal of Applied Ayurved Research ISSN: 2347- 6362

STANDARD OPERATING PROCEDURE (SOP) WRITING MADE EASY

Thakur Sudarshan K.[1], Tak Anjna[2], Phull Gaurav[3], Phull Rekha[4].

[1]M.D.Ras Shastra and Bhaishajya Kalpana, Senior Consultant, National Institute of Ayurvedic Pharmaceutical Research, CCRAS, Patiala. Punjab. India.

[2]M.D. Prasooti Tantra and Stri Roga, Associate. Professor of Prasuti Tantra & Stree Roga, Abhilashi Ayurvedic College & Research Institute, Mandi, H.P, India.

[3]M.S. Shalya (Sangyaharan) Clinical Registrar Sangyaharan, CBPACS, New Delhi,India

[4]M.D. Kaya Chikitsa, Lecturer Kayachikitsa, MLRA College, Charkhi Dadri, Hayana, India.

ABSTRACT :

Documentation is an essential activity conducted in all the scientific and technical establishments/agencies. The process of documentation has changed a lot with time and became more and more scientific and professional. Now a day any organization for getting any authority or certification like International Organization for Standardization (ISO), should have quality standard documentation of all the activities going on in its premises or network. In spite of having a sound understanding of the ethics, activities and quality policies, writing a SOP may look to be time consuming and complex task. This article is tailored specially to provide a ready format for writing a SOP. This review paper highlights important areas of considerations and steps forwards in a sequential manner to reduce the possibilities of errors. By following these steps in a chronological manner one may easily write a SOP on any activity or operation to ensure good practices in any organization especially in a department involving technical activities.

Key words: Documentation, SOP, Standard Operating Procedure, Standardization, format, SOP format.

INTRODUCTION: Standard documentation is a vital activity in a genuine and certified organization. These standard documents may be named differently in different fields, organizations or work places but the word SOP; standard Operating procedure is the most common name used for this. This SOP is documentation of an operation or activity, describing what and how it is done. The SOP refers to operation and maintenance of equipments or objects and activities in an organization and further the documentation describing a manufacturing process is named Master Formulae.

Though every organization may have different requirements but all have a common goal to provide error free and uniform quality services or end products. Here is a compilation of points, practiced now a day to write SOP with all possible allowable variants under any heading. These variants may be used and altered, molded, shuffled or edited to meet the needs of that particular organization. Also SOP is also not a static document; it needs continuous revision, updation, and replacement from time to time. This revision protocol has also been explained in this review.

Standard operating procedure is a written document that describes,

1.A specific procedure or set of procedures so established[1,2].

2.Established procedure to be followed in carrying out a given operation in given situation[1,2].

3.To lay down a procedure for the preparation, approval, authorization, control and revision of standard operating procedure[3].
4.Step by step information on how to execute a task[4].
5.The procedure that must be followed to carry out operation[5].

OBJECTIVE: To lay down a procedure for the preparation, approval, authorization, control and revision of standard operating procedure[3] also[6,7,8];
1.To ensure compliance standards are met.
2.To ensure everything goes according to schedule.
3.To prevent failures in manufacturing.
4.To ensure safety.
5.To maximize production.
6.To prevent any adverse effect on the environment.
7.To be used as training material.

SCOPE: This sop is applicable to;
i. All SOPs[7,9,10.]
ii. Department/Section/Area)[8,9,10].
iii. Standard operating procedures and associated records of actions taken or, where appropriate, conclusions reached should be available for various activities in the organisation and for manufacturing process.
iv. Preparation and implementation of Master formula. Manufacturing process documents should be called as Master formula rather than SOP as per WHO GMP guidelines[11,12].

RESPONSIBILITY:

1.Designee[7]**:**Preparation, Revision, Periodic Review, Training, Implementation.

2.Operator: Review, Implementation.

3.Executive/Supervisor: Periodic Review, Training, Implementation.

4.Head of Department:Checking, Approval, Conducting Training and Implementation of SOP[5].

5.Head Quality Assurance Department/Site Head/General Manager[7]**:**Authorization, Distribution, Control and Retrieval of SOPs, also Ensuring Preparation, Review, Training and Implementation cycle to follow.

