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A REVIEW ON STANDARD OPERATING PROCEDURE (SOP)

Ranjeet Kumar Bhargav[1]*, Rehana Parveen[2], Samia Naaz[3], Umang Anand[4] and Sadik Ansari[5]

*[1,2,3,4,5]BBS Institute of Pharmaceutical & Allied Sciences, Greater Noida (U.P.), India.

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***Corresponding Author**
Ranjeet Kumar Bhargav
BBS Institute of Pharmaceutical & Allied Sciences, Greater Noida (U.P.), India.

ABSTRACT

SOPs are living documents that detail written instructions describing specific steps to follow in all activities under defined condition. SOP[1] is necessary to ensure the continuity of processes to achieve quality performance and quality product/preparation. The purpose statement identifies the goal of the SOP. It answers the question of why the SOP is being written. For example, "The purpose of this Standard Operating Procedure (SOP) is to specify the processes used to manage SOPs". The purpose statement needs to be detailed enough so that the intended user can recognize what the docs. They must be revised continuously to manage the same quality. Standart operation procedures have an important role in the processes which cannot be known before, so with SOPs, management groups will manage more useful works with less time. This study tries to explain which techniques are used, what are necessary and which type of works needs must be done for writing SOPs.

KEYWORDS: SOP, Written, steps, technical.

INTRODUCTION

Standard Operating Procedures[1] (SOPs) is a set of written instructions that document a routine or repetitive activity followed by an institution. The term "SOP" is sometimes used synonymously with term such as protocols, instructions, and worksheets. There are different definitions[2] for SOPs depending on the area where it is being applied. Working life has become quite different from 20 years ago. Decision-making mechanisms and procedures are becoming more important as more advanced technology is added. Procedures play an important role against quality, environmental, health and safety problems. People often learn or remember how to do things according to the procedures. SOP is a document that shows

how an application will behave during application (Akyar, 2012). SOP is a continuous instruction (Genelkurmay Başkanlığı Yayınları, 1950). It is an instruction set (Url-1) which is to be followed in operation (Intepe, 1980).

An SOP is an array of instructions or steps to maximize business requirements to safely complete a business without affecting the environment in the negative (Anderson, 2017).

Standard operation procedures, documents describing in detail the tasks and operations to be performed as standard (Milli Eğitim Bakanlığı, 2011). SOP is the policies, procedures and standards in the disciplines of production, marketing, management needed to be successful (Url-2). Some US institutions (FEMA, EPA, universities) have been involved in standard practice procedures. These studies have been carried out by taking into consideration the existing problems in real life. Many organizations do not have standard guidelines or even actively use them because of traditional causes, even if they have. In the absence of procedures for the construction of a work, they rely on their previous training and experience. This shows that there are no standard and good solutions in the organization and how things are done. Some traditional organizations have standards, but nobody uses them. In such situations, standards are often out of date and have lost their realities, so people know that it is not right to use them.

Today, the aim[3] of SOPs is to ensure that all employees perform their performance in the same way. When all employees perform their tasks properly, it becomes possible to perform controlled experiments to test the effect of various changing process parameters (Akyar, 2012). A concept[4] of well-written SOP to a newcomer can be a life saver. If a key staff member leaves the office for a reason or is not at work, the job does not have to stop. With reference to SOPs, other emergency tasks can be undertaken and can be done correctly, even for the first time.

FUNCTIONS OF SOPs

- An effective catalyst to drive performance improvement and improve organizational result.
- SOPs are to create the level of quality and accepted practice for a specific procedure.
- The foundation of every good quality system.
- SOP is a compulsory instruction.

- A document which describes the regularly recurring operation relevant to the quality of particular activity.
- Specifies in writing what should be done, when, where and by whom.

Common to all the definitions regarding an SOP is that it is applied to a task or function[5] or operation procedure being undertaken. It provides the details/instructions (chronological steps) of how the task should be carried out. It is an authorized document (officially approved).

