

GMP Training Systems, Inc.

Creators of the GMP Ready-to-Use Training System™

Good Written Procedures = Compliance

**David C. Markovitz
President, GMP Training Systems, Inc.**

Good written procedures are a key element in successful organizations. Preparing good written procedures is critical for compliance and ultimately in avoiding FDA inspection observations -- which greatly benefits the individual, the organization, and the company.

In reviewing FDA 483 Observation Reports and Warning Letters over the years, one thing stands out -- People do not do what they are supposed to do -- they do not follow written procedures.

We have addressed this issue in our training workshops for many years. Attendees have suggested several reasons for this problem. The following are some of the most common reasons given for people not following written procedures.

- They did not know a written procedure existed.
- They were not trained in the written procedure.
- They did not understand the written procedure.

- They could not find the written procedure.
- The written procedure was too long. If it takes longer to read the procedure than to do the procedure, problems occur.
- They thought they remembered how to do the procedure, hence they didn't read it.
- They found a better way to do the procedure, and applied the better way.
- They were told to skip the written procedure and go from memory, or just figure it out.
- The written procedure was poorly written and hard to follow.

Most of the above reasons relate to the quality of the writing of the procedures. Writing good procedures is a vital key to eliminating almost all of the above problems.

The following discussion will address the reasons people do not follow procedures. We then discuss the characteristics,

preparation, and implementation of well-written procedures – procedures that people will follow.

ADDRESSING THE PROBLEMS

Dealing with the issues described above is not difficult. It requires the discipline to address each of these in detail. Further, there must be a quality system or process in place to manage corrective actions. A system to maintain these good practices should be established and continually maintained.

The following are suggested solutions for the problems identified above and how to successfully manage these issues.

Employees Did Not Know a Written Procedure Existed

Ensure that each person has a list or roster of those written procedures that they are responsible for understanding and following. Supervisors should be responsible for ensuring that their people know what written procedures apply to their jobs and that they are trained and understand each of those procedures. A job certification process can help ensure that people are familiar with the written procedures that impact their work.

Employees Not Trained in the Written Procedure

Maintain accurate training records and generate timely reports to ensure that everyone who is required to be trained in a certain written procedure has successfully completed the training.

Employees Did Not Understand the Written Procedure

After being trained in a procedure, a person should be able to demonstrate that they understand it and know how to properly implement it. This is best done one-on-one with a supervisor or trainer, and should be documented.

Employees Could Not Find the Written Procedure

Ensure that applicable written procedures are accessible at or near where the work gets done. Ensure that everyone knows where the specific locations of written procedures are that apply to their work.

The Written Procedure was too Long. *If it Takes Longer to Read the Procedure than to do the Procedure, Problems can Occur*

Write crisp and concise written procedures. An effective written procedure takes into account what the operator should already know about the process and not have too many details in the written procedure. Too

much detail is just as bad as not enough detail in a written procedure. Work to attain the “Right Dose” of detail in preparing your written procedures.

Employees Thought They Remembered How to do the Procedure -- So They did not Read it

This requires constant reminding that following the written procedures is critical for success. This also requires the discipline to adhere to quality standards as well as effective leadership and management.

Employees Found a Better Way to do the Procedure, and Applied the Better Way

It is not unusual for those doing the job to discover better ways to do that job. But in a GXP environment, changes must be evaluated and approved. Then the written procedure must be updated and everyone who uses it must be trained in the revised written procedure. Everyone should be aware of and familiar with your Change Control system, and how to use it.

Employees Were Told to Skip the Written Procedure and Go from Memory, or Just Figure it out

This is a leadership and management issue. Ensure that your managers and supervisors are practicing GXP compliance

and setting the right example – all the time.

Written Procedure Was Poorly Written, and Hard to Follow.

Prepare good written procedures.

WHAT IS A GOOD WRITTEN PROCEDURE?

A good written procedure is one that works and is easy to follow. A good written procedure is one that has the following characteristics:

- Clear -- Understood by everyone who works with it
- Concise -- Contains the “right dose” of detail
- Follows a standardized format
- Contains graphics and/or pictures where appropriate
- Has a logical flow -- a step-by-step approach

Clear – Understood by Everyone Who Works With the Procedures

Consider the people in your workforce who use the written procedures. Some questions to consider are:

- What is their educational background? Do you have people with advanced degrees in one of the sciences? Are you writing procedures for people who haven't taken a science

- class in high school, and graduated from high school twenty years ago? Be sure to address any “education gaps” that may exist in your organization.
- What are their language skills? How many people in your workforce speak more than one language? This is critical where their primary language is different from the language in which your procedures are written. Be sure to address any “language gaps” that may exist in your organization.
 - Do your written procedures contain unique words and/or phrases or company jargon? Do they contain acronyms and/or abbreviations? How do new people learn the unique words, phrases, acronyms, abbreviations, and company terminology or expressions? A company Glossary of Terms that new people receive upon joining the company is useful.