FORMAT OF SOP:SOPs shall follow a scientific format, and are written with the view that they will be used by persons trained in the procedure[11]. So to prepare a new format these guidelines may be followed;
1.Format from regularity authority.
2.Pre-existing format of organization.
3.A simple step format; it is just a bullet list of simple sentences telling the reader what to do[4].
4.Hierarchical Steps format: For long Procedures, involving few decisions to make, clarifications and terminology[4].
5.Flow chart format: - More like map[4].
6.Newly developed format: A new format to suit the requirement of equipment/procedure/department/site. May include a combination of all formats having simple sentences,flow charts, tables, pictures and or diagrams.
The formats and sample SOPs can be used, modified, or redesigned, according to organizational structure, and by the complexity of their manufacturing operations[11].

FORMAT REQUIREMENTS

Language

Though, pharmaceutical documents are primarily written in English language owing to WHO GMP preferred language. But If required, some of the sops shall be written in local language[3] in copies along with the language preferred by the regulating authority. Considering your user/audience[4] from workers, operators, supervisor and executives up to regulatory authority is necessary. While opting

English language, the type of font for the contents in sops shall be 'Times New Roman'. The text font size to be used and layout of contents of sops shall be as detailed in table 1[3]. Though, organizations may develop their own standards keeping in view regulatory authority guidelines.

Parts and Contents of SOP As per layout of pages, all SOP's shall consist of ; -

1.Header

2.Body/Content

3.Footer

1.Header: Header part of the SOP should remain common for all pages excluding format and annexure[5];

It may have following contents;

1.NAME OF INSTITUTE/ ORGANISATION/COMPANY AND PLACE.

2.LOGO OF ORGANISATION.

3.STANDARD OPERATING PROCEDURE

6.TITLE OF SOP:

e.g. Standard operating procedure for cleaning/operation/maintenance of equipment with equipment number.

5.DEPARTMENT:Eg.Production/Quality Assurance etc.

6.LEVEL[5]:-e.g. 0, 1 or 2 ;

1. Level "0" : - Instruments/ Equipment Procedures related to each Department.

2. Level "1" : - General procedures of each department.

3. Level "2":Organization Policy.

7.SOP NO. : e.g. NPP/PG/SOP000-00

8.COPY No. :It is represented e.g. As "Copy No. 02 of 08".

9.EFFECTIVE DATE: Means this SOP starts with effect from dated; and this date is stamped by QA/Head Works[3], after final authorization process.

10.SUPERSEDES: Previous/Obsolete SOP No. With Effective Date should be mentioned here and in case of new SOP it is marked as "NEW INTRODUCTION"[3].

REVIEW DATE (2YEAR -2 MONTHS); Though it is considered exactly 2 years after effective date of SOP[3,4,5] yearly[11]; but practically, as maximum 2 months[5] are permissible for review of a SOP, Review date 2 years minus 2 month is justified so that review duration may not be a period without effective SOP. Revision No is represented as; 00: - New SOP, 01: - first revision, 02: - Second revision and so on.

11.NAME WITH DASIGNATION, SIGNATURE & DATE : In blue ink[3] of;

a.PREPARED BY: Who wrote the SOP. Actual Operator/Supervisor[5] of equipment or procedure and in case of SOP of SOP (SOP No. 001 i.e. Preparation, approval, Authorization, Control and Revision of sops, person best know about SOP writing should prepare SOP.

b.CHECKED BY : Person who is really through the subject, Department in-charge usually[5].

c.APPROVED BY:By two authorities[5];

i.Head of concerned Department and

ii.Head Quality Assurance.

In case of QA SOPs, first approval shall be done by Assistant Manager and above authority and second approval by Manager and above of quality Assurance[3].

d.AUTHORIZED BY : (The person finally authorizing the SOP i.e. Head QA/QC/Location Head/ Regulatory)[5].

In case of QA SOPs, location QA Head shall authorize all the SOPs except[3] the SOP No. 001(i.e. Preparation, approval, Authorization, Control and Revision of sops), This SOP shall be authorized by Vice President of Corporate QA[3].

The protocol may be followed with equivalent to above authorities in different organizations.

