

Standard operating procedures

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OBJECTIVES

- Define Standard Operating Procedures (SOPs);
- Explain the importance of SOPs;
- Discuss the role of SOPs in the control of processes and procedures in pharmacy;
- Discuss key steps for developing SOPs;
- Discuss the use of SOPs in training of staff;
- Describe how to effectively and actively use SOPs;
- Describe how to monitor compliance with SOPs.

Definition and understanding about SOPs

SPECIFIC OBJECTIVES

- Define SOPs;
- Differentiate SOPs with other terms.

WHAT ARE SOPS?

A standard operating procedure (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 terms such as protocols, instructions, and worksheets. There are different definitions for SOPs depending on the area where it is being applied.

Other definitions of SOPs are:

- A written document that describes in detail, step-by-step, how a procedure should be done;
- A set of instructions with the force of a directive that defines or standardizes a procedure or specific function;
- An effective catalyst to drive performance improvement and improve organizational results;
- SOPs are to create the level of quality and accepted practice for a specific procedure;
- The foundation of every good quality system;



- A document which describes the regularly recurring operations relevant to the quality of a particular activity;
- A SOP is a compulsory instruction;
- 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 or operation or 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).

The components of SOPs are as follows:

- Scope - the activity which is to be covered by the SOP;
- Objective - the purpose of following the procedure;
- Responsibility - who will be carrying out the activity;
- Procedure - instructions on what should be done;
- Audit - to identify areas of improvement.

DEFINITION OF TERMS

Several categories and types of SOPs can be distinguished. However the name "SOP" may not always be appropriate, and other terms may be used instead. These include policy, guideline, procedure, regulation, rule or protocol.

A *policy* is a guiding principle or course of action adopted toward accomplishing objective or objectives. It describes the general principle that will guide behaviour or a definite course or method of action to guide and determine present and future decisions. A *guideline* is a statement, indication, guide or outline of policy by which to determine a current or future course of action. A *procedure* prescribes specific ways of doing specific activities. It's the document which regulates the formal steps into an action. It provides a series of steps followed in a particular order. A *regulation* is a rule or order prescribed by authority to regulate conduct. A *rule* is a principle set up by authority, prescribing or directing action or forbearance. A *protocol* is a detailed plan of a scientific or medical experiment, treatment, or procedure.

Importance of SOPs

SPECIFIC OBJECTIVES

- Explain the importance of standard operating procedures;
- State the benefits of standard operating procedures;
- Discuss the benefits of SOPs in the pharmacy.

IMPORTANCE OF SOPs

Standard operating procedures are essential in order to maintain:

- Consistency - which helps to maintain the level of services offered and therefore maintains good pharmaceutical practice at all times;
- Accuracy - to ensure that the services are offered with highest level of attention, care, and due diligence to guarantee safety of the patient and confidence of both the patient and the health worker;
- Reliability - this ensures that the outlined processes are dependable to achieve outcomes;
- Validity - to legalise processes within the pharmacy.

People need consistency to achieve top performance and that is what SOPs provide. They reduce system variation especially in systems where quality is very important e.g. manufacturing. Having SOPs in place in a





hospital, the pharmaceutical staff is able to show that they operate systems of practice which are safe and which encourage continuous improvement.

BENEFITS OF SOPs

SOPs provide benefits to the facility in different aspects and at organizational level.

IMPROVED PRODUCTIVITY AND PERFORMANCE

SOPs help to assure the quality and consistency of medicine supply activities. People need consistency to achieve top performance. Productivity and performance are improved when jobs and tasks are done in a consistent way. SOPs help staff to do that by giving clear instructions, which are available to all staff that does a certain task. Thus nobody should have to ask another person on how a job has to be done.

IMPROVED QUALITY OF PRODUCTS AND SERVICES

The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization, even if there are temporary or permanent personnel changes.

COOPERATION AMONG STAFF

SOPs provide an opportunity to fully utilize the expertise of all members of a department or team. People tend to be supportive of the things they help create. Involving employees in developing SOPs can help assure the final product is more complete, useful and accepted. The SOP also helps senior managers to delegate responsibilities, and among staff, it assists in clarifying the roles of staff with respect to specific tasks.