ADVANTAGES[7] OF SOP

1. Placing value only on production while ignoring safety, health and environment is costly in the long run. It is better to train employees in all aspects of a doing a job than to face accident fines and litigation later.
2. It provides people with all safety, health and environmental and operational information necessary to perform a job properly.
3. It assures that all operations are performed consistently to maintain quality control of processes and products. Consumers from individuals to companies want products of consistent quality and specifications. SOPs specify job steps that helps standardize products and therefore quality.
4. By following SOPs, you help ensure against process shut downs caused by equipment failure or other facility damage.
5. Following health and environmental steps in SOPs ensures against spills and emissions that threaten plant neighbors and create community outrage.
6. To ensure the approved procedures are followed in compliance with company and government regulations. Well written SOPs help ensure that government regulation are satisfied. They also demonstrate a company's good-faith intention to operate properly. Failure to write and use good SOPs only signals government regulators that your company is not serious about compliance.
7. To serve as a training document for teaching users about the process for which the SOPs are written. Thorough SOPs are used as the basis for providing standardized training for employees who are new to a particular job and for those who need re-training.
8. To serve as a check list for co-workers who observed job performance to reinforce proper performance. The process of actively caring about fellow workers involves one worker

coaching another in all aspects of proper job performance. When the proper procedures are outline in a good SOP, any co-worker can coach another to help improve work skills.

9. To serve as a check list for auditors. Auditing job performance is a process similar to observation mentioned in the previous item only it usually involves record keeping. SOPs should serve as a strong basis when detailed audit check list are developed.
10. To serve as an historical record of the how, why and when of steps in an existing process so there is a factual basis for revising those steps when a process or equipment are changed. As people move from job to job within and between companies, unwritten knowledge and skills disappear from the work place. Properly maintained written SOPs can chronical the best knowledge that can serve new workers when older ones moved on.
11. To serve as an explanation of steps in a process so they can be reviewed in accident investigations. Although accident are unfortunate, view them as opportunities to learn how to improve conditions. A good SOP gives you a basis from which to being investigating accidents.

TYPES OF SOP

1. Technical SOP
2. Non-technical SOP
3. Administrative SOP
4. Legal/Private SOP
5. Productional or operational SOP

SOPs may be written for any repetitive technical activity, as well as for any administrative or functional programmatic procedure, that is being followed within an organization. General guidance for preparing both technical and administrative SOPs follows and examples of each are located in the Appendix.

✓ **Guidelines for Technical[8] SOP Text**

Technical SOPs can be written for a wide variety of activities. Examples are SOPs instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using an immunoassay kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatile organic compounds or trace metals), or how to conduct a bioassessment of a freshwater site. Technical SOPs are also needed to cover activities such as data

processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation.

Citing published methods in SOPs is not always acceptable, because cited published methods may not contain pertinent information for conducting the procedure-in-house. Technical SOPs need to include the specific steps aimed at initiating, coordinating, and recording and/or reporting the results of the activity, and should be tailored only to that activity. Technical SOPs should fit within the framework presented here, but this format can be modified, reduced, or expanded as required. Examples of technical SOPs are located in the Appendices A, B, and C.

In general, technical SOPs will consist of five elements: Title page, Table of Contents, Procedures, Quality Assurance/Quality Control, and References:

1. Title Page - See Section 3.1.
2. Table of Contents - See Section 3.2.
3. Procedures - The following are topics that may be appropriate for inclusion in technical SOPs. Not all will apply to every procedure or work process being detailed.

a. Scope and Applicability (describing the purpose of the process or procedure and any organization or regulatory requirements, as well as any limits to the use of the procedure),

b. Summary of Method (briefly summarizing the procedure),

c. Definitions (identifying any acronyms, abbreviations, or specialized terms

d. Health & Safety Warnings (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; listed here and at the critical steps in the procedure),

e. Cautions (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results; listed here and at the critical steps in the procedure),

f. Interferences (describing any component of the process that may interfere with the accuracy of the final product),

g. Personnel Qualifications/Responsibilities (denoting the minimal experience the user should have to complete the task satisfactorily, and citing any applicable requirements, like certification or “inherently governmental function”),

h. Equipment and Supplies (listing and specifying, where necessary, equipment, materials, reagents, chemical standards, and biological specimens),

i. Procedure (identifying all pertinent steps, in order, and the materials needed to accomplish the procedure such as:

• Instrument or Method Calibration and Standardization

• Sample Collection

• Sample Handling and Preservation

• Sample Preparation and Analysis (such as extraction, digestion, analysis, identification, and counting procedures)

• Troubleshooting

• Data Acquisition, Calculations & Data Reduction Requirements (such as listing any mathematical steps to be followed)

• Computer Hardware & Software (used to store field sampling records, manipulate analytical results, and/or report data), and

j. Data and Records Management (e.g., identifying any calculations to be performed, forms to be used, reports to be written, and data and record storage information).

