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REVIEW

Application of Lean Thinking in Pharmaceutical cGMP Training

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Current Good Manufacturing Practices (cGMP) consist of the regulations, guidelines and recommended practices issued by the FDA and other international regulatory authorities, as well as by the current industry practice. They form the basis for the production and the testing of pharmaceutical products that are safe and effective for human use. Regulatory publications are necessarily vague so that manufacturers have the opportunity to incorporate innovations into their products. Thus, the practitioners of cGMP must strive to be up to date on the latest innovations. cGMP compliance ensures that the products which are produced, meet specific requirements for identity, strength, quality, and purity.

Developing a Successful Training Programme is increasingly becoming an essential requirement to satisfy regulatory agencies; for example:

In the US, the CGMP Guide published by the FDA defines in 21 CFR § 211.25: "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. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that the employees remain familiar with the CGMP requirements which are applicable to them.

In Europe, the requirements for the GMP-compliant manufacture of drug products are laid down in the EU GMP Guide. Chapter 2 says that: "The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel) and for other personnel whose activities could affect the quality of the product."

The Canadian GMPs require that: "All personnel must be aware of the principles of GMP that affect them and must receive initial and continuing training which are relevant to their job responsibilities." Completing our proven training programs will ensure you meet these training requirements (GMP Regulation C.02.006 Interpretation 5).

The Indian "Schedule M" Part I, Section 6.6 requires that: The licensee shall ensure in accordance with a written instruction that all personnel in the production area or into Quality Control Laboratories shall receive training which is appropriate to the duties and responsibilities which are assigned to them. They shall be provided with regular in-service training.

Who is Responsible for the training program? The procedure should define as to who is responsible in the organization oversight of training efforts, design and delivery of the training events and auditing to be sure that a training program is working. Normally, the responsibility of GMP training is a part of the quality

assurance (QA) department or there is a separate GMP training cell with the support of the individual operations area. Some companies include GMP and skills training as part of the human resources (HR) organization. Use caution; some HR groups are not sensitive enough to the special compliance issues that are part of GMP training: It is not just another "soft skill" topic, a "nice-to know" course, or one that a generalist can teach.

Qualification of instructors. GMPs require that instructors be qualified; in a cGMP training procedure, you have a chance to define what that means. One way is to establish minimum instructor requirements such as successful completion of basic and advanced GMP training and communication skills such as successful completion of a presentation skills workshop. Then, for each course, define what additional knowledge or skills the instructor needs. For example, an instructor of a course in basic GMP and quality auditing should have experience as an auditor. Sometimes it is difficult to find good trainers who also have solid experience or knowledge in a particular technical area. For example, I've seen experts in computer validation who are competent in developing and executing protocols, but are noticeably uncomfortable in leading a class. That is an excellent opportunity for co-teaching: an experienced instructor helping to lead the formal sections of the course and the expert serving as a resource to relate experiences and answer questions. If a co-teaching approach is used, both people should be qualified as a team, and that should be provided for in your training procedure. The quality unit should review and approve potential instructors.

Who is to be trained? In this part of your procedure, identify the general audiences for training. This includes operations, maintenance, lab and technical staff; it also includes a permanent management (A person who has signed a letter of offer with regards to permanent employment. This person may either work full time or part time.) (read 21 CFR 211.25b), contract (A person who provides a service or performs a task on behalf of a company, but is not employed by the company.), temporary (A person who has signed a letter of offer with regards to employment, where the hours of work are not regular and may vary, based on the business requirements to meet a short-term need), and consulting personnel. As I work with drug and pharmaceutical managers, I encourage them to give some GMP training to everyone. Because GMPs are product-critical, everyone in an organization needs to have some "GMP literacy." As you consider audiences for training, do not forget senior- and executive-level management who make GMP-related decisions. Temporary (temps) and contract personnel present a particular training challenge. Organizations like to use them for flexibility and to keep head counts low. That doesn't excuse a company from the GMP procedure training requirements. One company that made extensive use of temps was told by local FDA investigators that FDA would review temp and contractor training in future inspections.

Types of training covered by the procedure. GMPs call for training personnel in the application and interpretation of GMP regulations and in the tasks that they perform. Various types of training programmes are conducted and documented at pharmaceutical manufacturing locations.