Concise - Contains the “Right Dose” of Detail

Ensuring the “Right Dose” of detail can help avoid written procedures from becoming too long or being too short. Determining what you cover in training versus what details you put in the actual written

procedure is a key consideration.

Standardized Format

Your organization should have a standardized format to which each written procedure should adhere.

Graphics and/or Pictures Where Appropriate

There is an old adage: “A picture is worth a thousand words.”

Adding graphics like flow charts, diagrams, and pictures can help clarify as well as shorten a written procedure. In the past we didn’t incorporate many graphics, diagrams, or pictures because it was hard to do, time consuming, and expensive. Modern technology has made adding a graphic as easy as a click or two from a digital camera or smartphone.

Graphics, diagrams, and pictures are helpful in showing how to clean a piece of equipment, or set-up or disassemble a piece of equipment. The possibilities are endless in finding applications where graphics, diagrams, and pictures can help the written procedure become easier to understand and follow. Many people, if not most people, are visual learners. We learn with our eyes. So adding visuals to your written procedures helps make them better procedures.

Logical Flow – A Step-by-Step Approach

Think of some of the instructions you may have encountered with things you have bought as a consumer. Trying to follow those procedures sometimes leads to frustration and angst. We often wonder – “Who wrote this procedure or instruction manual and what were they thinking?”

A good example of well developed instructions using a logical flow comes from Lego™ building blocks. In fact, Lego™ building blocks not only follow a logical step-by-step approach, they consist of all pictures. Another good example is furniture from IKEA. Most furniture available from IKEA must be assembled, and their instructions follow a step-by-step approach and are mostly pictures. They even include the tool you need for assembly.

Ensure that the written procedures you develop have a logical flow and follow a step-by-step approach.

PREPARING EFFECTIVE WRITTEN PROCEDURES

We have found that the optimal way to ensure that we write good procedures is to involve and include the “right people” in their preparation. Who are these “right people,” and how should

new procedures be implemented?

Team Approach

Writing a good procedure requires a team approach. The appropriate Subject Matter Experts (SME) and two or more users of the procedure should work together to develop the procedure. Writing a procedure by committee takes longer than by a single individual in an office. However, there are some important tangible benefits gained from this approach. Some of these benefits include:

- The users of the procedure may point out details that the SME may have overlooked.
- The SME can help the users better understand the aim of the procedure and some of the nuances of implementing and following that procedure.
- The users can help identify the possibilities of what might go wrong during the implementation of the procedure.
- An enhanced relationship between the SME and the users develops. When issues arise during production, it becomes easier and often quicker to access the SME for help or advice.
- The users often begin referring to the written procedures as “our”

procedures rather than “the” procedures or “their” procedures. “Our” procedures brings with it ownership, and increases the probability of those procedures being followed all the time.

Conduct a Pilot or Trial Run before Implementation

It is always a good idea to try a new or revised written procedure on a small scale before final implementation. Ensure that all the users as well as the SME are present for this test or trail run. It is not unusual to discover unanticipated details during the test run that should be addressed in the procedure.

FINAL THOUGHTS

Preparing and following good written procedures is a major

key in compliance – and ultimately in avoiding FDA inspection observations. This is good for the individual, the organization, and the company for many reasons. Regulatory observations are an embarrassment that reflect poorly on everyone. Avoiding observations saves money. Responding to an FDA 483 Observation Report or Warning Letter takes resources, time, and money. Also, stress is avoided by not having to deal with corrective actions and FDA imposed deadlines.

Having and following good written procedures also leads to less rework, less scrap, reduced costs, and higher profits – all of which are good for the company.

David Markovitz is the Founder and President of GMP Training Systems, Inc., (www.GMPTrainingSystems.com) a top tier provider of GMP training products and services. David can be reached at David@gmptrainingsystems.com and at 714-289-1233.

Get a copy of our ebook, GMP Makes Good Business Sense. It's free, go to www.gmptrainingsystems.com and click on Free ebook.