

Procedures

Improving Their Quality

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Procedures are essential for any plant's effectiveness and efficiency, and they are a regulatory requirement in the pharmaceutical industry. Although significant resources are spent on procedures, their quality is generally poor and the procedures system is not well designed or well managed. Procedures frequently are not clear, simple, accurate, or user friendly. This article offers suggestions for improving procedure quality and procedure system effectiveness and efficiency.

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Standard operating procedures (SOPs) are essential for any plant's effectiveness and efficiency. In pharmaceutical plants they are also a regulatory requirement. Thus, the expenditure of significant resources on procedures is not uncommon. A Parenteral Drug Association (PDA) survey found that a typical pharmaceutical company must manage an average of 1250 CGMP-required SOPs and that the average maintenance burden is 15,000 h per firm (1). Document management can amount to an estimated 10–15% of total operational costs (2). Given the importance of procedures, their costs, and how prominently they figure in CGMPs, one would expect that the quality of the procedures and of the procedures system would be good. Having evaluated procedures and their systems throughout the years, however, I have concluded that this is not the case. In general, procedures are not clear, simple, accurate, or user friendly, and their systems are not well designed or well managed. This article offers suggestions for improving procedure quality and procedure system effectiveness and efficiency.

Purpose of procedures

Procedures provide information about how to perform tasks safely, efficiently, and effectively. They describe processes and the important steps in the processes, and they help workers remember how to perform their tasks. They should describe the best practice that results from an organization's ongoing learning. Procedures also are used to help train employees.

Procedures are not an end in themselves—they do not guarantee good performance or results. More important are well-designed systems and processes, qualified employees, and a motivating company culture. Procedures support process-people-environment but do not create good processes, qualified people, or a good working environment. Performance problems are more likely to result from poor processes and systems than from the existence or not of a procedure.

Two types of procedures can be identified: those that are product specific such as manufacturing instructions and analytical test methods, and SOPs that are general in nature and apply to all products. The other class of documentation is called a *record*. A record provides information about how a task was actually performed; it provides history. The remainder of this article will focus mainly on SOPs, although many of the ideas discussed can be applied to product-specific procedures and records.

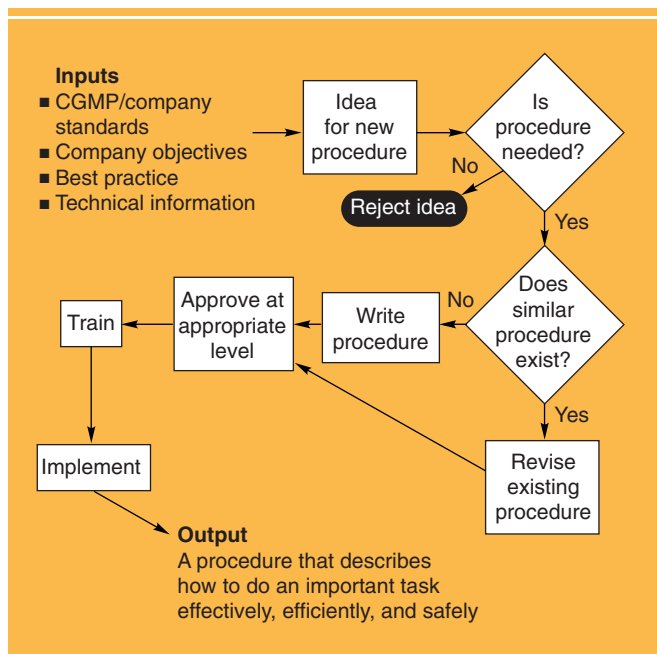


Figure 1: Procedures process.

Users' procedures survey

1. Strongly disagree 2. Disagree 3. Somewhat agree 4. Agree 5. Strongly agree

Procedures accurately describe the work I do. _____
 I can easily read and understand my procedures. _____
 I can easily access the procedures I need. _____
 I can easily and rapidly get procedures changed. _____

Quality of procedures

I have never seen an SOP about SOPs that describes the quality specifications of a procedure. Instead, this procedure usually confines itself to requirements for format, approval, distribution, and control. Most SOPs are too complex, too long, and too poorly written to be truly useful to the person whose task they presumably describe. As an auditor I frequently find it impossible to clearly determine what a person is supposed to do after reading an SOP. Procedures should be written for the user, and that person decides whether the procedure is good, helpful, and intelligible. The sidebar, "Users' procedures survey," is an example of a user survey that can indicate whether or not a user is satisfied with procedures.