4. Quality Control and Quality Assurance Section - QC activities are designed to allow self-verification of the quality and consistency of the work. Describe the preparation of appropriate QC procedures (self-checks, such as calibrations, recounting, reidentification) and QC material (such as blanks - rinsate, trip, field, or method; replicates; splits; spikes; and performance evaluation samples) that are required to demonstrate successful performance of the method. Specific criteria for each should be included. Describe the frequency of required calibration and QC checks and discuss the rationale for decisions. Describe the limits/criteria for QC data/results and actions required when QC data exceed.

✓ **Guidelines for Administrative[9] or Fundamental Programmatic SOP Text**

As with the technical SOPs, these SOPs can be written for a wide variety of activities, e.g., reviewing documentation such as contracts, QA Project Plans and Quality Management Plans; inspecting (auditing) the work of others; determining organizational training needs; developing information on records maintenance; validating data packages; or describing office correspondence procedures. Administrative SOPs need to include a number of specific steps aimed at initiating the activity, coordinating the activity, and recording and/or reporting the results of the activity, tailored to that activity. For example, audit or assessment SOPs should specify the authority for the assessment, how auditees are to be selected, what will be done with the results, and who is responsible for corrective action. Administrative SOPs

should fit within the framework presented here, but this format can be modified, reduced, or expanded. An example of administrative SOPs can be found in Appendix E.

In general, administrative/programmatic SOPs will consist of five elements: Title page, Table of Contents, Purpose, Procedures, Quality Assurance/Quality Control, and References.

1. Title Page - See Section 3.1.
2. Table of Contents - See Section 3.2.
3. Procedures -The following are topics that may be appropriate for inclusion in administrative SOPs:

a. Purpose – (identifying the intended use of the process)
b. Applicability/Scope (identifying when the procedure is to be followed),
c. Summary of Procedure,
d. Definitions (defining any words, phrases, or acronyms having special meaning or application),
e. Personnel Qualifications/Responsibilities (identifying any special qualifications users should have such as certification or training experience and/or any individual or positions having responsibility for the activity being described),
f. Procedure,
g. Criteria, checklists, or other standards that are to be applied during the procedure such as citing this document as guidance for reviewing SOPs), and
h. Records Management (specifically, e.g., as forms to be used and locations of files).

4. Quality Control and Quality Assurance Section - Describe any control steps and provisions for review or oversight prior to acceptance of the product or deliverable. This can include test plans such as verification and validation plans for software or running a "spell-check" program on the finished document.

5. Reference Section - Cite all references noted in the body of the SOP. A copy of any cited references not readily available should be attached to the SOP.

OBJECTIVES

1) Help to assure quality and consistency of service.
2) Help to ensure that good practices is achieved at all times.
3) Provide an opportunity to fully utilize the expertise of all team members.
4) Help to avoid confusion over who does what(role clarification).

5) Provide a contribution to the audit process.
6) To protect the health and safety of employees, and to protect the environment.
7) To ensure the processes continue and are completed on a prescribed schedule.

POINTS TO BE CONSIDERED DURING WRITING SOPs

Write an SOP to be as long as necessary for a specific job. All jobs differ in the number of steps required to complete them properly. Short-changing someone by providing short and incomplete SOP sets up failure. Write an SOP to satisfy the definition of SOP not a standard company format that no one has thought about in years.

- People tend to ignore long SOPs because they cannot remember more than 6-12 steps. If your SOP goes beyond 10 steps, consider this solution.
- Break the long SOP into several logical sub-job SOPs'
- Write an accompanying shortened SOP that lists only the steps but not detailed explanations of those steps.
- Make the long form SOP a training document or manual to supplement the shorter sub-job SOPs mentioned earlier.
- Consider the work culture within which people work. If you write for people in a culture in which shortcuts are accepted practice, explain the reasons behind certain steps so that SOP users will understand the importance of following all the steps in the proper order.
- Consider the age, education, knowledge, skill, experience and training and work culture of the individuals who will be performing the SOP steps.
- Keep in mind that many people do not read all the steps before starting on step one. Many people read a step, perform it. Read the next step, perform it, and soon.
- Once you have completed writing an SOP, have several workers test it and give you feedback. If you did not consult safety, health and environmental experts prior to writing the SOP, have them observe the SOP being tested so they can add comments.
- Review the effectiveness of SOPs after weeks and make necessary changes if in the field practice.

