Writing Procedures That Contribute to Performance

By James L. Vesper

When writing procedures consider:

- **The company's style guide**

- **Experience and characteristics of the procedure's users**

- **The type of task, e.g, administrative, cognitive, decision-making**

- **Where the procedure is needed**

- **Scope**

- **Level of detail**

- **Use of words, e.g., active, difficulty**

- **Bullet points**

- **Subject-matter experts**

James L. Vesper *is executive producer of pharma programs for Learnwright, LLC, and also founder and president of LearningPlus, Inc., 1140 Highland Avenue, Rochester, NY 14620, 585.442.0170, fax 585.442.0177*

Even a very fast reading of the GMPs for the United States, Canada, and the European Union will reveal a phrase that is repeated over and over: "There shall be procedures for…" Having and using documented procedures is a way of life in pharmaceutical and biological companies.

We all know why procedures (or standard operating procedures, SOPs) are important. They define how a task is to be performed to achieve a specified outcome, standardize the way a task is to be performed so as to minimize variation, form the basis for training the task performers, provide an informational tool that supports the performers, and, of course, to fulfill a regulatory (GMP) requirement.

Anyone spending even a short amount of time in our industry knows some of the difficulties involved with SOPs. They change frequently, are not always followed, take too long to review and approve, are inconsistent and slightly different from department to department, are not written for end users, are not detailed enough or are too detailed, don't match how the job is really done, and (the list continues). Procedures are more than simply functional documents that define a task or tell what to do or how to do it. Procedures are the results of a process that includes generation, review, approval, implementation, distribution, maintenance, and control. Most of the procedural difficulties listed above have their roots in activities that are inadequate or improperly controlled.

Before you write your first SOP, you need to plan carefully what your company's procedures will look like and how they are to be written. That "style guide" covers more than just the appearance of the procedure; it needs to include the points discussed here. Once these issues are resolved and agreed on, the generating, reviewing, and approving of a procedure will go much faster. Additionally, the resulting SOPs will be easier to use in training and will contribute to better, more consistent performance. This article focuses on the writing of procedures. A future article will discuss training on SOPs and assessing the user's knowledge and performance of proceduralized tasks.

Before Writing

Before writing your first SOP,

you need to consider what procedures are needed, what procedures have already been written, the experience and characteristics of the users (the "performers"), the type and amount of training intended, and how the SOPs will be used in "real life."

Choose the type of procedure. SOPs are of three main types: administrative tasks (rules or rule-based, such as who has permission to enter a particular area); cognitive tasks (a decision-making activity, for instance, reviewing laboratory notebooks); and motor tasks (such as setting up a fermentor). These distinctions have some overlap.

Determine where a procedure is needed. To determine where an SOP is needed, create a flow chart of an operational area and identify the processes involved and the tasks within those processes. Those tasks become your initial list of procedure titles. The SOPs you write will define how those tasks are to be performed. If procedures already exist, they can be mapped against the listed tasks. Comparing flow charts or titles of different areas can show where common procedures are or could be used to aid in standardization.

Sometimes people will ask whether an SOP is required. When I'm asked that, I respond by asking them several questions: Is the task or activity important? Is more than one person involved? Does the task or process affect the safety,

identity, strength, purity, or quality of the product? Does the task need to be done consistently? If the response to any of those questions is "yes," I recommend that a procedure be written.

Determine the scope of the SOP. Another frequently asked question is "How long should a procedure be?" What that question usually means is, "How broad should the procedure be?" In part, that depends on whether a procedure describes a process with many tasks (performed by various people in different departments) or whether the procedure defines one task and the steps needed to accomplish that task. Sometimes, companies use more specific types of functional documents called *work instructions* to provide details on how one person accomplishes his or her job. Although some companies distinguish between SOPs and work instructions, others do not. Whatever such functional documents are called, they need to be well constructed to support actual performance.

Large companies generally have a hierarchy of procedures that follow from corporate policies. As the procedures get more localized, they are more focused on how a department or area operates. For example, one large multinational company has the following policies and procedures that go from general to more specific:

Corporate Quality Policy: Sterility Assurance (Level 1),

Corporate Procedure: Use of

Media Fills in Aseptic Drug Product Filling (Worldwide) (Level 2), and,

Site Procedure: Use of Media Fills for Parenteral Products Aseptic Processing Validation (Level 3).

Industry practices and preferences differ, but a good practice is to have procedures covering the related tasks that one person (or one team) does at a particular time. For example, for a given piece of equipment, the related tasks could include set-up, operation, disassembly, cleaning, troubleshooting, preventative maintenance, and calibration.