1.BODY/CONTENT: It Should have following contents;

OBJECTIVE/PORPOSE: This section must mention the intended use and applicability of SOP. It must start with letter "To" and must be one sentence or maximum two sentences statement only[5].

2.SCOPE: This sop is applicable to;

i. ..Documents/machine/procedure of

ii. Department/Section/Area)

3.RESPONSIBILITY:

I. Designee II. Operator III. Supervisor.

4.ACOUNTABILITY:Head of Department.

5.PROCEDURE: Primary contents**;**

a.Clear, concise, chronological[8,11], procedure details should be mentioned.

b.SOP shall be written in active voice, command verbs[4], as instruction[8].

c.Comprehensive flow chart, picture, design and examples for calculation[8,11] and how to do, if possible (not to make it lengthy but to keep it short.

d.Frequency, Special precaution and safety considerations must be discussed.

e.All possible deviation should be written.

REFERENCES : The references, cross-references like SOPs, machinery or equipment manuals, books, guidelines, acts or online references and abbreviations used shall be elaborated at the end of respective SOP.

ANNEXURES: Format, tables etc to fill, machinery or equipment manuals, charts, diagram, flow chart etc. Linked to SOP.

ABBREVIATIONS: All the abbreviations used in the document shall be tabulated.

SOP DISTRIBUTION[5]: Details of distribution and retrieval of SOP with copy no. And date shall be recorded. **Table 2**

DOCUMENT REVISION HISTORY[3]: Table 3

FOOTER: It should have;

Format number

IDENTIFICATION NUMBER: There are also the identification systems or codes devised to number and track both information and documents. These are SOP numbers, equipment numbers, form numbers, receiving codes, and batch/lot numbers. These numbering systems should be designed so that procedures, processes and materials can be traced throughout the data records[11].

SOP No:

1.16 Character SOP No.[3].e.g. NPP/PG/SOP001-00 (N. Pharmaceuticals Place/Production General /SOP001-00Revision No.)

• Relating with above example; First two characters denotes Organization Name, e.g. NP is N. Pharmaceuticals.

•Third character denotes site, e.g. P for Place.

• Fourth character is Slash (/).

•Fifth and sixth character denotes Department or Section code e.g. PG for Production General and QA for Quality Assurance, WH for Warehouse etc.

• Seventh character, is slash (/)

• Eight ,ninth and tenth characters, denotes "SOP"

•Eleventh, Twelfth & Thirteenth characters denotes serial number of SOP, starting from "001"onwards.

• Fourteenth character is dash (-).

• Last two characters denote Revision No of SOP.e.g. First new SOP of QA shall have SOP number as NPP/QA/SOP001-00.2.8 character sop no.[5].E.g. PP001-00 (Pharmaceuticals Production 00100Revision No.)

3.7 character SOP no.[3].e.g. PPP-001 (Place Pharmaceuticals Production-001).

FORMAT NO.[3]: The format number used for preparing the SOP is mentioned in the footer block. The font size of the format no. Shall be in Times New Roman Font:

10, Style: Regular. The format numbering system shall be as follows: Format number shall consist of total sixteen characters[3]. e.g. NPP/PG001/F01-00; (N. Pharmaceuticals Place/Production General 001/Format01-00Revision No.). {Decoded like SOP No.}. Here 001 is SOP number to which the format is linked, F is Format, rest all is explained like SOP No. This format number shall appear on all the SOPs.

EQUIPMENT NO.:A in house coding protocol may be followed to ensure uniformity and avoiding repetition of number coding. , like SOP NO. e. g. NPP/PG/EQP001-00. Here EQP :- Equipment and rest all can be explained like SOP No.

PROTOCOL TO FOLLOW TO GENERATE AND REVIEW SOP[3,5]

(cycle time not more that 7 days)[5]. And total maximum time with training and implementation two months[5.]

Steps:

1. Draft of SOP by user department[9].
2. Draft copy stamped/watermarked on each page[3].
3. Discussed and Tested on;

i. Not known to procedure/Machine[4] ii. Actual user/worker[4].