DEVELOPING SOPS FOR VARIOUS PROCESSES CARRIED OUT IN THE PHARMACY

ROLE OF SOPS IN THE PHARMACY

Through SOPs, service delivery in the pharmacy will be consistent. Patients should be served and counselled in the same way irrespective of whether attended to by Mr A or Ms B. Medicines should be ordered on schedule, received, distributed and dispensed in concordance with the required standards. And all other processes in the pharmacy should be standardized to ensure consistency.

SPECIFIC OBJECTIVES

- Describe the steps involved in developing SOPs.
- Describe the steps involved in writing SOPs.
- Discuss the different formats for presenting SOPs.

DEVELOPING OF SOPS

A SOP can be created by modifying an existing one or by writing down the steps taken when performing specific tasks in your operation and following a template of choice. When developing SOPs one must choose a process which will be easy to implement. It is easier to modify an existing SOP to suit the needs of an institution, however in some cases one might be forced to develop a new one from scratch. Before developing an SOP, one must assess the need and then review available resources. One should start developing the activities that are done most often. Assess areas in your operation in which standard procedures are necessary, start with those in which you are currently communicating most often e.g. dispensing. Review available resources to use as a template, or start fresh using these elements.

STEPS INVOLVED IN DEVELOPING SOPS

a) Preparation for SOP development;
b) Information gathering phase;
c) Write the SOP;
d) Test the SOP;
e) Sign-off the SOP;
f) Release the SOP;
g) Update and maintain the SOP.

CONTENT OF SOPS

Since each pharmacy operates and functions differently depending on varying circumstances, and has its own ways of carrying out certain procedures, the SOPs in different pharmacies will differ. However, the basic content, structure, and the concepts of SOPs will obviously be the same. The make-up of the SOPs should meet a minimum number of requirements:

1. SOP Name;
2. Scope of the SOP;
3. Aim or Objective of the SOP;
4. Processes/Steps to be carried out, in sequential order;
5. Whose responsibility it is to carry out the SOP;
6. Scheduling review.

STEPS[10] FOR WRITING SOPS

➢ NAME THE SOP

The name is important for identification, filing and retrieval. The naming should use descriptive action words. The name of the SOP should uniquely identify it from other SOPs within the pharmacy by using a SOP number. Mention also the name & address of the pharmacy/hospital.

➢ WRITE A SCOPE

The scope indicates what is covered from the beginning to the end of the process. To define the scope one needs to answer the following questions:

- Which specific operations or tasks within the pharmacy will be covered?
- Which are not covered?
- Who is the SOP written for?

➢ AIM OR OBJECTIVE OF THE SOP

This part indicates the purpose for following the procedure.

➢ WRITE THE DETAILED STEPS FOR THE TASK

In this step one provides an overall description of the tasks involved in carrying out the particular activity. The active voice and present verb tense should be used. The term "you" should not be used, but implied. It should also include any equipment that may be used e.g. tablet counters. Procedures should include all steps that are essential and that should be performed the same way by all workers. Omitting any of these essential steps may lead to

confusion for the reader or performance variation among different workers. On the other hand, procedures should not be so detailed that they are cumbersome and impractical for everyday use.

- **RESPONSIBILITY**

Who is responsible for carrying out the procedure and who ensures that staff members are suitably trained to carry out a procedure? In a working pharmacy this would also include contingency plans detailing what to do in cases of sickness or holiday leave, etc.

- **REVIEW**

This step shows how the process is monitored to ensure that it remains useful, relevant and up to date. It should include a schedule for review. The date when the SOP was prepared/reviewed should be indicated as well as the name and signature of the person/s who made/reviewed the SOPs.

PRESENTATION[11] OF SOPS

The best SOP format is one that, given the situation, does the best job of accurately transmitting the necessary information and facilitating consistent implementation of the SOP. A SOP can be presented in different formats.

- **SIMPLE STEPS**

These are easy to write and follow and work well for short, simple, straightforward tasks. It is used in processes that are fairly repetitive with very limited decision making.

