

# ***GMP Training Systems, Inc.***

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

## **Effective Follow-up Strategies to GMP Training**

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The ultimate measure of the effectiveness of a training process is its positive impact on the performance of a business. Viewing training as an ongoing process rather than as an isolated or periodic event helps ensure that training will have a positive impact. Very often, participants of a training session complete the session excited and enthused. Interest drops off rapidly if management shows no or little interest in sustaining the drive to keep GMP alive, making GMP a Lifestyle within the organization. That's why effective follow-up is crucial to making your investment in training pay off.

Successful training consists of three important phases; Planning the Training, Conducting the Training, and Effective Follow-up after the training. Previous articles addressed the first two phases.

Training should not stop when a training session is complete. A follow-up strategy or strategies should be developed to reinforce what the participants have learned. This article will explore several proven techniques for ensuring that the training conducted will have the desired impact.

### **Training as a Process**

First and foremost is to view training as a process. Many organizations use the term "Training Program." This in itself is limiting. The word program usually denotes something that has a start and a finish. A process, on the other hand, is

generally regarded as having no end. It's like a river, flowing constantly. You may call that river by the same name every time you see it, but there's different water flowing down its banks. Like a river, our training process can be comprised of an ongoing series of programs or modules.

Each of these programs or modules can be developed, delivered, and documented. Consider the "c" in cGMP, which stands for current. The GMP regulation itself is open to interpretation and is constantly being reevaluated. We must strive to keep our GMP training process current.

The cGMP 21 CFR – Part 211 (cGMP for Drugs) states that "Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them."

"On a continuing basis and with sufficient frequency" is included to ensure that we not only stay current with the law, but also share that new knowledge with everyone in our organization, where it applies to their jobs. This means that we have some translation to do. The interpretation of "on a continuing basis" is fairly clear. It is generally meant to mean that an employee will be expected to receive some dose of GMP training throughout his or her career with the company.

“With sufficient frequency” is not as clear. One way to help determine sufficient frequency is by asking the question, “What’s the right dose?” That is – what’s the right dose of training for each particular work group? Sufficient frequency of GMP training for people working in a sterile filling environment may be monthly. For someone working in Accounts Payable, an annual overview of GMP may be considered sufficient.

Our job as training professionals is to determine the “Right Dose” of GMP training for each work group, and design a process to deliver the appropriate training at the appropriate intervals. “One size fits all” is not an appropriate strategy for most organizations.

Deliberate and careful thought must be given to design an optimal strategy to make GMP come alive and stay alive in your company. And effective follow-up to training is crucial to making a GMP mindset or GMP Lifestyle come alive stay alive.

### **Follow-up Tips**

#### ***Feedback Sheets at the Session.***

Distribute feedback sheets at the conclusion of the training. Allow five minutes at the end of the session for this activity. Ask the participants to complete these and leave them with the instructor before they leave the room. One question to ask on this feedback sheet is “What is the most important point(s) you learned in this session?” The responses will help you determine whether your objectives in conveying the planned message got through.

It also causes each participant to summarize in her/his own mind what was covered in the training session, thus, starting the follow-up immediately at the conclusion of the event.

***Feedback Sheets after the Session.*** Distribute feedback sheets two to three weeks after the conclusion of the training session. In some organizations, this can be done electronically, using the company E-Mail system or Intranet. One important question to ask here is “What is the most important point(s) you remember from the GMP training session you attended recently?”

This causes the recipient to think back and review the content of the class. They may even look up the handouts from the training session to determine their response. Wow! – actually look at the material again after the session – for many people that alone is an achievement.

***Reference Material.*** Refer to the handouts from the training as Reference Workbooks. Encourage participants to treat these as their personal GMP reference guide. Prepare a personalized three-ring binder for participants to keep all their GMP handouts in. They bring their binder to each training session. In some areas, you may have to provide a place for the employees to keep these. We want to avoid treating the handouts from the training sessions as if they were trophies – sitting on a shelf gathering dust.

***GMP Training Team or Advisory Team.*** Consider forming a GMP training team or GMP advisory team. This team

would determine the follow-up activities for the facility. This team can be cross-functional in structure and be comprised of individuals selected to serve for a limited time, perhaps six months.

The rotating membership keeps viewpoints fresh and sustains ongoing energy to keep the follow-up efforts moving. A GMP trainer(s) should be a permanent member(s) of the team to ensure continuity.

**Newsletter.** Many organizations have a company newsletter that is published on a regular basis. Create a GMP Corner in your newsletter. Include a short paragraph or two highlighting a section of the regulation and how it applies to your company. Identify the task of writing the copy for the newsletter as a career development activity and assign it to someone from one of your operations areas.

This can be a one-month assignment, or a three-month assignment, depending on the frequency of the newsletter. Having the person sign their name as a byline to the column gives them recognition throughout the company – often a reward for doing extra work.

**Table Toppers.** Develop a GMP message of the week and print these on heavy cardstock. When folded in half, the cards can stand up (like a name tent at a training session). Place one of these on each table in the cafeteria, lunchroom, or breakroom. These should be changed weekly. This is another career development activity for some “rising stars” in your organization. This gives them an opportunity to contribute to the performance of their company in

ways usually not associated with their functional responsibilities.

**Department Meetings.** Include GMP as a topic for every departmental meeting. Sometimes just a mention of GMP keeps people alert and reinforces that management takes GMP seriously enough to include it as an agenda item along with discussing performance measures, goals and objectives, safety, and other issues commonly covered in departmental gatherings.

