# GMP Training Systems, Inc.

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

# Three Key Considerations in Developing Written Procedures that Work

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

Developing written procedures that are effective and understood by everyone in an organization is not an easy task.

Many written procedures are done in a hurry to meet deadlines or are "cranked out" by people who have little or no training in writing good procedures.

There are three key considerations to take into account when preparing written procedures. This article will present these considerations as potential gaps in the process.

By addressing these gaps before you embark on developing written procedures, one improves the likelihood that your written procedures will be effective.

**Education Gap**

It is not unusual to turn to Subject Matter Experts (SMEs) to prepare written procedures. In some instances the SME may have advanced education and experience in the system or process. One example we've seen is a Scientist or Engineer with an advanced degree writing a procedure that will be used by someone who didn't even take science in high school (and completed high school 22 years ago).

This can lead to an understanding gap. If the Operator does not understand the written procedure, then the Operator faces a dilemma.

1) The Operator can go to their Supervisor for help.

2) The Operator can turn to their co-workers for help.

3) The Operator can attempt to contact the SME who prepared the written procedure for help, or even attempt to contact those who approved the written procedure.

4) The Operator can guess what is meant and proceed.

5) Stop. Remember that Operators are usually working to deadlines in a Production environment. There is little time afforded to choose the right path forward.

What is the Operator to do if they cannot find the Supervisor?

What if the co-workers cannot provide any help?

What if the SME and/or approvers are not available?

Too often the Operator has only Option #4 to choose from – guess and proceed.

In the GMP (Good Manufacturing Practice) regulated companies, this is known as LMP – Lucky Manufacturing Practice!

Many times the operator gets lucky and guesses right, usually based upon experience or memory. But every once in a while, the Operator will guess wrong, and a problem occurs.

In some companies Option #5 – Stop – is expected and acceptable behavior. However, in many companies someone stopping a process in a production area is frowned upon or discouraged. Sometimes the discouragement is done in subtle ways.

## Remedy for the Education Gap

GOOD - Ensure that those who will be implementing and using the written procedures understand those procedures before starting the process.

Effective training in each written procedure is part of the answer. And the key is EFFECTIVE TRAINING. Reading a procedure and signing a form saying that one has read and understands the procedure is usually NOT effective training for most people.

Effective training should be conducted in a non-threatening manner where people are encouraged to ask questions and demonstrate that they understand and can follow the procedure under consideration.

BETTER - Involve the people who will be implementing and using the written procedures to review the procedure BEFORE the procedure is approved for use.

Facilitate a method for feedback in improving or revising the procedure under consideration based upon feedback from the operators/users.

BEST - Involve the people who will be implementing and using the written procedures to participate in developing the

procedure. Have one or more of the Operators work with the SMEs to develop the written procedure.

Yes, this will take longer. But the end result will be a procedure that is better understood by the Operators, thus eliminating Lucky Manufacturing Practice from your company.

You also get ownership of those procedures by those responsible for implementing them. The operators often refer to those procedures as OUR procedures, not THE procedures or THEIR procedures when they have participated in developing them.

Once a draft of a written procedure is completed, it may be useful to use a readability index to determine the comprehension level/readability of the document. There are several indices available on the Internet. Microsoft Word™ also has a readability function.

## Language Gap

In the United States, many companies employ people whose primary language is not English. Thus, there is wide variation among the fluency in the English language among employees in many companies.

This language gap can present a serious problem if some people cannot read and/or understand the written procedures. This is a growing problem facing industry in almost all regions of the United States.

### *Remedy for the Language Gap*

Implement an assessment before hiring people for positions where reading and understanding your written procedures is critical.

Check with your Human Resources department on what assessment may be appropriate and what governmental guidelines and regulations exist before implementing any language assessment.

If you already have people working at your company where English fluency is a problem, then you can help them improve their English language skills.

Community colleges are a valuable resource for English as a Second Language (ESL) courses. Many companies have contracted with local community colleges to conduct ESL courses for their employees in order to improve the English fluency of their workforce. You can work with the community college staff to design an appropriate assessment of your employees and design an appropriate course of action. A post assessment can be designed to

determine whether the desired fluency level has been attained. Community colleges are generally easy to work with and affordable.