Simple Steps Example

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible;
2. If necessary, count out desired number of units using a spatula or knife on counting tray or clean sheet of paper. Avoid touching medicine product with hands, as contamination may result;
3. Recount number of units before packing into the container
4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package:

• Quantity

• Batch No.

• Expiry date
• Times at which the medicine is to be taken
• Patient's name
• Date

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and labelling contain the correct medicine, strength, quantity, dosage form, and directions for use.

❖ HIERARCHICAL STEPS

Hierarchical steps is an extension of the simple steps format, this format works better for tasks that require additional detail or sub-steps within each primary step. It allows the use of easy-to-read steps for experienced users while including more detailed sub-steps as well.

Hierarchical Steps Example

Stocktaking SOP

1. Prepare for the stocktaking

• Schedule the day and time when stocktaking will be done;

2. Assign staff to conduct the stocktaking

3. Organize the storeroom

• Arrange products according to FEFO;
• Make sure open cartons, boxes are visible;
• Separate damaged or expired products.

4. Count the usable products;

• Count products according to their dispensing units;
• If you have a bottle that contains individual capsules or tablets, estimate the quantity. If a bottle of 1,000 capsules is 2/3 full, then estimate 650 or 700 capsules. If you have a one-litre bottle of syrup that is ½ full, then estimate 0.5 litres;
• Update the stock keeping records. (The stock keeping record is the Tally Card);
• Write the date the stocktaking is done and the word "Stocktaking" in the Issued/Received column of the tally card;
• Write the quantity of the product that you count during stocktaking;

• The Stock on Hand quantity listed on the Tally Card should match the quantity that you have counted;

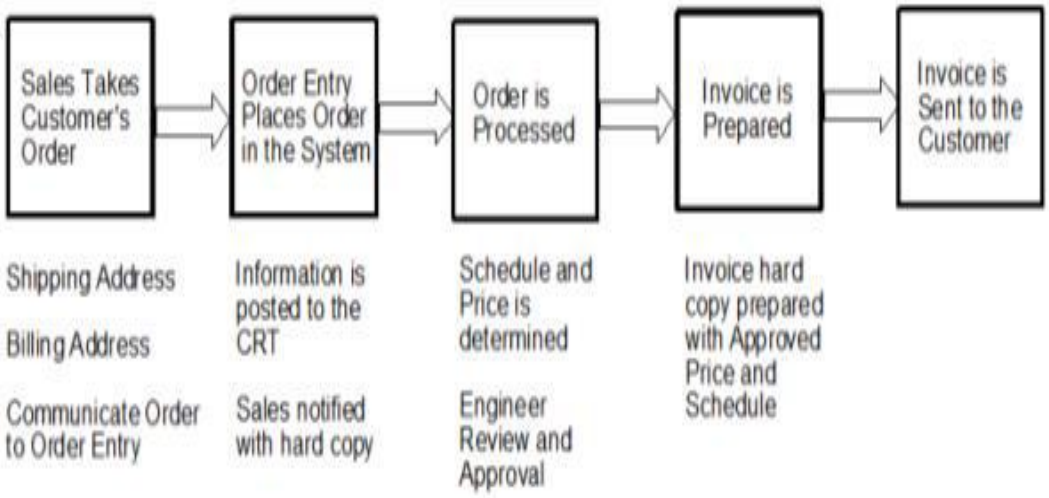
5. Take action based on the results of the stocktaking

• If the number of products counted during stocktaking does not match the quantity listed on the Tally Card, update the Tally Card balance by adding or subtracting the excess or missing quantities in the appropriate column in the Tally Card;

• If expired or damaged products are found, dispose of them following established procedures. Subtract the quantity from the Tally Card balance and update the current balance.

❖ GRAPHIC FORMAT

This is a graphic version of the two previous formats. It works well for tasks where activities must be done in a specific order and where an easy to follow reminder at the job site is useful. The graphic format breaks long processes into shorter sub-processes that consist of only a few steps. Workers can learn several short sub-processes more easily than one long procedure.



❖ FLOWCHART FORMAT

Flowcharts are simply a graphic way to present the logical steps in a decision-making process. A flowchart provides an easy-to-follow mechanism for walking a worker through a series of logical decisions and the steps that should be taken as a result.

❖ **ANNOTATED PICTURES**

This format works well for people who cannot read or where a language barrier exists. Pictures can dramatically reduce the need for written explanations; this format helps to shorten complex and detailed SOPs.

