

GMP Training Systems, Inc.

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

Practical Preparation for Effective GMP Training Six Steps to Success

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Conducting an effective GMP training session does not happen by accident. One might sometimes conduct a good training session with little or no preparation, but it's unlikely. Effective training without adequate preparation is analogous to manufacturing without proper controls. The latter can be called an example of **LMP** - *Lucky Manufacturing Practice*. Training, just as manufacturing, is too important to rely on luck.

The late Dr. W. Edwards Deming taught that 85% of the impact is in the first 15% of the process. Training is a process and effective GMP training is a result of careful planning. Therefore, we should invest considerable energy in this first 15 percent of our training process. One critical part of planning in the training process can be viewed as Setting the Climate.

Peter Senge, author of *The Fifth Discipline* and Director of the Systems Thinking and Organizational Learning Program at MIT's Sloan School of Management, says that "The learner learns when the learner wants to learn."

Those of us responsible for GMP training have the responsibility to create the conditions where our learners come to our training sessions ready and wanting to learn. Proper preparation, (Setting the Climate), can make the difference between just another GMP

training session, and one resulting in a positive memorable experience which helps develop competence among our workforce. Laying the foundation for an effective training session starts long before the session begins.

Proper Preparation for Effective GMP Training consists of Six Steps:

- **Step One** - Establish the objectives and expected outcomes.
- **Step Two** - Prepare the training materials.
- **Step Three** - Determine class size and optimal seating arrangement.
- **Step Four** - Reserve the space.
- **Step Five** - Prepare the participants.
- **Step Six** - At the training session.

Step One - Establish the objectives and expected outcomes.

The drug cGMP regulation, 21 CFR - Part 211.25, states that "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good

manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions." Employees' functions are very specific; training should be specific, too.

Specific training objectives and expected outcomes should be developed in order to design a training course that's on target. These can be divided into two clusters: "Must knows" and "Must do's".

"Must knows" describe information or knowledge which the participant must know in order to do their jobs effectively. The regulation clearly states that knowledge of the regulation and written procedures is required, thus, a must know. And just as the regulation itself sets out the minimum requirements (CFR 21 Part 210.1), just knowing the regulation as written is the minimum knowledge required.

It is very useful to have people understand the intent of the regulation and some understanding of the evolution of food and drug law. It is also critical for success to teach specific interpretations of the regulation that your company has made.

"Must do's" describe how the knowledge is to be applied on a daily or task-by-task basis in order to do their jobs effectively.

Step Two - Prepare the training materials

Hand-out materials are always a good idea. Well prepared materials help in retention and reinforce the importance of the GMP to the organization. Depending on the scope of the training, this can range from a sheet or two of paper stapled together to a three-ring binder. In either case, make sure that participants have space to take notes on the material. This can be on space designed into each page, or as additional notes pages.

Depending on your budget, prepare these materials as professionally as possible. Remember, you're teaching Good Manufacturing Practice, with its emphasis on quality products.

Make sure that your training materials themselves are high quality products. (This means no poor quality copies of fuzzy materials, spotty graphics, or worn out originals. If GMP means "quality", what do sloppy or 'less than professional' materials suggest?)

Step Three - Determine class size and optimal seating arrangement

The aim of training is learning. Things to take into consideration in determining class size include:

- The length of the training session.
- The specific topic(s) of the training session.
- The amount of interaction anticipated and/or required.

- Whether small group exercises are going to be a part of the training.
- Seating arrangements. Maximize the opportunity for each participant to see the faces of the other participants. This has been proven to enhance learning.

We recommend that twelve be the minimum class size and thirty be the maximum size. With groups larger than thirty, it becomes easy for someone to attend without really participating. With groups smaller than twelve, effective discussion and interaction is limited.

Step Four - Reserving the space

Reserve the training room for the specific dates and times required. Remember to reserve the room an hour or so before the actual training is scheduled to begin so that the room can be prepared and set up. Arrange for any audio-visual equipment to be in the room and set up before the training is scheduled to start.

Make sure you provide a room with enough space (elbow room) for people to be comfortable. If you expect people to be taking notes, make sure that tables are available. DO NOT cram people into a room where they have inadequate space. Remember, the aim of training is learning.

Having enough elbow room and table space to lay out materials is critical to learning. If dealing with hotels or convention centers, ask to see the rooms in advance. If that's not feasible, ask to see a diagram and layout of the

room being considered. Most hotels and convention centers will recommend rooms based on their own capacity numbers. Beware: Many hotels and convention centers calculate their room capacity numbers based on squeezing people in, not the comfortable learning environment desired.