**Generation Gap**

Consider those now entering the workplace for the first time. The generation now entering the workplace – this year's college graduates – were born in 1991 or 1992. This year's high school graduates were born in 1995 or 1996. Think about their life experiences. They are the digital generation.

- They don't remember life before computers.
- They have never seen a floppy disk.
- They have only seen a typewriter in a museum.
- They don't remember life before cell phones.
- They don't remember life before e-mail or texting.
- They use text messaging more than e-mail.
- They use their phones to text message, not to make calls.
- They don't remember life before the Internet.
- They don't remember telephone modems, and the slow speeds of browsing the World Wide Web with a telephone modem.

- They don't remember the Soviet Union or the fall of the Berlin Wall.
- They don't remember the gulf war in 1991 - Desert Storm. To them it is in the same category as the Vietnam and Korean wars – history lessons.
- They don't remember cassette tapes or records.
- They have only seen a record player, hi-fi, or stereo in a museum (or at their grandparent's house).
- They have never been to a music store to buy music, except perhaps when they were toddlers and were with their parents.
- They don't (or barely) remember VCRs and VHS tapes.
- They don't remember when MTV only played music videos.
- They've never been to a drive-in movie.
- Tweet is something we do, not birds.
- Spam is unwanted emails, not processed meat in a can.
- Clockwise or counter clockwise may have no meaning – they grew up with digital clocks.
- If you mention President Bush, they don't say "Which one?" They don't remember George H.W. Bush, President from 1989

to 1993. They only know George W. Bush, President from 2001 to 2009.

- If you mention the name Clinton, they think of Hillary before they think of Bill.
- If they hear the word Beatles/beetles, they think of insects, and not of John, Paul, George, and Ringo.
- If they hear the word mouse, they think of computers before they think of rodents.

And here's the big one.

This generation created their own language. It's called text messaging. It was created by young people throughout the world. They use no capital letters. No punctuation. Abbreviations galore. Acronyms many people have never heard of. And no governing body to determine rules for the application of this new language.

Now we hire these young people and ask them to write Standard Operating Procedures. OMG! LOL!

### Remedy for the Generation Gap

An effective and powerful employee orientation process for integrating new people into the company is paramount in developing an effective workforce.

One important objective of a new employee orientation process is to help a new employee feel welcome and that by joining the company they will be a part of something important.

An effective orientation process conveys the importance of each job in the company and helps people see that they will be making meaningful contributions to society, and not just having a job.

There are several critical points to cover in an effective orientation process. Here are some important points that should be included.

**History of the company** – Most companies have an interesting story surrounding how the company was established. Make sure that everyone knows this story.

**Products and/or services** – Make sure that new employees know and understand what your products and/or services are, how they are used, why they are used, and who uses them.

**Customers** – Make sure that new employees know and understand the company's customers and the impact that a

defective product or service might have on the customer.

**The Big Picture: How work gets done in the company** – Make sure that new employees see how a product gets made or how a service is provided. Flow charts are helpful here. Help new people see where they will be fitting into the Big Picture. Knowing who their internal customers and suppliers are helps optimize communication throughout an organization.

**The Role of the FDA and other Regulatory Bodies** – Make sure that new employees know and understand that your company is regulated by the US FDA and/or other appropriate governmental agencies. This knowledge lays the groundwork for why company policies and procedures must be followed.

**GMP Compliance** – This is where new employees should get their initial dose of GMP training. Make sure that new employees know and

understand the importance of following GMP, and the consequences to them and to the company of non-compliance.

**Your Company Policies and Procedures** – Make sure that new employees know and understand that following your company policies and procedures is an important aspect of GMP compliance.

**Conclusion**

There are several factors that contribute to developing effective written procedures. Addressing these three gaps will go a long way in ensuring that the written procedures you develop will work to help you become more compliant. Having written procedures that are clearly understood by everyone makes them easier to follow, which in turn leads to less rework, and results in lower costs and higher profits.

*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.*

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