A Risk-based Approach to GMP Training: One Size Does Not Fit All

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"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." This is the current wording of 21 CFR Part 211 Subpart B, Section 211.25 (Personnel Qualifications).

How is your organization interpreting and applying this section of the regulation? Many companies interpret this to mean something like – "We conduct annual GMP training for our production employees." Or it may even be interpreted as – "We conduct annual GMP training for all of our employees."

- Is this adequate?
- Will an annual dose of GMP training for some of your employees be acceptable to FDA? Will an annual dose of GMP training for all of your employees be acceptable?
- Does all employees include temporary employees?
- Does it include consultants or contractors?
- Does it include custodial staff, if your custodial operations are outsourced?
- Does it include members of the security force, if the security service is outsourced?
- Does it include maintenance personnel?
- Does it include those working off shifts – evenings, nights, weekends?

An annual refresher GMP course developed as a one size fits all approach may be easy to design and administer, but it is an approach fraught with danger. Consider the risks involved.

- Someone whose job directly deals with exposed product may not learn enough about GMP requirements to prevent contamination, mix-ups, or errors from occurring.
- Someone whose job is far removed from exposed product may be burdened with learning GMP regulations that have no bearing or impact on their specific responsibilities.
- Someone who was off the job due to disability, maternity leave, jury duty, or even vacation may miss the training session.
- Contract employees may miss the training altogether if they are not on the official company roster.
- Temporary employees may get too little training to ensure the safety of your products.

This article will help you develop a GMP training approach that meets the regulatory requirements and addresses this from a risk-based perspective. Deciding who requires what training is critical to getting started. Who should

develop and conduct the training is another key component of a successful GMP training process.

Who should develop and conduct the training?

The regulation states that "Training in current good manufacturing practice shall be conducted by ***qualified individuals***." What are the qualifications of a GMP trainer? A qualified trainer is certainly someone who has done more than read through the regulations. It is certainly someone who has done more than worked in the operation for a long time.

It's highly suggested that your company start by listing the qualifications required to teach GMP in the organization. Perhaps even develop a job description for a GMP trainer. Depending upon the size of your company, this does not have to be a full-time position. It can be duties associated with another job title. The important thing here is to document the qualifications.

Some suggestions for qualifications include:

- Experience working in the industry – a minimum of five years is recommended.
- Extensive knowledge of the GMP regulations. This is best attained by attendance at GMP seminars and courses offered by many industry providers.
- Knowledge and demonstrated expertise of adult learning theory and techniques. This is best attained by attendance at courses offered by industry providers. The American Society for Training and Development (ASTD) can offer guidance here.
- A demonstrated aptitude for teaching and training. There are several instruments available to assist in this determination.
- A passion for teaching. This is tough to objectively measure, but can often be detected by the level of enthusiasm an individual shows when talking about this endeavor.

Most successful GMP training processes utilize a combination of inside and outside resources. It's important to have company employees teach aspects of the regulatory requirements. It demonstrates that "We believe in these regulations, and our policies and procedures are aligned to comply with them." Employees of the company can also clearly demonstrate how the company policies and procedures address each aspect of the regulations. A sound objective of any GMP training process should be to gain the commitment of all employees to comply with the regulations and all company policies and procedures. Too often, training sessions appear aimed at coercing employees into compliance. I have experienced that by focusing on efforts to gain commitment among the workforce, compliance comes along naturally.

The efforts of your internal delivery of GMP training should be augmented with the use of outside experts. It's amazing how the credibility and status of your internal trainers goes up after employees are exposed to training by the outside

expert. There's something unique about hearing the facts from an outsider, especially if it's information that you've heard from your internal trainer. It's a way to validate the knowledge and credibility of your internal training force. An outside expert can also lead your people in discussions regarding leading issues within FDA, something internal people may not have the time or resources to do. An outside expert also comes free of any "organizational baggage" which may negatively impact the learning process.

Choosing an outside expert to help with your GMP training process should be carefully considered. Here's some questions to help you select the right expert.

- Do they have the technical knowledge?
- Have they worked in industry?
- Do they have hands-on experience in being on the receiving end of an FDA inspection or customer audit?
- How well can they connect with and relate to your employees?
- Do they have good presentation skills? (or are they a lecturer? Lecturing is a surefire method for a disastrous GMP training event – face it, regulatory training is not the most exciting topic, but it DOES NOT have to be boring.)
- Do they know how to design and deliver an interactive training session?
- Are they willing to coach and mentor your internal training people?
- Are they willing to work with you to customize the training?
- Are they willing to do the research required to ensure that the training they develop and conduct reinforces your internal themes and messages?

An outside expert in GMP training should be considered as a partner in your GMP training process. Your internal and external GMP training team can ensure that you have a state-of-the-art training process, and that your employees are getting the right dose of training when they need it.

Who gets the training and how much should they get?

The regulation states that "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and 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 as they relate to the employee's functions***." (21CFR Part 211 Subpart b, Section 211.25)

So the short answer is EVERYBODY IN THE COMPANY needs GXP training. Everyone working for the company is engaged in the manufacture, processing, packing, or holding or a drug product in some fashion. A clerk in Accounts Payable could impact the relationship with a supplier of a critical raw material. An Information Systems analyst could impact the operation of critical software

used in the manufacturing process. A sales person could make promises to a customer that could impact the production schedule. A service technician may discover valuable data in the field that could lead to product improvements. A security officer may leave a door ajar that could impact the safety and efficacy of a batch of product. We could write a scenario for every job in your organization and how that job is ENGAGED in the manufacture, processing, packing, or holding or a drug product.