FACILITATING TRAINING

SOPs are useful tools for training staff especially new members. Having complete step-by-step instructions helps trainers ensure that nothing is missed and provides a reference resource for trainees. For employees filling in on jobs they do not perform on a regular basis, an SOP can be an excellent reference document on how a task is done.

SAFETY AND LEGAL PROTECTION

SOPs minimize opportunities for miscommunication and can address safety concerns. Correct and consistent use of SOP can help keep employees safe at work and may provide some legal protection from national regulatory agencies.

EVALUATION

SOPs provide a contribution to the audit process. Having SOPs can encourage regular evaluation of work activity and continuous improvement in how things are done.

BENEFITS OF SOPs IN THE PHARMACY

SOPs give clarity to the pharmacy personnel, to follow steps/procedures, systematically, and uniformly. SOPs assist the pharmacy personnel to know who does what, and when, thus avoiding confusion, and function overlapping. They assist to ensure that good pharmacy practice is followed and achieved at all times. SOPs are useful tools for training new members of staff. And they help to assure the quality and consistency of the service, and thus minimize harm to the patient.



Role of SOPs in ensuring quality of services in the pharmacy

SPECIFIC OBJECTIVES

- Describe the purpose of SOPs;
- Discuss the role of SOPs within pharmacy.

INTRODUCTION

SOPs describe a systematic approach to maintaining and improving the quality of patient care. They provide directions and structure.

PURPOSE OF SOPs

The purpose of SOPs is to ensure that essential job tasks are performed correctly, consistently, and in conformity with internally approved procedures. SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They must be well written, if not, they are of limited value. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with organizational policies and in some instances government regulation. By having SOPs in place, pharmacy staff is able to show that they operate systems of practice which are safe and which encourage continuous improvement.

Manager's role in a workplace is to create an environment that leads to high performance. This can be done through development and implementation of SOPs. This high performance is based on:

- Standardized systems - Must exist to ensure consistent work is done and that performance evaluation is clear and fair. SOPs help to create consistency in work; they are the foundation for high performance.
- Training and coaching - Essential to give people the opportunity to understand clearly and perform at their best. SOPs help to guide training and coaching and ensure that people are doing tasks the same way.
- Feedback - Critical to continual improvement of systems and motivation of employees. Feedback gives direction about how an individual, group/team, or procedure is performing. SOPs are important for fair feedback as otherwise different people might have had different information.

These three factors are coming together in the performance triangle as shown below **Error! Reference source not found..**



FIGURE 1 THE PERFORMANCE TRIANGLE

WHEN ARE SOPs APPLICABLE?

- When variation must be controlled;
- When safety risks are present;
- When numerous people perform the same procedure;
- When outside advisors' input is needed;





- When management wants to create a “culture of improvement”;
- When objective feedback on performance is desired;
- When steps and decisions can be standardized.

HOW TO USE SOPs

Review and reinforcement by management is required. Current copies of SOPs should be readily accessible in the work areas for reference. Even the best written SOPs will fail if they are not followed.

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.

Developing SOPs for various processes carried out in the pharmacy

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

- Preparation for SOP development;
- Information gathering phase;
- Write the SOP;
- Test the SOP;
- Sign-off the SOP;
- Release the SOP;
- Update and maintain the SOP.



PREPARATION FOR SOP DEVELOPMENT

Put together a team to undertake the effort. SOP development should be an inclusive process that considers the input of everyone within the department. All members of staff that will be affected by the SOP should be involved in the development process. Hospital managers who write procedures without input from other members of staff run the risk of upsetting workers and producing a poorly written SOP. Incorporating the members of staff will increase buy-in and produce better SOPs. The process creates teamwork among workers and managers. In the preparatory phase, it is important to identify one individual within the organization with the skills and expertise in the particular area to lead the development process. Then select other people to form a team to support this individual to prepare the SOP. And ensure support from management.

INFORMATION GATHERING PHASE

Identify and prioritize an area for SOP development. For an activity to become the topic of an SOP, it must be either subject to regulations or it must address an important task within quality control systems or between quality systems and other functional units. SOPs can be established for every task within the pharmacy. SOPs should be made to cover different functions that are carried out in a pharmacy, and following legal & ethical procedures should always be kept in mind while writing and following the SOPs.