4. Corrections done (if required).
5. Sent to reviewing authority[3,4,5.] (DepartmentHead/QA/QC/Regulatory[5,10]).
6. Any comments evaluated by the department head and incorporated in draft copy (if necessary[5].
7. Corrected Final copy printed on the approved format[5].
8. Sent (along with change history log) [3] for Approval and Authorization.
9. Approval and Authorization done and signed by all concerned[5].
10. Back in User Department
11. Submitted to QA department as original Copy (stamped as Master Copy) along with change history log[3]. Kept in strict supervision of Head QA[5].
12. Draft copy destroyed[3,5].
13. Training[5].
14. Issuance of SOP[5] (as photocopies of Master copy) by QA department to respective department Stamped as "CONTROL COPY".
15. Implementation[4,5.]
16. Further Review intermittent or scheduled.
17. Retrieval of old (previously issued) copies from respective departments[5].

STAMPING/MARKING OF SOP: To mark the sops during the development process or distribution, SOP is stamped usually on Top Right[5] as;

MASTER COPY : - Red Colour[5]
CONTROL COPY : - Blue Colour[5]
OBSOLETE : - Blue Colour[5]
DRAFT COPY : - Blue Colour[3]

ENSURING SUCCESS AND ACCURACY IN DEVELOPING SOP[4]:

1.Writer of SOP: Usually the initial draft of an SOP is written by the person performing the procedure or by someone who knows the procedure well. Supervisors review the SOPs for completeness and content and QC or QA staff approve for regulatory compliance[11].

2.Test The Procedure[4]: It is best to have a handful of people test your SOP. But ensure the person representative of normal reader with positive attitude for the success or work. Here also first of all test on a person who has never done it before so that his prior knowledge may not help him.Secondly test with the actual worker/supervisor[4].

3.Review of SOP: Have the SOP reviewed by the advisor/Head and quality assurance team[4].

4.Authorization Protocol: Strict authorization protocol to follow.

5.Training of Worker/Supervisors: Practically most important aspect to remove the fear to use new document and so successful SOP implementation.

Authority: - QA department.

Training Coordinator/Organizer: - Head of Department[5].

Training record is kept.

6.Issuance, Control and Retrieval of SOP:

Responsibility: Document section, QA department.

It should be done with necessary entries in SOP distribution/review and retrieval record documents[5].

7.Implementation of SOP: A positive environment should be developed about documentation procedures among actual users. Should be more like accepted than forced.

8.Revision of SOP: Periodic and as per requirement. The document should be regularly reviewed and kept up to date[12].

i. Must be processed as per SOP of "Change Control Procedure"[5,11].

ii. "Document Change Request Form"[5] should be properly filled and signed and attached with the SOP; submitted to Document Section by the respective department.

iii. All old copies of SOP, must be returned to document section for reconciliation and destruction of obsolete copies.

iv. Master copy in document section is marked "Obsolete copy"[5] and stored in the "Obsolete file" along with "document change request form"[5].

v. The newly revised SOP shall go through same process of Authorization as generation of sops.

ABBREVIATIONS:

1. SOP : -Standard Operative Procedures.
2. EQ. No. : - Equipment No.
3. WHO : - World Health Organization.
4. i.e. :- That is.
5. GMP : Good Manufacturing Practices.
6. e.g. :- For Example.
7. SOP :- Standard Operative Procedure.
8. NP :- N Pharmaceuticals.
9. PG :- Production General
10. P :- Production
11. QC :- Quality Control.
12. F :- Format
13. TNR :- Time New Roman.
14. B :- Bold.
15. U :- Upper Case

ANNEXURE:

i. Format sop.
ii. Machine manual.
iii. Sop cleaning/operating machine.
iv. Sop regent handling.
v. Standard abbreviations.

REFERENCES:

1. thefreedictionary.com [Dictionary on internet]. (cited on 2016 Feb 02) Available fromhttp://www.thefreedictionary.com/standard+operating+procedure .

2. Houghton Mifflin Harcourt Publishing Company, American Heritage® Dictionary of the English Language, Fifth Edition.. Published by Houghton Mifflin Harcourt Publishing Company. (Cited on 2016 Feb 02). [Reference on internet]. Available from:http://www.thefreedictionary.com/standard+operating+procedure.

