Audit Preparation: A Key Element of an Effective GMP Training Process

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Audits are a useful tool in maintaining an effective Quality System. Conducting GMP audits often reveal gaps and inconsistencies in our systems and processes. In order to identify any gaps and inconsistencies, the auditor must know the requirements and the current regulations. The auditor must know what he/she is looking for. Preparation for the audit is an important aspect in conducting an effective audit.

The Internal Audit Exercise

One method we have used in maintaining an effective GMP training process is to incorporate GMP audit preparation into the training process. Here's how it works.

Presentation

Start the training session with a discussion on the importance, purpose, and value of audits. Be sure to position audits in a positive light. An effective audit collects meaningful data which is used to improve and optimize our systems and processes.

Group Assignment

Divide the group into small groups of no fewer than three people and no more than five people. Assign each group a section or more of the GMP regulation to examine. The objective for each group is to develop questions and an audit checklist for each section of the regulation.

Group Discussion

The individuals in each group will need ten to fifteen minutes to read their assigned section. Each group should then discuss the requirements of their assigned section and work together to create questions that an auditor would ask during an audit. The late Dr. W. Edwards Deming, the famed quality guru who lived from 1900 to 1993, taught that the questions are more important than the answers. Asking good questions leads to discovery. And audits are all about discovery.

The real value of this exercise is that the participants of the training session actually study

the requirements of the regulation with an eye towards understanding. This technique can be far more effective than sitting through another lecture on the GMP sections.

When the small groups begin to discuss their assignment (after reading the appropriate section of the regulation) they often begin by asking themselves the following questions.

- What does this mean?
- What must one do in order to comply?
- How will we know whether the system or process is in control?
- How will we know whether the system or process is in compliance?
- What questions can we ask of the people working in the system or process under review?

These questions tend to generate discussion which in turn leads to a better understanding of the regulations and requirements. Groups are then challenged to develop questions that can be asked during an audit. We have found it useful to provide some primer questions to help some groups get started. Here are some primer questions in clusters relative to certain sections of the regulations.

Primer Questions

Materials

Do we carefully control the components used in manufacturing?

Do we pay close attention to the control numbers assigned to our product components and to the individual lot numbers assigned to our finished product?

Do we know and understand our responsibility to build quality into our products?

Records

Do we carefully document our work by recording all necessary information immediately on the batch or history record?

When and where a signature is required, do we sign our names legibly and in non-water soluble ink?

When the batch or history record requires it, do we mark down the date and time we started or completed the job?

Do we validate our work by checking and double checking all critical operations to make sure there are no mix-ups or errors?

Buildings

Do we have adequate space in our work areas to safely and effectively perform our jobs?

Do we minimize the chance of product contamination, mix-ups, and errors by helping control the internal environment of the workplace?

Do we quickly report any conditions in our workplace that could be a potential source of product contamination?

Equipment

Do we perform routine maintenance on equipment and do we check to see if any measuring and testing equipment has been properly calibrated?

Do we keep accurate equipment logs and do we promptly report any maintenance problems to the right people?

Do we keep equipment and tools clean and store them in the proper manner?

Procedures

Are there written procedures that provide a "blueprint" or "step-by-step" instructions for performing our jobs?

Do we know and understand these procedures and do we carefully follow them?

Do we regularly check our written procedures and make sure they are accurate and up to date?

When we see an easier or better way, do we go ahead and deviate from our written procedures, or do we discuss the change with the right people first, and work through our Change Control procedure?

Do we make sure that we've received training on each procedure we use? Especially when they've been changed.

People

Do we have the necessary education, training, or on-the-job experience to perform our assigned functions?

Have we identified and learned the "must knows" for our jobs? For example, do we know and understand the safety standards and regulations that apply to our jobs?

Have we acquired the necessary skills or "most do's" that specifically relate to our jobs? For example, do we keep accurate records and do we safely operate our equipment?

Do we practice good personal hygiene?

Do we always wear the proper clothing and personal protection equipment in the workplace? And do we wear the clothing and equipment properly?

Working with the Data

It's important that each group write these questions down. We ask groups to come up with twenty to thirty questions. This technique pushes them to seek questions after the obvious handful of questions are developed. Most groups don't reach twenty, but most come close. It requires deeper thinking to get beyond the obvious few. Allow about ten to fifteen minutes for the groups to develop their questions. This tight timeframe (or deadline) helps groups focus on the task, and not get sidelined talking about anything but the topic at hand.

The next step in the process is to have each group present their list of questions to the entire training class. It is not unusual during this process for others in the class to think of additional questions. Asking the entire group to contribute additional questions helps prompt this process. Make sure you capture and write down these additional questions.

Now that all these questions have been prepared, it is a great opportunity to collect these and have someone organize these into an Audit Checklist.

Conclusion

This exercise of developing audit questions breaks the monotony of lecture and discussion of the GMP regulations. People are challenged to understand the intent of the regulation and think about how to assess compliance. This ultimately leads to a better understanding of the requirements and thus moves the people in the organization further along the journey of maintaining compliance with the GMP requirements.

A logical next step is to organize the participants into audit teams, where they conduct actual internal audits within your organization, using the checklist of questions developed in the training session.

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