A needs assessment should be done to:

- Evaluate existing systems to determine what is happening and/or not happening;
- Evaluate existing systems to understand who does what;
- Help identifying gaps in practices and resources;
- Help in prioritization of SOPs & target setting.

So where should one start? One should start by gathering existing SOPs that cover the areas from the hospital and from your department. Analyze what you have, and where the gaps are. Then start editing existing SOPs and creating additional SOPs for the needed areas.

In prioritizing, you are looking for areas where there are bottlenecks (these are processes in a system that limits performance). Where do you have a lot of delays in the system? Delays imply you are not utilizing efficiently the resources available to you. Are there steps and decisions that can be standardized? And finally are there tasks that can be improved? Once you know all this you can select an operation for SOP.

WRITING SOPs

Standard operating procedures are instructions that should be understandable to everyone who uses them. Procedure writers must use short, direct sentences so readers can quickly understand and memorize the steps in the procedure. Information should be conveyed clearly and explicitly to remove any doubt as to what is required.

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:

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

STEPS 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 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.

TABLE 1 ADVANTAGES AND DISADVANTAGES OF THE SIMPLE STEP FORMAT FOR SOPs

Advantages of simple steps	Disadvantages of simple steps
Easy to write.	Lack of detail.
Easy to follow.	Tends to get long if detail is included.
Logical flow.	Keeps all steps at same level.
	Does not handle decisions well.

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.

TABLE 2 ADVANTAGES AND DISADVANTAGES OF THE HIERARCHICAL STEP FORMAT FOR SOPS

Advantages of hierarchical steps	Disadvantages of hierarchical steps
Easy to write. Easy to follow. Logical flow. Handles details very well. Allows different levels of steps.	Does not handle decisions 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.



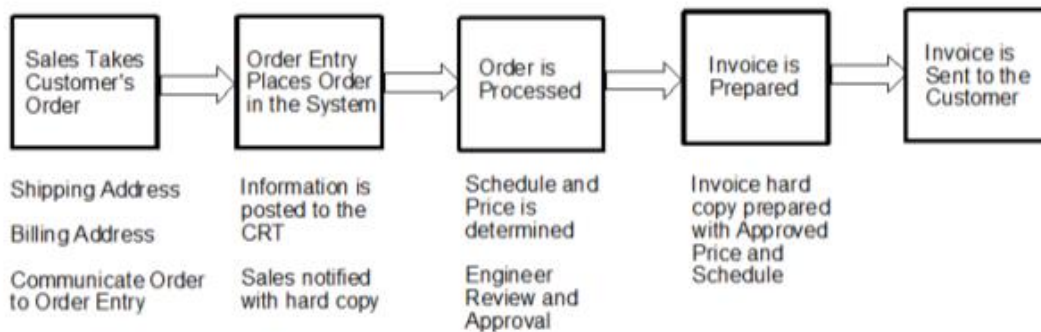
GRAPHIC FORMAT

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.

TABLE 3 ADVANTAGES AND DISADVANTAGES OF THE GRAPHIC FORMAT FOR SOPs

Advantages of graphic format	Disadvantages of graphic format
Easy to write. Easy to follow. Logical flow. Handles long procedures well.	Does not handle decisions well.

FIGURE 2 GRAPHIC FORMAT EXAMPLE:



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.

TABLE 4 ADVANTAGES AND DISADVANTAGES OF THE FLOWCHART FORMAT FOR SOPs

Advantages of flowchart format	Disadvantages of flowchart format
Easy to follow. Logical flow. Handles decisions very well.	More difficult to write Does not handle decisions well.

Flowchart example

See worksheet 29_4_3 for an example of a flow chart.

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.

The people who will use the format: If they are visual learners, perhaps a series of pictures or a flow chart will work best. Physical limitations, such as poor eyesight, may necessitate large clear print or big bright pictures and plenty of light such as the Annotated format.

How the SOP will be used: Depending on the intended use at the time, the SOP may be written or presented differently to be more effective.

- As a reference manual - more explanatory detail.
- Used for basic training - less detail may be desirable.
- Used for in-depth follow-up training or retraining - more detail useful.
- As an on-the-job reminder - less detailed overview that is readily accessible.