You can write an individual SOP for each task or one procedure covering all the tasks. A better choice would be to group into one procedure those tasks that are done by one team or individual during "normal" operations (for example, set-up, operation, disassembly, and cleaning). The other tasks (troubleshooting, preventative maintenance, and calibration) would be separate SOPs. No right or wrong way exists for procedures: Smaller, shorter procedures are easier to develop and maintain, but you end up with more of them. From a user's point of view, several two- to six-page procedures are less intimidating than one 30-page document.

Identify who will use the procedure. *Primary users* are those who actually perform the tasks defined; *secondary audiences* are those who may need to know something about the

procedure but do not directly use it. Who are your primary users? Are they experienced? Is your work force stable in its turnover and hiring? What is the reading level of work personnel in the language in which the SOPs will be written? How will staff actually use the document? Will workers have the procedure open in their work areas (the expected practice with laboratory methods), or will they use it only as a reference? How frequently will users perform the task? How much training will they be given? Your answers to these questions will shape the amount of detail contained in your procedure.

Decide on a level of detail. A major decision to make before writing any SOP (or before revising a procedure system) is defining the level of detail that should be met. The "Levels of Detail" sidebar provides examples of differing amounts of detail in driving from New York's LaGuardia Airport to a hotel in Park Ridge, NJ. The "Appropriate Level of of Detail" box suggests when less or more detail may be appropriate.

The minimum amount of detail in a procedure should include the "critical whats" (the required steps defining what is to happen), the "critical hows" (the substeps defining how each step is to be performed), and when applicable, the "whos" (that is, who performs those steps and substeps) if more than one person is involved. *Criticality* is defined as that which is necessary for a performer to be successful in accomplishing the

goal of the procedure. In part, criticality depends on the performer's training, experience, and education. As the detail level increases (along with the length of the document), the definition of criticality widens. For SOPs with "high" and "fine" levels of detail, less critical "hows" are included.

Hazards exist in using high or fine levels of detail: Such procedures can be hard to read and follow. Also, they can be unforgiving: If one of the very fine details changes, the procedure is technically wrong. Therefore, the challenge is to create a useful document that defines the process or task only to the necessary

---

Appropriate Level of Detail

A higher level of detail is called for when:
- Task is infrequently performed
- Many different people are involved
- Little variation in performance can be allowed
- Task is critical
- Training is not comprehensive
- Little time to practice

Examples of detail levels:

Gross
Drive from LaGuardia (LGA) Airport to Park Ridge Marriott.

Low
Drive from LaGuardia (LGA) to Park Ridge Marriott
1. LGA to Garden State Pkway.
2. Take GSP Exit #172
3. Follow Mercedes Rd to Marriott.

Medium
Drive from LaGuardia to Park Ridge Marriott
1. Follow Grand Central Pkwy to Triborough Bridge to George Washington Bridge.
2. Take GWB to 80W
3. Take 80W to Garden State Pkway
4. Taken GSP to exit 172…

High
Drive from LaGuardia to Park Ridge Marriott
1. Follow Grand Central Pkwy to Triborough Bridge
2. Use lanes for Major Deegan Expressway.
3. Take George Washington Bridge to NJ
4. Once across GWB, find route 80W
5. Take 80W to Garden State Pkway
6. Taken GSP North to exit 172, Park Ridge/Montvale (last NJ exit)
7. Take first right to Mercedes Blvd
8. Take next right to Brae Blvd (look for sign on left)

---

level of standardization.

Not all the SOPs throughout your company need the same level of detail; it is reasonable to write to the needs of the users. Different sites or departments may have different needs. (Companies that write work instructions typically focus on a particular task and the particular person (or job position) responsible for that task.)

Use the SOP for training. Elements of a procedure that help with training include the SOP's purpose and its scope. The purpose can be equated to the goal of a training event: The scope (where and to whom the procedure applies) is useful in identifying those who need to be trained.

Assess the users' reading ability. Although some companies have examined the reading levels of their work force, many have no idea. In lieu of data, a rough guide is to write procedures used in operational areas to a 7th-grade level and those used by professional staff to a 10th- to 12th-grade level. In some areas, however, such as Toronto, Miami, or Puerto Rico, it may be important to write at a simpler level because of the population's diversity and the number of people having primary languages other than English (such as Hindi, Chinese, French, Russian, or Spanish).