CHOICE OF FORMAT

Which is the best format? It is the one that, given the situation, does the best job of accurately transmitting the necessary information and facilitating consistent implementation of the SOP. The following considerations will influence the choice of the format: the scope and complexity of the SOP, the people who will use the format and how the SOP will be used.

Scope and complexity of the SOP: How many decisions will the user need to make during the procedure? How many steps and sub-steps are in the procedure? Routine procedures that are short and require few decisions can be written using the simple steps format. Long procedures consisting of more than ten steps, with few decisions, should be written in hierarchical steps format or in a graphic format. Procedures that require many decisions should be in flowchart format.

MAKING EFFECTIVE AND ACTIVE USE OF SOPS

1. SPECIFIC OBJECTIVES

- Describe steps involved during implementation of SOPs;
- Discuss how SOPs can be used to train staff in the pharmacy;
- Explain where SOPs can be kept;
- Discuss the importance[12] of compliance monitoring;
- Monitor compliance of SOPs.

2. INTRODUCTION

SOPs need to be actively used within the department. For this reason, it is important to properly plan the implementation of SOPs and expect challenges and resistance. It is also important that the use of SOPs is monitored to assess whether they are used correctly.

3. IMPLEMENTATION OF SOP

The following are steps involved during succesfull implementation of SOPs:

Plan for results;

Design SOPs with definite results in mind. This improves communication and cooperation with stakeholders and leads to appropriate monitors;

Review draft internally and externally

Write a first daft. This gives a basis for discussion and educes excessive speculation about how to begin. Plan an internal review to access ideas and build commitment and buy-in. Plan an external review to access ideas and expertise and build commitment and buy-in;

Pre Test the draft SOP: Let someone unfamiliair with the job try to follow the procedure;

Publish the SOP: In workplace and provide the employees with information.

Train staff on applying the SOP

Define the learning objective. Explain and demonstrate both why and how each step is done. Give opportunity for learner to practice. Observe and make key corrections. Provide appropriate feedback. Be patient, follow up as needed with coaching;

Overcome resistance

There are different attitudes from workers that the implementer may need to overcome. These attitudes are mostly due to fear that the workers would like to express. However in all situations there is always a solution;

Attitude: "We've done it just fine the old way up to now!"

Problem: Fear of change

Solution: Explain need for change and listen to concerns. Overcome with communication.

Attitude: "This is no benefit to me, just extra work!"

Problem: What's In It For Me???

Solution: Share mission and values of the business. Explain how improvement benefits everyone.

Attitude: "The boss wants to micro-manage everything we do."

Problem: Lack of empowerment.

Solution: Encourage people to take an active role in shaping change and improving quality.

DESIGNING OF SOP

In designing of SOP Following points are considered

OBJECTIVE: To lay down procedure for the preparation of Standard Operating Procedures.

SCOPE: This procedure is applicable to all the SOP"s throughout the organization.

RESPONSIBILITY: Person Performing: Respective HOD"s of concerning departments

Person Monitoring: QA officer/ HOD QA

PROCEDURE: All SOP‟s shall be computer typed using Times New Roman font. Format of SOP shall be as per Annexure SOP/QA/002/1. Each SOP has: I) Header, II) Signature block and III) Body.

Header: Present on all the pages of SOP and includes Company Logo, Name, address & Concerned Dept.: Company Logo, (In capital bold letters of font size 16)

Document Type: Standard Operating Procedure (In capital bold letters of font size 14)

Ref. No.: It is like SOP/DC/YYY-Z Where DC depicts the department code as below: PE: Personnel Department PD: Production Department MT: Maintenance Department QA: Quality Assurance Department QC: Quality Control Department ST: Store Department PU: Purchase Department YYY is the sequential number starting from 001 for each department. And Z is the revision status, starting from 0 for the original version and 1 for the next version and so on. (In capital letters of font size 12).

Supersedes: It is the Ref. No. of the earlier version. (In capital letters of font size 12).

Effective Date: It is the date from which the SOP shall be put in use. The date format has to be DD/MM/YYYY, where DD indicates the date, MM indicates the month & YYYY indicates the year (e.g. 01/11/2007). Date shall be written with blue indelible ink pen.

Review Date: It is the Month & Year during which the SOP shall be revised e.g. 21/2013, written with blue indelible ink pen. It shall be maximum 2 years from the effective date.

