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Commentary: Training–Doing it Wrong!

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Without question the need for staff training is an essential element to attain quality and, as such, is a GMP prerequisite in every GMP code worldwide. The European Unions (EU) good manufacturing practices (GMPs) (in section 2) states that "All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs." The US current good manufacturing practices (cGMPs) (in *Code of Federal Regulations [CFR] Title 21 Part 211.25*) state 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."

However, these requirements, while stating the bare essentials, leave lots of questions to be answered. For example, in the US, training shall be by a "qualified individual"–what makes a "qualified individual?" Is this a training professional (perhaps an ex-teacher) who knows the theory and practice of teaching (perhaps only to grade school children, which is very different from teaching adults), but who does not know anything of the technology being discussed? Or is this a technical person who knows the technology inside and out, but who cannot get a message across? In thirty years of attempting to get an answer to this question, I have gotten nowhere!

I suppose that we need to start at the basics. What is the task that the person being hired to perform? It is amazing to me how many professionals in the pharmaceutical industry either do not have a job description; or they know that one exists but they have never seen it; or over the years the job that they were hired to perform has gradually morphed into a different job with different responsibilities, but no updating of the job description has ever happened. A proper job description needs to be in place and approved in order to interview a potential candidate–consider it the quality acceptance criteria, which if not met would result in the candidate not being hired. If you do not have a job description, then how as a manager can you objectively evaluate a potential candidate? If you have a job description, then you need to also ask the question–when hired, how will the candidate be expected to work to fulfill the expectations and requirements of the task? The answer to that is that there are standard operating procedures (SOPs) in place that define how work needs to be performed in order to fulfill the tasks described. So, before we begin any ideas of training, we need a job description in place and a set of SOPs for the job incumbent to be trained in–often termed the job description/SOP matrix.

Every position needs a description, a list of SOPs that when mastered means the incumbent can effectively perform the task, and a sub-list of core SOPs that must first be mastered in order for the incumbent to be allowed to work under supervision. Core SOPs for a laboratory analyst or for a weighing operator can be as mundane as "data recording," "performing calculations," and "understanding what an out-of-specification result is" (and yes, they happen in manufacturing too!).

There are two hiring scenarios that reflect themselves in training–the new hire that joins the company from school or college, and the new hire that joins the company from another company. The new hire from school or college is relatively easy to train; they have no previous knowledge or expectations–they are a blank slate. Harder to train are new hires whose heritage is another pharmaceutical company or an allied industry, such as the chemical industry, where the degree of exactitude we expect is not as stressed. Either way, a new hire with previous industry experience represents two challenges–the challenge of undoing his/her prior work habits, and the challenge of training him/her to work to the company's methods, a very different training exercise.

According to the regulations, there are two types of training requirements–GMP training and on-the-job training (OJT). OJT is the relatively easier of the two. OJT requires that the worker understand and work to the SOPs, the batch record instructions, and other company documents that define how a job is performed. GMP training is more difficult and perhaps more nebulous. It requires the worker to understand the concepts, philosophy, regulations, and implementation of GMP by the authorities. If a worker does not understand the

“why” behind the GMP requirements, then the GMP training has failed. Why is the use of “white-out” unacceptable? Why can quarantined raw material not be used in production? When I audit the effectiveness of training, I always ask workers these questions (amazing how often I get a blank stare as a response). Teaching the philosophy and engendering a mindset of “quality” is what GMPs are about. It is extremely difficult, and it is why all GMP codes worldwide require such training to be provided and frequently repeated.

For reasons that I have never understood, many companies regard repeat GMP training as a literal word-for-word repeat of the induction GMP training performed annually. In many companies, staff dread these sessions yet sit through them as a relief from the routine everyday activities of production, packaging, or lab work. Nothing is more boring than hearing the same presentation year after year after year (does this sound familiar?). And, again, for reasons that I have never understood, many companies have an annual GMP training day for all staff. Actually, it is usually not a full day, but typically one, two, or four (very occasionally six) hours depending on production or laboratory constraints; typically vice presidents and director level management always seem to find a reason why they are too important, too busy, too educated, or too erudite (pick any reason) to attend–even though the GMPs explicitly require their attendance. Actually, this is a western world, primarily arrogant US management, cultural issue. I am frequently invited by Japanese companies to present GMP training to management committees and to boards of directors; the exact people who need GMP training to understand the impact of their financial and strategic decisions on the company’s quality image, reputation, and regulatory compliance posture.