Microsoft Word has built-in readability testing tools (such as the Flesch-Kincaid grade-level score) that can provide a rough idea of a document's readability. The Flesch-Kincaid reading grade level for this article up to this point is 10th grade. For comparison, *The Wall Street Journal* is written at approximately a 12th-grade level, and *USA Today* is written at a 6th- to 7th-grade level. Short sentences, words with few syllables, and short paragraphs all contribute to more readable procedures.

Define the description format. One last item to consider before beginning to write is your definition of what the procedural description is to look like (the "guts" of the procedure). The most frequently seen format is the outline. Headings may be labeled A, B, C; 1, 2, 3; or with Roman numerals I, II, III. After that, indentations are used (for example, 1.2.1). If that format is used, don't use too many levels of indentation. (I once saw one that had seven levels: 4.2.2.1.2.1.3.)

Generating a Procedure

With the preliminaries completed, you know which processes or tasks need to be defined by SOPs and for whom they are intended, the level of detail needed, and the format to be used. You are ready to begin writing. Sitting in front of a fresh piece of paper or before a blank computer screen is intimidating. Where you do start? As Sholem Asch (one of the best-known Yiddish authors of the first half of the twentieth century) said, "Writing comes more easily if you have something to say."

Draw a procedural sketch. Before I start writing a proce-dure, I create a sketch that includes a simple flow chart, a telegraphic description of what is done at each step, the critical hows, when the step is per-formed (the "cue"), any specifications that need to be met, and any warnings, cautions, or other notes. From that sketch, I can easily write a procedure using the "official" template. An advantage gained by creating a procedural sketch is that the sketch can be done by those most familiar with the process or task - the subject matter experts (SMEs) - who may be intimidated if asked to write a procedure. Once the sketch is completed, a more skilled writer can easily and quickly write the procedure.

Use active words. A style issue comes into play when you are writing the SOP: How many words do you use? Narrative statements - with lots of words - can be difficult to work with. Actions or requirements are typically buried in such statements. Also, when it comes time for review and approval, more words provide more grist for people to argue over. Writing in a clear, active tense is best. "Telegraphic" wording structures are useful. Most writers are familiar with the rule of thumb that suggests using active verbs to begin sentences (for example, "Disassemble the spray head"). Studies have shown that when we read, we look at the first several words, skip over the middle, look for the period mark, and then, going backward from the period, read the last

three to four words in the sentence. That means we are usually a little lazy in our reading. But procedure writers use that to their advantage: They put the important information at the start or at the end of statements.

Use ranges whenever possible. For example: "Adjust pH to a target of 7.5 (7.0 to 7.8)," noting the allowable range in parentheses to reduce deviations. If ranges are used, be sure that they are consistent with the registrations, approvals, and validation studies.

Give SOP users sequence flexibility. When it is appropriate, use bullet points (?) instead of numbers or letters. Numbers or letters indicate that a sequence is being defined and that the steps must be performed in that order. Bullet points indicate the absence of hierarchy or sequence. An alternative is to put a note above the numbered or bulleted steps ("Note: the following five steps can be performed in any sequence").

Once the draft procedure is written, and before it goes into the official review phase, SMEs should examine it carefully. Sometimes people in other industries call that "validating" the draft procedure, but to us in the pharmaceutical industry, it is a much less rigorous task. It can be as simple as showing it to others who perform the task or talking through the steps in a small group of three or four people. The goal is to be sure the draft document is complete, correct, and "doable." Such steps make the formal review phase faster.

Review and Approval

When a draft procedure emerges from the generation phase, it is ready for review - typically two types of review. In *inspection reviews,* someone (it doesn't have to be a content expert) looks at the draft document to be sure it looks right; that is, that it has a unique title and number, all the pages and attachments are present, and the like. Next comes the *content review,* which does require expertise or a specific knowledge base. This would include the quality assurance, validation, and regulatory affairs departments and other departments as appropriate. A key to rapid, effective reviews is to make sure all reviewers know the style and level of detail required and also know the specific things to look for during their review. Having those criteria assigned (perhaps in your "Procedure on Procedures") minimizes the chance that something will fall through the cracks or that everyone will be a wordsmith. (Also, if the SOP was written in a telegraphic fashion using fewer words, fewer words will be worked over.)

Implementation. Before the effective date of a procedure, it needs to be communicated to, and training provided for, those who will use it. Because that is another large topic, I will cover implementation in a forthcoming article.

This article originally appeared in BioPharm Magazine. It is reprinted with permission of Advanstar. For more information about BioPharm and other products and services of Advanstar please go to www.biopharm-mag.com.