The various types of Training programmes are
Induction Training
cGMP Training for New joiners.
Refresher cGMP Training
SOP Training
External Training
Specific Training
On the Job Training
Snap test
Retraining

Induction Training:

During the Induction training program, any individual joining a manufacturing plant as a trainee or as a new employee has to undergo Induction Training. The QA or Training Dept personnel brief them on the following topics:

Personal hygiene

cGMP and its importance in the pharmaceutical industry.

The briefing is done orally and the document is signed off by the QA or Training personnel in the Training and the records are retained.

cGMP Training for New Joiners:

This program covers all new employees and trainees who join the organization. During this training, Employees are categorized into two groups for the cGMP training program.

Group – I comprises of employees with a Pharmaceutical Background either in Education or Experience.

Group – II comprises of employees without a Pharmaceutical background either in Education or experience.

Training is conducted for each category of employees on the following topics.
Basics of cGMP
Glossary of cGMP
Quality Management System
Process and Documents, flow / controls and procedures
Video CDs on relevant topics are also being included.
cGMP Training is conducted as classroom training. The training is followed by an assessment and is documented.

3. Refresher cGMP Training:

This training is classroom training which is conducted once in 6 months to 1 year duration covering cGMP requirements.
For refreshers, cGMP Training programs employees are divided into 2 groups.
Group – I
Group – II
Separate sessions are conducted for each category of employees.

4. SOP Training:
All employees undergo training on the procedures of the respective functions. SOP training is also given to employees from cross function wherever applicable. SOP training is given on the job or as classroom training. Refresher training is carried out whenever there is a major procedural change. These trainings are assessed and documented.

5. External Training:
The concerned department HOD nominates people for External Training, depending on the type of training and the need of training. The nominee submits a copy of all the training material pertaining to technical training to the QA or the Training department.

6. Specific Training:
Specific training is conducted in accordance with identified training. Specific training is on the job or Classroom training. The training is documented.

7. O
n the Job Training:
On the job training is carried out in the departments, wherever applicable. On the job training is assessed by the trainer with an assessment or a demonstration of the procedure by the trainee and the same is documented in the assessment record.

8. **Snap Test:**
Snap tests are surprise tests conducted in various departments on various topics. Snap tests are conducted to check the awareness and adherence to the systems and procedures.

9. Retraining:
Retraining is given to employees who are not qualified in any of the above assessments.
The minimum qualifying marks for the cGMP, refresher cGMP, SOP training and Snap Test assessments shall be 75%.
The score in the given assignments are converted to %, if the maximum marks are not equal to 100.
All training documents should be retained for a period of five years.
The same are to be destroyed and documented in the Destruction Record.

When training is conducted. GMPs require that training be ongoing. Most companies conduct formal GMP training or reinforcement training at least annually; some do it twice a year; a few do it quarterly. Training on specific GMP-related skills (such as conducting root-cause analysis) and on new, revised, and unchanged procedures should be considered here as well. (In an upcoming article, I will discuss frequency of SOP training.) Be realistic as you set training intervals so that you can actually accomplish what is defined.

Learner assessments. Your company's use of testing or assessment is described in this part of the training procedure, including the types of assessment used (such as pen and paper, "orals," computer-based or performance-based). A particularly important element is to determine what constitutes passing and what happens when an employee does not pass a test. You do not want to create the awkward situation of a person independently performing a GMP task on which he or she has been assessed and failed. Consideration also must be given to other legal issues of testing on the job if it in any way affects a person's salary or position.

Maintenance of training materials. FDA and regulatory agency expectations regarding GMP and regulatory compliance change over time. An SOP should include a provision for periodic review and the updating of training courses and events. All changes should be approved by the quality unit before being implemented. The plan also should consider the impact of new content on those who have already taken the course; alternatives to retaking the full course may be adequate.

