CHAPTER FIVE

Standard Operating Procedures (SOPs)

The act of performing clinical trials is a complicated business. It is bound by regulations and good clinical practice, with the overriding concern to protect the safety and welfare of study subjects. Sites must follow each protocol exactly and meet other sponsor demands. One of the best ways to ensure that all conditions are met is to formulate and follow Standard Operating Procedures (SOPs). SOPs are just that: the "procedures" and processes that you use and "operate" under that have been "standardized" to ensure that you perform them the same way each time. An SOP is nothing more than a clearly written description of how a particular task is to be performed.

SOPs are critical tools for successful business operations for all those involved in conducting clinical trials, to include investigative sites, sponsors and IRBs. They are essential for standardizing processes, ensuring that regulatory and organizational policy requirements are met, training new personnel and managing workload. This chapter covers the importance and value of SOPs, as well as present an approach for the development of SOPs at your investigative site.

Regulations do not require that investigative sites have SOPs. However, the regulations do state that "A sponsor shall select only investigators qualified by training and experience" (21 CFR 312.53) and that "[The investigator] will ensure that all [staff] are informed about their obligations" (21CFR312.53). This means investigators must be qualified to conduct trials, as well as be qualified in the disease area. It also means that investigators must ensure that all others assisting in trials are knowledgeable about the obligations and responsibilities. One of the best ways to ensure this is to have SOPs that cover clinical trial procedures and responsibilities. If the FDA audits a site, it will expect to see written procedures, and have them followed.

SOPs have several purposes. They ensure that the site has consistent processes that meet or exceed regulatory and good clinical practice (GCP) standards, and that all employees are familiar with these processes. They also ensure that processes are reviewed and updated on a regular basis. Having and adhering to good SOPs helps to ensure that audits by sponsors or by the

FAQ

If SOPs are not required by regulation, why should we bother with them?

Your site will be better prepared to conduct studies well, your processes will be consistent and you will look much more professional. Most sponsors (and the FDA) will expect a site that consistently conducts clinical trials to have SOPs.

FDA do not result in detrimental findings, and may also afford the site some legal protection.

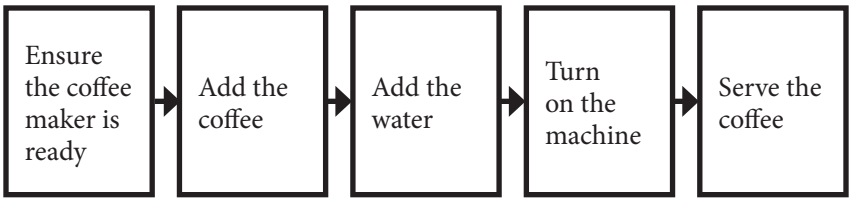
Writing SOPs

Writing SOPs is not an easy process. It is very time-consuming and involves analysis of processes. However, it pays big dividends when complete. There are many ways to approach the formulation of SOPs. One that has been used successfully by many organizations is described below.

Step 1. Map Your Process

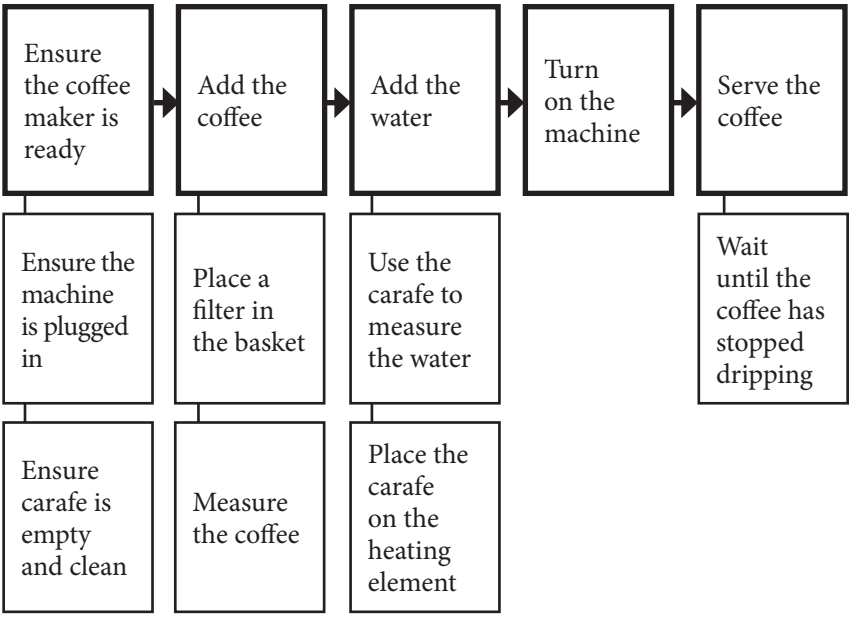
Process mapping is a procedure of laying out all of the steps in a process currently being used and analyzing the process with the goal of making it more efficient and easier to follow. It involves taking each step in the process and "mapping" it into a process chart. All the people involved in carrying out the task should be involved in mapping it into a process chart, and there should be free and open discussion while doing so. It is often discovered during this process that all involved people do not do things the same way, and have very different ideas about how the current process works and how it should be done in the future.

You will want to map the steps of your process into a flow diagram, with the primary and secondary steps shown. For example, if you were to map the process for making a cup of coffee, the primary steps might be:



Adding the secondary steps to the flow chart might result in a process that looks like the figure on the next page.

A convenient way to process map is to put a large, long sheet of paper on the wall (tablecloth paper) and write the steps on large (3" by 5") sticky notes.



This conveniently allows you to move them around easily as you are mapping.

Once you have the process mapped, you can add those responsible for each step to your map. It's easy to use the small sticky notes in several colors, with a different color representing each person/position you add.

When you have finished mapping, convert your process map to an outline in anticipation of the creation of SOPs. The outlines become the building blocks for your SOPs. The outline for the process we mapped above might look like this:

1. Ensure the coffee maker is ready.
    a. Plug in the machine.
    b. Be sure the carafe is clean and empty.
2. Add the coffee.
    a. Place a filter in the receptacle.
    b. Measure the coffee.
3. Add the water.
    a. Use the carafe to measure the water.
    b. Place the carafe on the heating element.
4. Turn on the machine.
5. Serve the coffee.
    a. Wait until the coffee has stopped dripping.