TABLE 5 THE BEST FORMAT FOR A SOP

Many decisions?	More than 10 steps?	Best SOP format
No	No	Simple steps
No	Yes	Hierarchical or Graphic
Yes	No	Flowchart
Yes	Yes	Flowchart

Making effective and active use of SOPs

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 of compliance monitoring;
- Monitor compliance of SOPs.

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.

IMPLEMENTATION OF SOP

The following are steps involved during successful 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 draft. This gives a basis for discussion and reduces 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 unfamiliar 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.

USE OF SOPS FOR TRAINING

SOPs are useful tools for training staff. The training can be associated with understanding the way of implementing certain tasks. Or used as a reference for knowledge updating. The staff members can either learn how to do a particular activity or can update their knowledge on certain aspects of a particular task. When using the same SOP in basic training, the SOP has less details. New trainees might be overwhelmed by large amounts of detail. For in-depth follow-up training or retraining, the SOP will contain more detail and background information explaining why certain things are done or the biology behind certain practices. The same SOP used as an on-the-job reminder should be readily accessible at the work site, easy to see, and quick to review and understand.

HOW CAN SOPs BE USED TO TRAIN STAFF?

Having complete step-by-step instructions helps trainers ensure that nothing is missed and provides a reference resource for trainees. For employees filling in on jobs (e.g. locum staff) they do not perform on a regular basis, an SOP can be an excellent reference document on how a task is done. All pharmacy staff should have a certain level of competency. This requires training to improve knowledge and skills of the staff. This results in quality services to the patients. Introductory training should also be done for new members of staff. Ongoing training is required to maintain the improved standards of staff. A training needs analysis can be carried out to establish the areas where pharmacy staff require training using existing SOPs. This training can then be implemented using SOPs for each particular area.

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.

Question: Where would you place the following SOPs?

- Dispensing to out-patients.





- Receiving medicines.

Answer: For dispensing the SOP can be pinned near the dispensing window or basically any where within the dispensing area. For receiving medicines the SOP can be placed in the store near the quarantine area.

COMPLIANCE MONITORING

It is important to monitor the compliance with SOPs, otherwise the development and implementation of SOPs was useless. It is crucial that everybody involved in a certain process is compliant to the SOPs. This means first all staff should use the SOP when performing a certain task. And secondly they should be able to adhere to the procedures as described in the SOP.

Monitoring compliance can be done by monitoring if the SOP is being used, reviewing the SOP and evaluating to find out if SOP is contributing to improved service delivery.

MONITORING IF THE SOP IS BEING USED

Periodic review of staff activities can be done as part of support supervision. All staff should be able to perform all the essential steps in the same way.

PERIODIC REVIEW OF THE SOP

SOPs must be current, relevant and guided by good practices. Scheduled review dates should be included in each SOP.

NEED TO EVALUATE IF SOP IS CONTRIBUTING TO IMPROVED SERVICE DELIVERY

Records can be checked to see whether they are completed properly. Findings of the monitoring exercise should be recorded. Corrective actions should be performed as it may be needed. This can be by organising regular feedback meetings with concerned staff to find out how useful they find the SOPs and where changes are needed or by retraining the staff.

PROCEDURAL DRIFT

If the SOP is not complied to, it could be due to procedural drift which is often caused by lack of buy-in or lack of feedback. Therefore it is critical to get buy-in from staff and encourage everyone to take “ownership” of procedures. Another reason of procedural drift is that the SOP itself maybe at fault. The user might have found a much superior way of doing the task, than the one described in the SOP.

If the cause lies with the SOP, this may be a signal for the SOP to be revised and updated accordingly, since continuous deviation in implementation is not acceptable. It is critical to set up a monitoring system and keep it going. It is important to assign responsibility for collecting information and providing feedback.

CONCLUSION

- Plan SOPs for specific results;
- Use an inclusive process, everyone really needs to buy in to them;
- Monitor performance and provide feedback to everyone;
- Create a “culture of continuous improvement”.

This file is a chapter of the Handbook for Pharmaceutical Practice EPP

Contact EPN for more information materials or the full Handbook on Pharmaceutical Practice

