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## Review Article

# Standard Operating Procedure (SOP): A Review

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## ABSTRACT

SOPs are living documents that contain written instructions explaining particular processes to be taken in all activities under specified conditions. SOP1 ensures process continuity in order to achieve quality performance and product/preparation. The purpose statement identifies the SOP's goal. It addresses the question of why the SOP is being written. Such like "The purpose of this Standard Operating Procedure (SOP) is to specify the processes used to manage SOPs". The purpose statement must be detailed enough for the intended user to understand the documents. Constant revision is necessary to maintain consistent quality. Standard operating procedures (SOPs) play a crucial role in operations that were previously unknown. By implementing SOPs, management groups can do more productive tasks in less time. This study explains the strategies, necessary tasks, and types of work required for producing SOPs.

## INTRODUCTION

Standard operating procedures (SOPs) in the pharmaceutical sector provide comprehensive methods to achieve desired results. SOPs strive to achieve efficiency, consistency, and quality output in pharmaceutical processes. The standard operating procedure limits the intervention for recording that satisfies the compliance requirements by providing easy evidence of operation, control over product traceability, and up-to-date calibration and validation status of equipment, preventing each individual from taking steps. Misinterpretation of each individual's decision-making process and the manager's ability

to offer control over the organisation, resulting in a reliable and efficient design. The establishment of standard investment methods in the pharmaceutical business adheres to regulatory criteria established by the United States Pharmacopoeia and the Food and Drug Administration for quality product manufacture.[1-4] Standard Operating Procedures (SOPs) are written instructions for an institution's routine or recurring activities. Synonyms for "SOP" include procedures, instructions, and worksheets. There are multiple definitions.[5, 6] SOPs attempt to ensure consistent performance

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among staff. [7] Proper employee performance enables controlled experiments to assess the impact of changing process factors. A well-written standard operating procedure [8] can save a newcomer's life. If a key staff member leaves or is absent, the job can continue without interruption. SOPs enable successful completion of emergency duties, especially for first-timers.

By compiling and standardizing these SOPs, the paper aims to provide a robust framework that facilitates compliance with regulatory guidelines such as those from the FDA, EMA, and ICH. This ensures that the pharmaceutical products not only meet the required quality standards but also improve the efficiency of the production process, reduce variability, and enhance the overall reliability of the drug supply chain.

In conclusion, the compilation of SOPs for tablets and capsules dosage forms serves as a critical tool for the pharmaceutical industry. It supports the consistent production of high-quality drug products, ensuring patient safety and therapeutic efficacy while fostering regulatory compliance and operational excellence.

### **FUNCTIONS OF SOPs**

- 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.
- 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.

All SOP definitions apply to a certain task, function, or operating method [9]. It provides step-by-step instructions for completing the task. This is an officially accepted document.

### **Advantages of SOPs [10]**

1. It provides people with all safety, health and environmental and operational information necessary to perform a job properly.
2. 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.
3. Following health and environmental steps in SOPs ensures against spills and emissions that threaten plant neighbors and create community outrage.
4. 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.
5. By following SOPs, you help ensure against process shut downs caused by equipment failure or other facility damage.
6. 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.
7. 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

Standard Operating Procedures (SOPs) can be written for recurring technical activities, administrative procedures, or functional programs within an organisation.

### **SOP Preparation**

The business should have a procedure in place to determine which processes or procedures must be recorded. SOPs should be written by professionals who understand the organization's activity and internal processes. These individuals are essentially the subject matter specialists who employ the technique or carry out the assignment. A team technique that can be applied, particularly for multi-tasking tasks, where the collective wisdom of the Participation is important, and it also fosters "buy-in" from prospective SOP users [11]. SOPs should be detailed enough for even those with limited experience or understanding to successfully repeat them. In the section on personnel qualifications, mention the necessary experience for the task at hand. Indicate if basic chemistry or biology require prior experience or additional training [12].

### **Formats for Standard Operating Procedures**

When draughting standard operating procedures, managers have a number of alternatives for arranging and structuring them. Your goal is to create an easy-to-understand and useful document for the assigned task. Two variables decide the appropriate SOP to use. How many initial selections does the user need to make to finish the procedure? Second, how many phases and substeps does the approach contain in total? Simple format steps can be used to write concise and straightforward routine procedures. For lengthy procedures with multiple stages and few options, a visual representation or step hierarchy is recommended. Use a flowchart to document

necessary procedures that call for plenty of choices [13].

### **Designing of SoP:**

When creating SOP Considered are the following points:

#### **Objective:**

Establish a process for creating standard operating procedures.

#### **Scope:**

The SOPs used by the entire organisation must follow this method.