A good procedure

- describes the purpose of the process or activity. Frequently one finds a statement such as "The purpose/objective of this procedure is to establish a procedure to [here the title is repeated]." For example, a change-control procedure rarely tells the reader why change control is important and what one is trying to achieve in the change-control process.
- emphasizes critical steps and does not contain trivia, unimportant details, or fundamental information that the user is certified as knowing from experience or training
- defines responsibilities
- lists activities sequentially. The core of a good procedure can be a process flow diagram.

- gives guidance in case of a problem and clearly defines decision points
- is simply written, preferably by the users. At a minimum, it is validated by the users. This validation can be completed during the training session or on the job.
- is concise, ideally 3–4 pages long. The likelihood of reading, remembering, and complying decreases with the number of pages. As Albert Einstein once said, "If you can't say it simply, you probably don't understand it."
- is simple and should be written for 6th- to 8th-grade readability
- makes liberal use of visual aids such as flow diagrams, photos, drawings, and color. A picture is worth a thousand words. A chart that is appropriately numbered and controlled could be considered a procedure.
- includes forms that ideally are self explanatory.

Procedures process

Figure 1 shows a possible procedures process. The output of the procedures process is a user-friendly document that describes how to perform all critical activities effectively, efficiently, and safely. The inputs to the process are regulatory and company standards, company objectives, benchmarked best practice, and technical information related to the task.

A process owner is an essential component in the procedures process. The process owner is responsible for

- the design and implementation of the process
- training all personnel in the process' use
- ensuring compliance with process requirements
- ensuring that only necessary procedures and procedures meeting the required quality specifications get into the system
- continuously improving the process
- measuring process performance
- reporting performance results to management.

Some possible measures of process performance are

- cost
- number of procedures
- currentness of procedures
- cycle time for procedures' approval
- correct the first time: procedures written and validated to meet the quality requirements the first time
- customer–user satisfaction survey.

For more information about measuring procedure process performance, see Reference 3.

The remainder of this article discusses some of the problems I frequently note while auditing this process. For more information about process audits, see Reference 4.

When is an SOP needed?

A plant that has too-few written procedures is rare today—too many SOP systems contain too many. This problem reduces compliance with written procedures and increases cost. Of course the plant with too many procedures does not necessarily have all the ones it truly needs. Most SOPs that describe the requirements of an SOP system do not offer guidance about when an SOP is needed. Furthermore, often no gatekeeper (i.e., the system/process owner) exists who has the responsibility

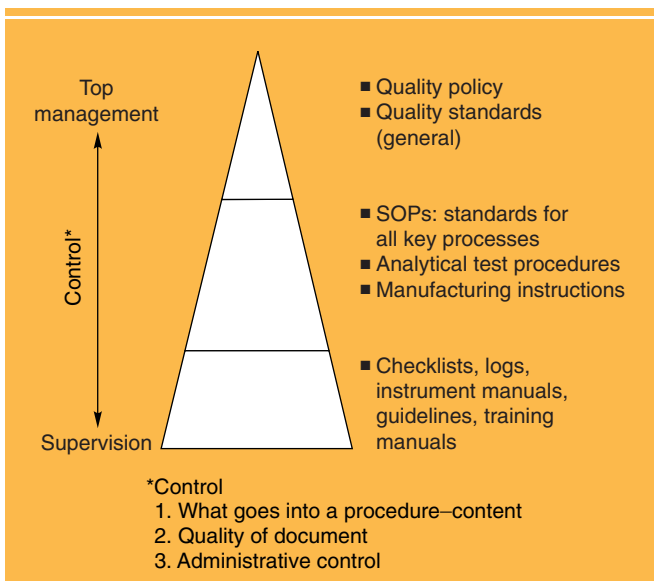


Figure 2: Procedures system control levels.

Some key quality processes

Audits	Product transfer
Change control	Quality planning
Failure investigation	Stability
Labeling	Supplier certification
Materials management	Testing methods
New-product introduction	Third-party contractors
Planning	Training
Product-quality performance	Validation
Product release	

to cull obsolete SOPs and keep unnecessary ones out of the system.

When is an SOP needed? is a difficult question to answer. An equally difficult question is, How much detail should be included in an SOP? Some unacceptable responses include “When in doubt write a procedure,” “Include everything,” and “More is better.” These solutions reduce the value and usefulness of SOPs, reduce compliance, and increase cost.

