

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

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

## **GMP and Safety**

### ***Employee Safety and Customer Safety***

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In the United States, every company is mandated by OSHA (Occupational Safety and Health Administration, a division of the Department of Labor in the Federal government) to conduct safety meetings on a regular basis. The focus of these meetings is on the safety of those working at the company.

GMP can also be viewed as a safety program - ensuring the safety of our customers/patients.

#### **Here's a Training Tip you can use**

When you conduct a Safety Meeting, reserve an additional fifteen minutes or so at the end to conduct a GMP training session. Your people are already gathered together and focusing on safety. (Getting people together is usually the biggest challenge.) Shift the conversation to the safety of your customers and, voila, you are now engaged in a GMP training session. Document this training with a GXP Training Record and you can fulfill FDA's requirement of conducting GMP training on an ongoing basis and with sufficient frequency to

assure employees remain familiar with current GMP requirements. Here are some ideas on developing an agenda for these short training sessions.

- Use a current or recent incident from your company for discussion on what could be done in the future to prevent such occurrences.

Focusing on real issues and their consequences has a riveting effect on most people. Make sure to focus on consequences to the customer or patient, consequences for the company, and consequences for the individuals responsible for the issue.

- Use citations from your internal audits for discussion on complying with the GMP regulations.

Here's an example. One department of a company had several observations on their internal audit related to general housekeeping issues.

The department manager did a walkthrough of the department with a camera and took dozens of pictures of violative situations. At the training session these photos were displayed using a project and it was quite embarrassing to those who worked in the area. Seeing these situations in pictures was quite different than seeing them in person.

Each picture tended to highlight the violation – there's something about seeing these images in isolation that is striking. The group then proceeded to develop and implement a plan to fix each situation and improve housekeeping overall.

In a subsequent training session, additional photos were taken of the implemented remedy. Then before and after pictures were used which provided everyone a sense of accomplishment and pride in their work.

- Focus the discussion on a US-FDA (United States Food and Drug Administration) issue in the news.

There seems to be a ready supply of issues, whether it's salmonella contamination in vegetables or pet food

contamination or a contaminated drug or a defective medical device.

- Choose a Warning Letter issued by US-FDA (find these on FDA's web site – [www.FDA.gov](http://www.FDA.gov)) and discuss the issues identified in the letter. Discuss whether your company or department is vulnerable to these same citations.

Another good use of FDA Warning Letters is to examine several in your industry and look for trends or "hot topics" that the FDA has been focusing on.

- Ask your participants to look for issues to discuss for the next meeting – getting them involved in this way keeps it on their mind a little longer.

They can look for issues within your company or from the news.

- Use one of the commercial GMP training products available to conduct GMP training. There are several to choose from.

Regular doses of GMP training is a proven method to keep GMP alive in your company and to guard against complacency. Complacency can be one of the leading reasons for cGMP violations. Complacency

affects our most experienced people.

It is particularly dangerous in jobs that tend to be routine, repetitive, and redundant. (Think about how many jobs in your operation that can be characterized as routine, repetitive, and redundant. It's quite a few.)

This is the primary reason why FDA requires that we "conduct cGMP training on an ongoing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them." 21CFR Part 211.25 (Current Good Manufacturing

Practice for Finished Pharmaceuticals)

**A final word about GMP training.** It's a challenge to continually train people on things they already know (or should know).

- Keep your training fresh and crisp.
- Don't be boring.
- Take time to plan and develop your training. Don't try to "wing it" by going in unprepared.
- Use examples and stories to reinforce critical points. People remember the stories.

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