Assume for a moment that I am the world’s greatest lecturer (which, of course, I am!), and you are the world’s greatest student (which, of course, you are!); repeated studies have shown that two weeks after a training session I present to you, for any task in any industry, you will remember only about 10% of the training delivered (and although repeatedly asked, I will not shorten the training session to cover just the 10% most important points–why, because then you’ll only remember 10% of that).

Think for a second–what is the job of the army? To defend the nation. How does it do that? By training soldiers in, among other things, how to shoot a rifle. Are soldiers trained to shoot once a year? Of course not. They are trained and drilled in the actions and reactions that they need to perform every day, in rain or sunshine, day and night, when they are fresh and when they are bone-tired. The army cannot wait for a soldier to be fired on by an enemy and only then have the soldier start thinking about what action he needs to take–actions need to be instinctive and ingrained. So it is in the manufacture of pharmaceuticals. Far, far, better than a once-a-year GMP training day, is every week to have a “GMP Moment,” a 15–20 minute departmental GMP session. Each week pick a different topic relevant to the department to discuss. For example, go over complaints received in the last quarter and how they can be traced to the department’s actions. Review a US Food and Drug Administration Warning Letter issued to another company, and discuss whether your department might be guilty of the same types of action, or inaction. Review new SOPs issued that week of impact to the department, etc. Small-dose repetitive training beats once a year mammoth sessions hands-down for training effectiveness.

All companies have some type of induction GMP training for new employees. Unfortunately, when exactly that training is provided depends on the type of new employee you are. Hired for permanent work, then you typically receive GMP training during your few days on-site; hired as a temporary worker, then your GMP training might be provided during the first week, the first month, the first quarter, or perhaps never–a situation which, from a product quality perspective, I have never understood. Customers deserve the best quality medication your company makes, regardless of whether it was packaged by a permanent or temporary worker.

Induction GMP training ranges from the brilliant, where concepts are explained and examples of the impact of non-GMP compliant practices on patients are elaborated on (see my article in a previous edition of this journal–“Death by GMPs” for good examples you can use in GMP training sessions), to the abysmal, where the regulations are read in monotone and each worker is provided with a pocket copy of the GMPs *(Conflict of interest note: in a former life, in my many years as a book publisher I made a fortune selling copies of “pocket GMPs,” knowing full well, that once distributed to staff, they were hardly ever looked at again!)*. Trying to sell GMP compliance to staff because “the regulations say we must” is like me trying to get my teenage son, a new driver, to obey the speed limit because “the regulations say you must drive slowly on residential streets”–a waste of time. Unless people understand the logic of regulations, the “why” of the regulations, they are an abstraction and will never become a way of life. I finally taught my son to obey the speed limit by having him volunteer at a hospital emergency room over a Christmas weekend where all the drunk and speeding drivers were being treated for wounds and injuries. The concept of death is not real to a teenager; if they do not obey the traffic regulations, the concept of becoming a paraplegic is very real–and seeing the victims drove the point home. Same with GMP training–it needs to be designed to push whatever button is relevant to the worker, analyst, manager, vice president, and board director (for whom I tailor GMP courses with data on the financial impact of non-quality that affected the company in the past year, and how GMP compliance could have dramatically, and positively, impacted the company’s bottom line).

Actually, the biggest training crime is the “talking head” GMP training session. Several companies I know have video recorded their boring GMP training into a two or four hour unedited video. New hires, or annual repeat trainees, need to sit through this–nobody to answer questions, just watching the monotone talking head, and afterwards signing a form that they had been through induction/repeat GMP training. If you think that the original training was boring and ineffective, watching the video is guaranteed to induce torpor, and retention of points drop to perhaps 1-2%. What a stultifying training, and what a tragic introduction to the company for a new hire! Many times

commercially sourced videos are not a lot better (but management feels better as they have paid a fortune for these tapes, and the authorities never quibble with commercial training tapes, so by definition they must be good!).

There are lots of things wrong with GMP training as performed by many pharmaceutical companies today. Yes, the regulatory requirements of the GMPs have been fulfilled, but what a waste of time and effort. And what a waste of an opportunity!
