

GMP Training Systems, Inc.

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

GMP Compliance *Start with the Basics*

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

The late John Wooden, legendary coach of UCLA's champion basketball teams in the 1960's and 70's, stressed the basics. The first activity at the first practice of each season began with a lesson on how to put your socks on and how to tie your shoes.

The new players were often surprised at this and would complain with phrases like, "Coach, we learned that in kindergarten." and "We already know how to do that."

But Coach Wooden would insist they do it his way, as he had proof that his way reduced the chance of blisters and reduced the chance of tripping on a loose shoelace during a game.

Essentially Coach Wooden had an SOP, or Standard Operating Procedure, for putting on one's socks and shoes. He often cited this as one of the major reasons for his record string of championship teams.

This was important not only for the two reasons cited above but it created the discipline among the players to follow the playbook, and listen to their coach.

So much of following GMPs in our organizations is the discipline to follow our policies and procedures, our playbook. Most companies that run into trouble with GMP violations with FDA and other regulatory bodies find that it is that discipline that is lacking. The policies are in place. The procedures are written and in place. But for a variety of reasons people in the organization did not follow the policies and/or procedures.

Reminding people of the basics of GMP is a good place to start in creating a habit of GMP compliance within the organization. Certainly new people need to know the basics. But reminding everyone on a regular basis reinforces the importance of GMP compliance.

Frequency of Training

Conduct GMP training on an ongoing basis. The job responsibilities and level of risk to the product should determine the frequency of the training. People who have direct contact with the product should have more frequent training than someone whose job has no contact with the product (like someone working in Accounts Receivable, especially if their office is separated

geographically from the manufacturing site). Shorter and more frequent training sessions keeps GMP fresh in peoples' minds.

GMP Basics

Here is an approach for focusing on the Fundamentals of GMP Compliance in your organization.

The following twelve topics constitute the fundamentals of GMP and everyone in your organization should be familiar with them. Consider building your GMP training process upon the foundation of these fundamental topics.

1. The History of the GMP Regulations

When people understand that the regulations were not written in a vacuum, but mainly in response to serious issues and shortcomings, it helps them see and understand the sense and logic behind the regulations. Be sure to tie in the fact that your policies and procedures were written to ensure compliance with the regulations and to ensure consistency in the final output – whether your final output is products or services.

2. Customers and their Expectations

Make sure your people know who your customers are and how your products and/or services help your customers. In our industries, often the ultimate customer, or user of the product, is called a patient. Product defects or product failures can result in injury or even death to the patient.

This helps our people understand the seriousness of their work.

3. The Big Picture

When new people join your organization, make sure they learn what your products are and how they are used and/or what your services are and how they benefit your customers. Ensure that they understand how their work and contributions fit into the overall scheme in your company. The more people understand how work gets done, the better their decisions become as they are faced with the decisions that are made on a daily basis.

4. Writing Good and Effective Procedures

Preparing good written procedures is not a natural talent most of us are born with. Rather, it is a skill that can be learned. Consistency in your processes is often managed by consistency in our written procedures. Your SOP #1 (Standard Operating Procedure #1) should be the SOP on SOPs. It should spell out the format and level of detail required. Outline the components of a well written procedure during your training sessions. It's easy to contrast a well written procedure with a poorly written one. Examples of poorly written procedures are all around us. Just read some of the procedures for consumer items that require assembly or instructions with home electronic gadgets.

5. Following Policies and Procedures for Consistency

Following policies and procedures leads to consistent performance. This topic is critically important in that it helps create the habits within everyone in the workforce to follow procedures. And to work to continually improve those procedures where needed. Here is where we also reinforce the need to document all deviations and discrepancies, no matter how minor or insignificant they appear to be.

6. Keeping Good Records

Our customers as well as the regulators expect our records to be accessible, complete, accurate, and legible. You should have an SOP on Good Documentation Practices for your organization. Standardize how you record the date and time. Stress legibility. This alone can reduce the number of mix-ups and errors significantly.

7. Managing Materials to Prevent Contamination, Mix-ups, and Errors

Labeling raw materials, work-in-process, and finished goods properly is another basic principle of GMP. Organization of warehouses and storage areas is critical here as well. Stress the benefits derived from maintaining a neat and orderly workplace.

8. Keeping Things Clean – Guarding Against Contamination

Cleanliness is critically important in our industry. Make sure everyone understands how easy bacterial contamination can occur and why it is so important to follow our cleaning procedures exactly as they are written.

9. Maintaining Our Buildings and Equipment

Buildings and equipment should be maintained in a good state of repair. Report any conditions that need attention, and follow-up to make sure that they are fixed. It's easy to let things slide if things aren't attended to promptly. Always check calibration stickers to ensure that equipment is not past due for calibration before using it.

10. Being Sure – Checking and Double Checking

Human beings make mistakes. That's why we create independent verification, or double checking, into our systems and processes. Dual signatures or sign-offs, are put into place as a safeguard against missing something that may be wrong, or missing. Ensure that your people understand that it's more than just a second signature, it is independent verification, and there is a process or procedure in place to properly conduct an independent verification.

11. Auditing – Checking our Systems and Processes

The purpose of an internal audit is to check on how well our systems and processes are doing. Unfortunately in some organizations an internal audit is used is to catch people doing things wrong and then to reprimand the people. This is a surefire way to ensure that no one will cooperate with the auditor.

Make sure your people know how audits are performed, and the overall benefits of identifying shortcomings and working to improve the systems and processes in place. Effective

audits are an integral part of a quality management system.

12. The Role of the FDA in Compliance

The FDA and other regulatory bodies worldwide represent the citizens of their respective nations. Their job is to ensure that the customers, or patients, can trust your organization to manufacture quality products that will result in no harm to the customers/patients. It's important to also make sure that your people understand the authority of the regulators.

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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