Documentation of participation in training events. Several elements figure into documenting when someone completes a training course. For leader led sessions, the minimum information is a sign-in sheet with the person's name, signature, name and number of the course, date of the session and the instructor's name and signature. The participant's signature attests that he or she has attended the complete session; the instructor's signature attests that the program was given and that the people listed did attend. Many companies enter the attendance list into a training management system e.g. Training Tracker. Your procedure should define how this is done, including verifying the transcription, retaining the sign-in sheets and controlling the system. Some e-learning courseware automatically feeds completion and testing information into a training management system. If such software is used, it also should be described in the procedure. If testing scores or pass–fail assessments are collected, it is useful to include them in the training management system.

Attendance in outside training and educational events (such as conferences and technical meetings) also should be documented because it contributes to a person's "education, training, and experience." Copies of certificates, continuing educational units (CEUs) and program outlines or mailers are useful records to retain. Some electronic training management systems have provisions for documenting outside events. Your procedure should define where such information is kept (preferably not as part of the person's confidential personnel files) and how long it should be retained (typically several years beyond the last date of the individual's employment).
Your training procedure also should consider keeping records on temporary and contract personnel who must meet GMP training expectations. Training management systems often are tied into a company's personnel and payroll database, which does not include temporary or contract people.

Documents and Records

1. Training Docket:

Training Dockets are prepared for every Training which consists of Training Material (If Applicable), Training Key or Questionnaire (If Applicable), Training Record, Filled in Questionnaire (If Applicable) and Training Summary (If Applicable)**.**

Personal Training Record

It is the responsibility of every individual to maintain and regularly update the Personal Training Record for each and every Training attended.

File of Induction Training: Current format of the HRD for Induction.
File of cGMP Training for New joiners: Training record, Training material with Key to questionnaire.
File of Refresher cGMP Training: Training record, Training material with Key to questionnaire.
File of SOP Training: Training record.
File of External Training
File of Specific Training: Training record,
File of On the job Training: Training record
File of Snap Test
File of Personal Training Record: Personal training
Certification of the employee
Trainer Qualification records

Case Study: Application lean thinking in the Pharma cGMP Training Department

This study is the implementation of lean thinking concepts, tools and processes in the Training department of the pharmaceutical formulation manufacturing unit, which is responsible for the approval of various elements of the training Program. The training department is a part of the Quality Assurance Section. The QA Section reviews and approves the GMP related training courses which are particularly important. The QA Section makes sure that the courses are completed and accurate and covers topics by using examples that are relevant and meaningful to the learners. The quality unit also reviews and approves GMP-training curricula for job functions or respective positions.

LEAN THINKING

Fundamental to lean thinking is the conversion of waste into customer-defined value (Womack, 1992). The training department serves four functions: Training Identification, Planning, Training and evaluation. Teaching is the most important function by the concern of the Training department and the SOP of the Training. Employees or Learners who join this respective manufacturing unit, are consumers of knowledge. Therefore, the study of lean thinking concepts, tools and processes concentrate on delivering values to these employees (Womack, 1996). Value can be defined as GMP knowledge that employees use in

their Job work and activities. The ultimate value that employees look for, can be divided into two parts: value to the Job i.e. cGMP compliance and value to personal interest. The value that employees can receive from the Training department depends primarily on two factors. One factor can be described as what employees learn, which depends on the Training topics structured under the programs which are provided by the training department and the details of knowledge under each programme.

The second factor is how employees learn. Because both factors depend on the Training department, the Training Department is responsible for structuring programs to provide the employees with a broad background in Pharmaceutical GMP and in-depth focus in their areas of work and to transfer the knowledge to the employees in the most effective ways.

There are two significant parts in delivering value to employees;what the employees learn and how they learn it. There is only one process that adds value to the employees in the pharmaceutical manufacturing unit and it is the process of transferring knowledge, which combines two parts to deliver value to the employees. Two important processes which deliver value to the employees are: the process of transferring knowledge to the employees and the process of assessing employees for the knowledge that they receive. Transferring knowledge to employees should include the objectives of each program and what they will learn. The "assessing employees" step should be able to evaluate the employees' performance to determine if they have learned the material.

1. THE PROCESS OF TRANSFERRING THE KNOWLEDGE TO EMPLOYEES

Program Objectives

The objectives of each training should be stated precisely. Employees are entitled to know what the Trainer expects them to learn. The whole course should be in place before the training begins. The Objectives should specify the performance measurement method that can be used by the employees and their Trainers.