Step Five - Preparing the participants

The participants in the training session must have the opportunity to prepare themselves both physically and mentally. What do we mean by physically preparing? Doing push-ups, sit-ups, jogging? No, not in this case.

To physically prepare we mean putting it on the calendar. Adjusting workload and tasks to accommodate the time away from the workplace. This may mean working extra hours in advance of the training. Or it may mean delegating certain tasks to others.

People appreciate when they can make these adjustments in advance of the training, thus avoiding paying a penalty afterward. Many people don't mind working extra hours or even taking work home if it's within their control. However, many people resent it when they're forced to work extra hours or take work home because they've been scheduled into a last minute training session.

Mental preparation is critical for learning to take place. Adequate notice of attending a training session gives the participants time to prepare. We suggest at least three weeks' notice. The format of the notice sets the tone for a successful training session. There are

some key pieces of information necessary. These include:

- The name of the training session.
- The learning objectives of the training session.
- The date and time, both starting time and ending time. Does the date conflict with any religious holidays? Is the date close to a three-day weekend?
- The location, and directions if necessary. Depending on location, where to park is good information to include.
- What they should bring with them.
- Who will be conducting the training session, and a little information about their qualifications.
- Whether any meals will be included. If meals are included, give special diets consideration by giving participants a process for replying with their requests.
- Why they've been selected to attend.
- A telephone number to call in case an emergency arises and they are unable to attend the session.
- A telephone number where others can leave messages while they are in the training session.

A cover letter serving as an invitation to attend the training session written by the appropriate person can also lend credibility and authority to this training topic. Receiving an invitation to attend a

training session written by the company President carries more clout than a broadcast E-Mail announcement sent by the training department. Many senior managers are flattered and more than willing to write these letters.

In some cases, it may be necessary to outline the content of the letter for them, or even prepare a sample letter for them to use as a template. This letter can re-confirm company commitment to GMP from senior management.

Both the cover letter and the logistics notice can be sent together, or the invitation could precede the logistics by a day or two. Remember, this takes place three weeks prior to the training session.

It's also a good idea to send out a reminder about a week before the training is scheduled. This reminder can take the form of a note from the instructor. Here the instructor can add to setting the climate by helping the participants feel comfortable with the instructor before they even meet.

Enclosing some simple preparatory assignment can further set the climate. This can be an article to read, a survey to complete and bring with them to the session, or other hand-out material. What's important here is a personal touch between the instructor and the participants.

The instructor can emphasize the importance of being on time by mentioning the start time and location in this note.

Step Six - At the training session

The instructor should be the first to arrive in the training room. It's advisable to get there early for several reasons. These include:

- Make sure the room is set up optimally.
- Make sure all the audio-visual equipment is working properly, spare bulbs are available for any projectors, and the knowledge of how to replace those bulbs.
- If using computer projection devices, allow extra time to ensure the proper hookups and computer settings are in place and working properly.
- Learn how to use any VCR and playback equipment. Familiarize yourself with the settings and controls as well as with remote control devices. Pre-adjust the volume of the playback device.
- Videotapes should be forwarded to the point where you want to start. Don't waste time during the training session having participants sit staring at a blank screen, copyright information, FBI warnings, ...
- Training materials can be set out at all seats.
- Name tents can be set out.
- Place a sign outside the room indicating the name of the training session being conducted. This will help participants unfamiliar with the area find their way. It may be necessary to place several signs throughout

the building if using a big building that most participants have not previously visited. If using a hotel or convention center, enlist the help of staff to position directional signs at entrances. You may even need the assistance of people stationed at various places to help participants find their way.

- Post a large sign (a flip chart sheet will do) with logistical details in a place where all participants are sure to see before the session begins. This will list start and finish times, break times (approximate), location of rest rooms and telephones, and any other housekeeping information. Then you won't have to use valuable class time to go over these administrative details. There's little impact with starting a training session with "The rest rooms are down the hall."

It's important to have all the above tasks completed before any of the participants arrive. They should arrive in the room with everything set. Now the instructor can devote time to making each participant feel welcome.

Greeting each participant personally before starting helps participants feel at ease. You can engage in small talk or ask about their current job or assignment. Telling them a little about yourself (self-disclosure) can also help participants feel comfortable. You can also learn about relevant issues which you can emphasize during the training itself.

You can ensure a successful start to a GMP training session by following these six steps to Practical Preparation for Effective GMP Training. You can create a checklist for yourself to make it easier to remember these critical steps to success.

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