#### **Responsibility:**

#### **Person Performing:**

The relevant HODs for the relevant department QA officer/HOD QA is in charge of monitoring.

#### **Procedure:**

Times New Roman typeface must be used for typing all SOPs. The SOP format must follow Annexure SOP/QA/002/1. Each SOP has:

1. Body
2. Header
3. Signature block

#### **Header:**

Located at the top of every page of the SOP and contains the related department's name and location.

#### **Company logo (in large bold characters, font size 16)**

Standard Operating Procedure Document (in uppercase, bold letters, font size 14). Reference

#### **Number:**

Similar to SOP/DC/YYY-Z.

In DC, the department code appears as follows:

#### **Department of Personnel:**

PE

#### **Production Division:**

Department of Maintenance

Department of Quality Assurance QC: Department of Quality Control. ST: Store Division.

PU: Department of Purchases.

The sequential number for each department is YYY, beginning with 001. And Z denotes the



revision status, where zero symbolises the initial version, 1 the next version, and so on. (in 12 point font and all caps).

#### **Supersedes:**

It is the reference number for the previous version. (in 12 point font and all caps). The Effective Date is the date the SOP will take effect. Dates must be formatted as DD/MM/YYYY, with DD representing the date, MM representing the month, and YYYY representing the year (e.g., January 11, 2007). The date must be written in blue permanent ink. Review date: The SOP will be changed on a specific date, such as 21/2013, and printed in blue permanent ink. The maximum term after the effective date is two years. Page number The format is similar to X OR Y, with Y representing the total number of pages and X representing a single page number. (Capital letters, 12 point font) It must be concise and descriptive. (In large bold characters, size 12) [14]

#### **Personnel Training and Compliance with SOPs**

Pharmaceutical items must be manufactured in accordance with current good manufacturing practices, known as CGMPs, as specified by regulatory bodies to ensure their safety and effectiveness. Quality control, or "QC" testing of manufacturing processes and final products, is an important component of the CGMP system. Regular reviews/audits of equipment and operating processes, also known as standard operating procedures (SOPs), are required to ensure quality control. Poor adherence to standardised operating procedures is commonly viewed as a risk issue, raising legitimate concerns about product quality and process safety.[15] The basic goal of personnel training is not just to enable job applicants to fulfil their duties in an arbitrary fashion. The process starts with an awareness of an organization's corporate philosophy, goals, business climate, operational scope, and employee job roles and responsibilities. Only then can the workforce get an awareness of the purpose of

personnel training, allowing them to better comprehend how to carry out their tasks in a given setting. Standard operating procedures (SOPs) are critical for effective personnel training because they ensure better uniformity and consistency while also giving guidance for ongoing tasks. Finally, a medically educated, qualified, and certified person is certain to give a pharmaceutical company a competitive advantage while ensuring quality, safety, and efficacy.[16]

#### **Documentation and Record-Keeping in Pharmaceutical Manufacturing [17-20]**

Proper paperwork and record-keeping are critical in a pharmaceutical setting. They are equally vital during the URS, Design, Build, and Testing phases of a project as they are when ordinary operations begin. It is especially crucial for skilled, trained staff to keep accurate records when operating in controlled situations. In general, a controlled environment is maintained to specifications, which are reviewed and rechecked at regular intervals to ensure that the prescribed operating conditions are satisfied. These operational conditions are often evaluated and documented numerous times each day in pharmaceutical manufacture. Controlled environment systems include air pressure, humidity, and particle counts, among other things. The frequency of checkpoints must be documented in approved procedures and signed off as completed and recorded by the responsible operators. Other critical aspects that must be documented include batch authorisations, building maintenance and alterations, equipment maintenance and repairs, and even noise in the plant that affects the overall operation of the controlled environment.

#### **WHERE TO KEEP THE SOPs?**

SOPs should be readily available to the appropriate personnel at all times. Maintain a master file of all SOPs and keep it secure with the pharmacy in charge. SOPs can be retained in an easily accessible file for staff reference and use.



SOPs for specific areas, such as handling medicines in the refrigerator, might be displayed prominently on the door.

## CONCLUSION

In this review work, the SOP concept was attempted to be explained. In India, various institutions operate under multiple legal regulations. This law and related documents outline the organization's rules. Institutions must comply with changes in laws and regulations. Standard operating procedures (SOPs) must meet area regulations. Organisations utilise various planning documents, similar to strategic plans, to steer and coordinate actions. These documents cover intervention, communication, and other plans. Plans outline operational objectives, tactics, signals, and projections. SOPs require these strategies in order for the institution to achieve its objective.

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## CONFLICT OF INTEREST

Not Applicable

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