Program Nature

The main objective of the training department is to have the Employees achieve the full understanding of the program. The Training Department cannot expect all Employees to master the program at the same time, but personalized lessons for each employee should be implemented to effectively deliver value to the organization. Smaller amounts of material are more digestible than larger amounts and the Employees will learn better if they are given frequent and immediate rewards.

Program Delivery

Because the whole programs are in place before the employees are enrolled, the trainer's responsibility for each program will be different from the traditional one. The program will be changed from different department - employee.

Modules

Two main characteristics found in GMP programs in the Training Department, are the content of knowledge and the application of knowledge. The instructional types of content-based knowledge must be self-contained and the Employees should be able to repeat these instructions without trouble. The application-based knowledge can be transferred to Employees in the form of instructions that let them practice to use the knowledge. The examples of these instructions are lab studyies, work projects, workshops, group discussions, problem solving and evaluations.

Support Systems

In order to keep the changes moving smoothly, the support system is created to help the Employees in the changed environment of the program. The support system includes creating on-line training and group communication and making the information available to everybody.

2. THE PROCESS OF ASSESSING EMPLOYEES FOR THE KNOWLEDGE THAT THEY HAVE RECEIVED

Test

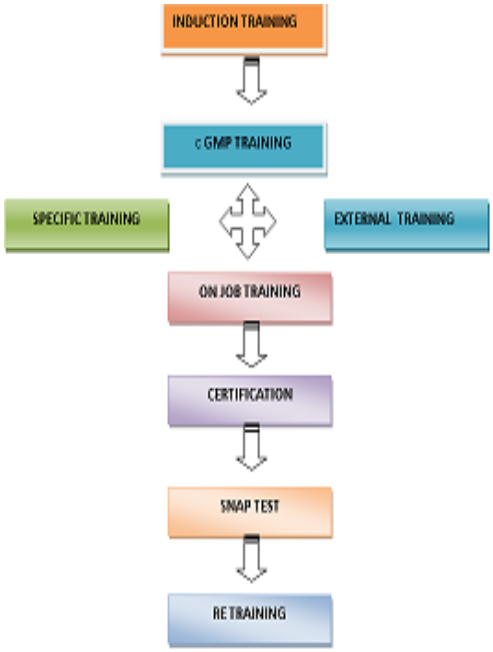
The employees should be examined to see if they have achieved the stated objectives. The tests should provide immediate feedback to the Employees so that they would have a chance to go back to the materials and achieve the objectives in the next attempt. The trainer should talk with an employee who needs help.

Grading

The grading system is divided into two parts; The Attendance and tests. There will be no marks for training attendance. In the test part, the Employees can take the test as many times as they need to pass it.

3. THE LEAN EDUCATION FLOWCHART

The figure below shows the lean process in the Training Department. By using this flowchart, the Trainer can monitor the Employees and respond to their actions quickly. Furthermore, this information can be used as an improvement opportunity. The trainer will be able to see as to which section the majority of employees have problem with. So he/she can make the necessary changes to reduce problems and improve the quality. When information from tests, questions from Employees and discussion with Employees and department heads are used, the opportunities for improvement are endless.



Table/Fig 1: Training Flow chart

CONCLUSIONS

The expected results of lean training and the comparison of lean training with traditional training are shown in the following table:

Table/Fig 2. The Comparison of Lean training with Traditional training

BEFORE APPLYING LEAN CONCEPTS	AFTER APPLYING LEAN CONCEPTS
Trainer has control on course contents and instructional styles	Employee benefits are the first to concern in creating instructions
Employees might not know what they will learn	The objectives are stated clearly to employees so they know what to expect
Boundary of content is not clear and might be different with different trainer	The whole course is planned out before, so there is a standard in each course

Knowledge is pushed to Employees	Employees study at their own pace
Only courses that have enough Employees are opened	Every course is opened every session
Employees might finish the course with poor understanding	Employees have better understanding with section perfection requirement for advance
Employees have to get advisor signature for class registration	The information is available for employees to decide what class they want to take
Programs and courses are hard to find	The information is available online and easy to access
Overload of assignment without an objective	Cross-department and personalized assignment is created

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