Commenting about when an SOP is needed, De Sain and Sutton state that “the consistency of operations must be ensured for all activities that directly affect the product or the decisions about product quality. ... The level of detail required in a procedure is affected directly by the level of expertise of the individuals performing the work and the rigor of training associated with the task” (5). Dunford quotes the ISO 9000 standard: “The range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work ... and the skills and training needed by personnel involved in carrying out the activity” (6).

Consistent with these authors, the key to solving the problem of too many procedures and their excessive length is to emphasize training. As personnel qualification improves, the quantity of SOPs and the detail in them can be decreased. This approach will produce better performance.

Leaving something important out of an SOP is always a risk. However, the risk is probably less than that associated with thousands of pages that are difficult to read, understand, and follow

and that make it nearly impossible to separate the important points from the trivial. In general, reducing SOPs by one-third and the total number of pages by one-half as well as reallocating expenditure to effective training would dramatically improve performance.

The procedures process owner must ensure that no SOP is accepted into the system unless it can be proven to meet clearly defined needs and criteria. Is the SOP absolutely necessary? Are all sections and parts needed?

Approvals

Approval is another typical challenge in the procedures process. A drawn-out approval process can negatively affect the correctness of procedures, user satisfaction, and cost. Not all procedures are equally important, and the approval step and the change-control process must acknowledge this distinction. Qualified users should be able to change lower-level procedures without upper-management approval and with minimum administrative bureaucracy. High-level approval and QA direct control should exist for only the relatively small number of very critical procedures. These critical procedures describe policy and set standards for key quality processes. In general they include how the plant will comply with the basic requirements of CGMPs and company standards. Probably no more than 100 of these top-level standard-setting SOPs are needed. The total system and procedures at all levels should be audited periodically by QA. Making these distinctions about the level of criticality and control of procedures enables the plant to empower employees within limits defined by the high level SOPs and to foster continuous improvement with minimum control.

The Quality Manual concept in ISO 9000 provides a good model for constructing this type of system. Figure 2 shows a three-level example of this system. The number of levels is arbitrary—more important is determining what type of information is assigned to each level and how the content, quality, and distribution of each document are controlled. The level of control should be related to the degree of risk.

Although regulatory bodies expect all procedures to be reviewed and approved by QA, the CGMP preamble in fact states that “the Commissioner intends to make the quality control unit responsible for ensuring that controls are implemented during manufacturing operations which ensure drug product quality, not that the quality control unit actually perform each one of the duties” (7). This concept is sensible—the quality unit could exercise its responsibilities for the correctness of all SOPs by means of training and audits while directly controlling/approving only the most critical SOPs.

The author recognizes that the comments in this section are controversial. Regulators today expect that the quality unit approve all procedures affecting the identity, strength, quality, and purity of a drug product.

Organization of SOPs

Procedures are normally organized by department and sometimes by CGMP chapter. The best way to organize procedures is by means of key processes/systems. Procedures define the best

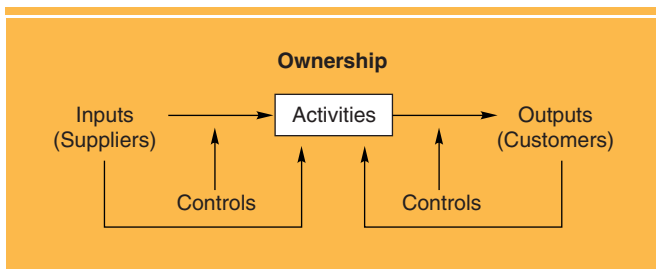


Figure 3: Process model.

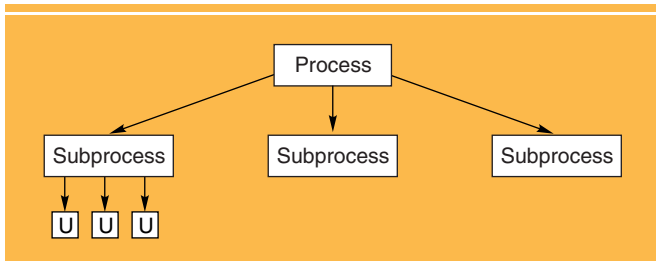


Figure 4: Procedure system model.

way to perform the activities in a process so as to achieve the desired output. Figure 3 shows the basic model of a process. Work gets done by process, and product or output quality is determined by process quality. The sidebar, "Some key quality processes," lists some of the most important CGMP-related processes. Factors are deemed critical depending on the process.