3. ChaudharyAnkur.pharmaguideline.com. [homepage on internet]. 2008. (Cited on 2016 Feb 02) from:Http://www.pharmaguideline.com/2011/07/sop-of-sop.html

4. Hadley Chris. wikiHow, 530 Lytton Avenue, 2nd Floor, Palo Alto, CA 94301 [Wikipedia on internet]. (Cited on 2016 Feb 02). Available from: Http://www.wikihow.com/Write-a-Standard-Operating-Procedure.

5. Manohar A. Potdar. cGMP for Pharmaceuticals. Medpress publisher. 2009.

6. arora P.L. Pharmaloids Amritsar. Importance of SOPs. page 8. Monograph; Workshop on developing SOP's Herbal health research consortium pvt. ltd. Amritsar. (printed on 2009 Aug 09).

7. Chaudhary Ankur.pharmaguideline.com. [homepage on internet]. 2008. (Cited on 2016 Feb 02) Available from: http://www.pharmaguideline.com/2011/05/sop-on-standard-operating-procedure.html.

8. ChaudharyAnkur.pharmaguideline.com. [homepage on internet]. 2008. (Cited on 2016 Feb 02) from:http://www.pharmaguideline.com/2008/02/sample-sop-example-sop-sop-format-sop.html.

9. ChaudharyAnkur.pharmaguideline.com. [homepage on internet]. 2008. (Cited on 2016 Feb 02) Available from: http://www.pharmaguideline.com/2008/01/pharma-sops.html.

10. Lachman L. & Lieberman H.A. Industrial Pharmacy. Special edition 2009. CBS publisher 2009.

11. Gillian Chaloner-Larsson, Ph.D, GCL Bioconsult, Ottawa Roger Anderson, Ph.D, Director of Quality Operations, Massachusetts Public Health Biologic Labs Anik Egan, BSc.,GCL Bioconsult, Ottawa. A WHO guide to good manufacturing practice (GMP) requirements Part 1: Standard operating procedures and master formulae. chapter 6 page 12. WHO/VSQ/97.01. Printed on 1997. [Monograph on internet] (Cited on 2016 Feb 02). available from: http://apps.who.int/iris/bitstream/10665/64465/1/WHO_VSQ_97.01.pdf

12. Ayush Project. Voluntry Certification Scheme for Ayush Products, Certification Criteria for Ayush Premium Mark, GMP requirments 4.4.5.5. [Monograph on Internet] (Cited on 2016 Feb 02) Available from:http://www.qcin.org/PDF/ayush_project/Certification_Scheme_AYUSH-who4.pdf

Corresponding Author: Dr. Sudarshan K. Thakur NIAPR, CCRAS, Moti Bag Road, Patiala, Punjab, India. Email:drsthakur@gmail.com

Source of support: Nil
Conflict of interest:None Declared

Table 1: FONTS AND LAYOUT OF PAGES[3]:

Content of SOP (Layout on pages) A4 paper	Size of Font
Header	
"ORGANISATION NAME" (on top left corner)	14 Bold in Upper Case
"STANDARD OPERATING PROCEDURE" & "TITLE"	12 Bold in Upper Case
Logo (on the top, right hand corner)	30 mm (L) x 6 mm(H)

"Restricted Circulation" "Pharmaceutical Ltd etc.." "Location", "Dept.", "Area", "Page", "SOP No.", "Revision No." "Effective Date", "Supersedes", "Review Date", "Initiated By", "Approved By", "Authorized By", "Name", "Signature & Date"	10 Bold in Title Case
Actual Title (detailed heading) of SOP	12 Bold in Upper Case
Body	
Subheadings	12 Bold in Upper Case
Write up of SOP	12 in Sentence Case
Footer	
"Format No."	10 in Title Case
Actual format number	10 in Upper Case

Table 2; SOP DISTRIBUTION:

Sr. No.	DEPT./SECTION	Copy No./Total No.(X)	Retrieval detail	Date	Retrieved by

Table 3; DOCUMENT REVISION HISTORY:

REVION NO./Date	EFFECTIVE DATE	REASON(REVISION)	REVISED BY
00- New Document **01 – 1st Revision** **02 – 2nd Revision** **And so on.**		**N.A.(New Introduction)**	