Now the question is - **What level of risk does this job have on the quality of our products?**

It's important to identify the level of risk for each job title in your company. Keep it simple by identifying High, Medium, and Low risk for determining the level of GMP training required. Start by asking the following questions.

- To what extent does this job impact the safety and efficacy of our products?
- What is the probability of someone in this position contaminating our product? (An accounting clerk working in a building one hundred miles from the manufacturing site has no chance of contaminating a product. A shipping clerk who handles finished packages before they are shipped has some chance, while an operator working in the filling room has a high chance of contaminating a product.)
- What is the impact on quality of a mix-up by someone in that position?
- What is the impact on quality of an error by someone in that position?

The table below demonstrates how one can graphically display and organize these into High, Medium, and Low risk situations. This table is presented for demonstration purposes only – your actual situation will determine the risk level for each job. (Table 1 Job Titles and Level of Risk)

	HIGH	MEDIUM	LOW
Sterile Fill Room Operator	X		
Accounts Payable Clerk			X
Production Supervisor	X		
Information Systems Analyst		X	
Security Officer		X	
Human Resources Benefits Administrator			X
Quality Control Analyst	X		
Receiving Clerk	X		
Shipping Clerk	X		
Compounder	X		
Scheduler		X	
Payroll Clerk			X
Cafeteria cook			X

Table 1 Job Titles and Level of Risk

Completing this table shouldn't take long. It's best done by an ad-hoc team of subject matter experts (internal people with knowledge about these positions). To make the task simpler, create a table for each department. For instance, a table for Materials Management could be created. In this table you might have positions such as Scheduler, Receiving Clerk, Shipping Clerk, Material Handlers, Purchasing Manager, Purchasing Clerk, and others. Determining level of risk also depends on their proximity to products being processed. The Purchasing people may be in a separate building and never actually enter the building where products are manufactured or stored. A Receiving or Shipping Clerk may have to walk through a packaging area in order to get to their work areas. Knowing policies and procedures for the packaging areas would become an important part of their training, where it would not be for the Purchasing people.

The objective is to design "the right dose" of training for each position. Several positions can be combined based upon their level of risk and their general job responsibilities. Starting with the premise that every employee receives a certain dose of GMP training as part of their new employee orientation, we can use the tables to determine what follow-up training is required and how frequently to conduct that training.

Of course, those positions with higher risk levels should be accorded more in-depth training and more frequent training. Guarding against complacency, or "rustiness on the job," is the main reason the regulation stipulates that "Training in current good manufacturing practice shall be conducted on a ***continuing basis*** and with ***sufficient frequency*** to assure that employees remain familiar with cGMP requirements applicable to them."

How frequent should we conduct GMP training?

The answer is IT DEPENDS. It depends on the risk factor. It only stands to reason that those positions with a higher level of risk should get training more frequently. Keeping people fresh is paramount if the level of criticality is high. Commercial airline pilots have to be re-certified in their jobs every six months. Are only the bad pilots called in for re-certification? Of course not. All pilots are required to pass the re-certification process.

The employees of the airlines who check us in at the gate or handle our baggage have a different dose of training and re-training for their positions. Sending someone's bags to the wrong location, although irritating to us passengers, does not carry the same risk level to the passengers as a pilot who reacts too slowly or overreacts when caught in a wind shear situation.

Sufficient frequency of GMP training for someone working inside a sterile filling area, a position with a high-risk level, might be interpreted as once each month. This can be a formal GMP training session with an instructor and handouts or workbooks. Another month it may be a portion of a department meeting dedicated to discussing GMP issues,

with a Supervisor presiding. It may be specific GMP lessons embedded into a game show format during a particular month. It may be a guest speaker from a different department. It may be a formal class with an outside expert. It may be something slightly different each month. As long as it's planned as part of an overall training process, the delivery method may vary. In fact, it should vary, not only to keep it interesting, but also to appeal to the different learning styles among those attending the training.

Consider someone who may work in Human Resources as a Benefits Administrator and their risk level is low. Perhaps their office is in a separate building and they have no authorization to enter any building where product is either manufactured or stored. What is sufficient frequency of GMP training for this person? The general GMP training provided in the new employee orientation process may be sufficient for this position, unless there are changes to the regulations or the company's policies and procedures. An annual workshop on GMP may be desirable to ensure that these folks continue their vigilance of working in the health care industry.

This training should focus on how their specific responsibilities impact and affect the commitment to GMP throughout the company. Using the example of Benefits Administrator, consider the impact on employee morale of changes to employee benefits. Poor morale often increases the probability of mix-ups and errors throughout the work force.

Document the training

Make sure to document each training session. There are several commercially available training documentation software packages available. Make sure you use one that can provide the appropriate reports. The biggest benefit of preparing reports is in keeping track of who has received what training. This can be quite a task with peoples' vacation schedules, jury duty absences, and other absences due to illness, family leave, disability, and other reasons people miss work. Scheduling people to attend the make-up sessions is easier with the proper reporting structure in place.

This documentation also provides proof to FDA that you have a training process in place that is working. Your risk assessment training tables are also useful to show to FDA during an inspection as further proof that you have a well-designed GMP training process that uses the risk-based approach.

Training as a Process

Viewing your GMP training activities as a process, and not just a series of events, can help you ensure an ongoing commitment throughout the organization. Determining different levels or "doses" of training geared to specific groups is the best course of action.

One size does not fit all.

Specific targeted training is more effective over the long term. Basic introductory courses addressing all three risk levels should be part of someone's training plan when they join the company. They then can enter the process of on-going GMP training with their colleagues. How much training they receive and how frequently they receive it depends on many factors. Using the risk-based approach is a simple and easy to implement method to design and manage this process.

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