The sidebar, "Organization of procedures by process," shows how the recommended structure starts with a master, high-level controlled SOP that describes the process and its key steps or variables. The purpose describes what must be achieved by this process and what is an acceptable output. This master is supplemented with a few "daughter" or subprocess procedures, also high-level procedures that define in more detail the requirements for the key steps in the process. Figure 4 shows how the department or unit-specific procedures could fit into this structure.

The advantages of this type of SOP organization are that

- it is consistent with a system/process approach to quality
- it integrates activities cross-functionally
- it facilitates the establishment of approval levels
- it reduces the likelihood of duplication and contradictions
- it is aligned with the concept of process ownership.

Management of the SOP system

Generally, administrative aspects of the SOP system such as distribution and filing are well managed. On the other hand, overall system management, frequently characterized by the lack of a system owner, is generally poor. If a system owner exists at all, his or her responsibilities are limited. Ideally a system owner

- eliminates redundancies in the system
- eliminates obsolete SOPs
- ensures that SOPs meet their quality requirements and are user friendly
- manages SOP change controls
- distributes SOPs
- ensures that SOPs are current
- ensures that new or changed SOPs are valid only after training has occurred
- provides training about the SOP system
- measures system performance and periodically reports results to management
- continuously improves the system.

Procedures audit

Management frequently complains that employees are not following procedures, a stance that implies that the procedures problem is with the workers. However, I have noted that more than 90% of the problem is with the procedure system itself, for which management is responsible. An audit to determine why procedures are not consistently complied with would include the following questions:

- Does a procedure exist that covers the noncompliance in question?
- Is it a good procedure; i.e., does it comply with the requirements previously described in this article?
- Was the employee trained in the use of this procedure? Was the training well designed and effective?
- Did other extenuating circumstances exist such as insufficient time; an unavailable but essential resource, tool, or material; supervision that indicated compliance was not important?
- If a procedure was in place and it was clear, the training was adequate and timely, and no other excuses such as human error or not paying attention explained why the procedure

was not followed, could the process described in the procedure be made more fail safe?

To reiterate, most often the problem is not with the individual but with the system. Telling the employee to be more careful will not solve the problem. Improving the process involved and the procedure that describes the process is the only solution.

Conclusion

Given that SOPs are so important and that they consume so much resource, a system may nevertheless work poorly because

- no overall system owner exists who has requisite skills to manage the procedures system
- procedures are seen as a regulatory requirement and a necessary evil; they are not written for the user

Organization of procedures by process

Master SOP (for each key process)

- Purpose
- Flow chart (key elements or subprocesses, decision paths)
- Definitions
- Required explanations.

Supplementary "daughter" SOPs (for each key element or subprocess)

- Purpose
- Flow chart (key elements or subprocesses, decision paths)
- Definitions
- Required explanations.

- defined criteria about what constitutes a good procedure are lacking, and no control exists for the quality of the procedure
- the staff does not include an overall system owner with the requisite skills to manage the procedures system.

As with all systems, the procedures system must be well designed and managed to be effective and efficient. I have suggested several improvements to the procedures system in this article. What do you think?

Recommended reading

The book, *The Practical Guide to People-Friendly Documentation* by A. Escoe (3), is useful and stimulating. I recommend it to readers who are charged with improving procedures systems.

References

1. PDA Letter, May 1999.
2. D. Gingell, *Pharm. Technol. Europe* (4), 2001.
3. A. Escoe, "The Practical Guide to People-Friendly Documentation," (ASQ Quality Press, Milwaukee, WI, 2001) pp. 99–114.
4. J. Nally, R.G. Kieffer, and J. Stoker, "From Audit to Process Assessment—The More Effective Approach," *Pharm. Technol.* **19** (9), 128–140 (1995).
5. C. De Sain and C.V. Sutton, "Standard Operating Procedures: Content, Format, and Management," *Pharm. Technol.* **20** (10), 110–116, 1996.
6. T. Dunford, "Taking the Myth Out of Documenting Work Instructions," *Quality Progress* (12), 1998.
7. CGMP Preamble, *Federal Register* **43** (190), p. 45033 (29 September, 1978). **PT**