#### **Monitor and Measure**

**Performance.** Identify key metrics for your work group and measure them on a regular basis. It may be number of mistakes per month, the score on an audit, or the number of documents returned from the Documentation Control department needing corrections or completion before a product can be shipped. Post these measurements, best displayed as run charts or control charts, for everyone in the group to see.

**Peer Audits.** Identify audit teams within work groups. After appropriate training on conducting audits, have teams perform audits on other areas of the company. This is an effective technique for getting people to “brush-up” on their GMP knowledge on their own. They take the time to prepare themselves for the upcoming audit. Auditing is also a great way to change the mindset of both those serving as auditors and those being audited. This process expands the sphere of GMP knowledge.

**Safety.** Most organizations have regular safety trainings and safety meetings. Management’s commitment to the safety and welfare of their employees,

along with federal regulations developed and enforced by OSHA, as well as state regulations, drive these activities. The focus is on the safety of the employees.

GMP focuses on the safety of the customers. So in that sense, GMP can be considered a safety issue. Combining forces with those responsible for safety can help stretch training budgets, reduce the time employees spend in meetings, and create a mindset that safety for everyone (employees and customers alike) is important to the success of the company.

**Current Events.**Special sessions can be convened to discuss current events. This may be a GMP issue that occurred in your company – either at your site or at another location. It may be an issue that occurred with one of your competitors. It may be something you found in the newspaper, or in FDA Consumer, a regular publication from the FDA, or something you saw on last night's news broadcast. Excerpt the article or summarize the event and ask how the problem could have been prevented.

If the company produces products that are similar to yours, ask if your systems can prevent similar problems at your facility. If a meeting isn't possible, post the material on a bulletin board.

**Bulletin Board.**Display GMP information on bulletin boards. These can be located at strategic places where people pass by frequently. These can also be electronic bulletin boards – for those with electronic access. The maintenance of these bulletin boards

can be another career development activity for high performing individuals.

Often, original artwork or photos can be included as part of the display. Find the hidden talent, the artists or photographers in the various work groups. They are often excited and proud to “show off” their work to their colleagues.

**GMP Contests.**Conduct GMP contests periodically. Pass out a word search puzzle or a crossword puzzle. Completed entries must be submitted by a certain date. All the correct entries will be combined and one will be chosen at random to win some nominal prize. Or all winning entries win some nominal prize.

The objective is getting people to review GMP, learning on their own. Keep these simple and fun. Inexpensive software exists for creating crossword puzzles and word searches – check your local software store.

**GMP Themes.**Declare a company wide GMP theme for the quarter. This calls for four themes each year. Go through the regulation. One theme can be “Keep it Clean,” focusing on cleanliness and organization. The office areas can participate by having everyone clean out their offices or cleanse the memory of their computer of old E-Mail messages. Another theme can be “Write it Down,” focusing on accurate documentation. With the GMP regulations, there are enough themes to sustain this activity for about three years – then start over by repeating the first theme again.

The GMP training conducted during the theme period can stress the theme. This is a good solution to on-going training efforts once people have gone through the initial comprehensive GMP training for their area of responsibility.

### **Put a Face on Your Customer**

For many organizations, the customer is called a patient. This individual often isn't choosing to purchase your product, he or she is getting your product perhaps in an Emergency Room, or at an accident scene, or at a pharmacy. Many customers are parents purchasing infant formula for their newborn, or just the weekly groceries to feed their families.

Many customers are generous donors of blood and blood plasma. All of these people trust that everyone in your company knows their job and performs their job diligently every day. They trust that no shortcuts were taken to design, manufacture, process, pack, store, or distribute these products.

Each training session should serve as a reminder that there's a customer who is putting their trust in you. This serves as a vivid reminder as to why the regulations were promulgated and are enforced. Even though the word customer and patient cannot be found in the GMP regulations, they are why we do what we do.

Consider taking photographs of some customers and displaying those photos where everyone can see them every day. Place a banner along with the photos that says, "We trust you." or "We're counting on you." Reaching

employees as caring human beings, as parents and family members, goes a long way in helping them take GMP seriously.

Work with your Sales and Marketing departments and invite a customer in to address your employees in person, or even on videotape. This is a powerful way to reinforce the importance of GMP and that it's more than just a regulation.

### **Summary**

These are only a few ways you can follow-up on your training efforts. There are probably many more that you can think of that would work in your company. Choose those activities that will work with your people. Offering a variety of activities over time keeps your GMP training efforts "fresh." Don't try to implement them all at once. Remember to consider the resources available to make these things happen as well.

Making GMP a Lifestyle, and not just a regulation, goes a long way in making compliance easy. When people have an understanding of why things are done a certain way, and why strict adherence to Standard Operating Procedures is required, we all stand a better chance of producing high quality products, services, and information and assuring our customers that they are receiving the very best efforts of all of our employees.

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Markovitz, David C., "Practical Preparation for Effective GMP Training: 6 Steps to Success," [www.gmptrainingsystems.com/resources](http://www.gmptrainingsystems.com/resources)

Markovitz, David C., "Conducting GMP Training: Do's and Don'ts for Success" [www.gmptrainingsystems.com/resources](http://www.gmptrainingsystems.com/resources)

FDA Consumer is available at <http://www.fda.gov>.