Page No.: It is like X OF Y. Where X is the individual page number and Y is the total number of pages. (In capital letters of font size 12)

Title: It shall be clear and descriptive. (In bold capital letters of font size 12).

Signature Block: It shall be below the header and only on the first page of the SOP. (Titles in the rows & columns shall be in bold letters & other text in normal letters of font size 12. Name and designation shall be typed. And signature and date shall be put in blue indelible ink pen)

Prepared by: Signature with date, name and designation of the person from user department who has drafted the SOP.

Verified by: Signature with date, name and designation of the HOD or the person from user department who has verified the draft of the SOP.

Authorized by: Signature with date, name and designation of the person authorizing SOP, DGM QA or HOD QA.

Body: It shall contain the subject matter, which is written in the following Manner

OBJECTIVE: It shall define the purpose of the SOP.

SCOPE: It shall define the area of application.

SOP RECORD CONTROL

GDP procedure should describe the types of workbooks/notebooks that may be used – typically these are hard-covered with sown/sturdy binding; avoid spiral bound workbooks or logbooks as pages may be removed. In an emergency, if no official means to record an observation is available, then:

1. Initial, date and provide a comment on the paper record of the observation and attach to the official hardcopy record as soon as possible.
2. Transcribe and attach the data to the official record and annotate „Transcribed, see attached original". The transcription must be signed and dated by the Preparer and filed/stored together with the original record.
3. The data must be checked for accuracy by a second staff member.
4. Investigate why an official record was not available at the time. Implement corrective actions so that the same situation may not arise again, e.g. create a form for the record, amend the procedure, change the process so that the record is captured electronically etc.

Using true copies

1. Sometimes there is a need to use a copy of an original document or record, e.g. attaching a copy of a report to a non-conformance record. So that it is apparent that the record is not the original:
2. Stamp or write on the front of the copied documentation, „True Copy".
3. Sign and date the „True Copy" amendment.

Modifying records in a compliant manner

The company GDP procedure should stipulate how data or entries may be amended. This should include details on:

1. Any standard abbreviations used, e.g. „not applicable" (NA or N/A) etc.
2. Unacceptable practices, e.g. using „ditto" marks (") to indicate the same entry as above, leaving empty fields in a form, etc.
3. Who is responsible for checking documentation amendments or general GMP compliance of logbook pages over time?

Initially SOP is prepared by concern department as draft and draft is reviewed by dept. head and final draft is send to QA department that convert a draft to a final documents checked and approved by authorize person. Control copies are issued to concern department and issuance records are maintained. After approval of documents such as sops quality assurance must

ensure that all users/concerned department gets training before the implementation of the sops record of such training must be maintained. A training co-coordinator preferably the head of user department or any designated individuals shall be responsible for organizing the training. After successful implementation of training on any sops, the sops become effective. Original sops are stamped as "MASTER COPY" with red ink, master copy are stored under supervision and photocopy of master copy duly stamped as "CONTROL COPY" in blue color. Sops distribution list should be maintained for issuance records, change in sops need to initiated change request and all issue copies are retrieve and new one implemented with training.

WHERE TO KEEP THE SOPS?

SOPs should be readily available to the relevant staff at all times. A master file of all SOPs should be maintained, which should be securely kept with the Pharmacy in-charge. All SOPs may also be kept in another file, which is easily accessible, for reference/use of the staff. Certain SOPs may be put up in prominent places, at the point where they are actually applicable, e.g. SOP for handling medicines in the refrigerator may be pasted on the refrigerator door.

CONCLUSION

In this review work, SOP concept was tried to be explained. many institutions in India, is working with multiple rules set by the law. This law and other documents include the rules of the organization. When there is a change of law, these institutions are obliged to comply with changed laws and regulations. The Code of Federal Code Of Federal Regulations for drug product manufacture‟s states (Subpart F, CFR Part 211.100) *"There shall be written procedure for production and process control designed to assure that drug product have the identity, strength, quality and purity, they purport or are represented to possess."* If an institution is authorized for a territory of the central government, it operates under some regional protocols or standards. In such cases, SOPs are obliged to comply with regional regulations. Like strategic plans, many organizations use some other planning documents to guide the organization and coordinate activities. These documents include intervention plans, communication plans and other plans. Plans define operational objectives, strategies, signals and forecasts. SOPs need these plans in order for the institution to complete its mission.

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