100 TIPS FOR TRAINING THE GMP TRAINERS

By Rajkumar Gupta, Managing Director Perfect Pharmaceutical Consultant Pvt. Ltd and Director Global Institute of Regulatory affairs, Pune
Mr. R.M. Gupta (M. Pharm.), is a free lancer consultant for US DMF, COS, ANDA, ACTD, CTD, eCTD and other regulatory submissions. guptarmg1952@gmail.com
He is associated with Perfect Pharmaceutical Consultants Pvt. Limited (http://sites.google.com/site/ppcdmf) and Global Institute of Regulatory affairs (Pune, India).

He is dedicated solely to pharmaceutical regulatory profession.

He is well recognized GMP auditor and cGMP Trainer of Trainers (cGMP TOT) for

Pharmaceuticals (Parenteral/Liquid Orals/ Tablets/Capsules/Vaccines/Beta lactam) /API/Herbal/Medical Devices/ manufacturing Facilities

This article is solely written by him to guide, educate and training cGMP Trainers at large. The article is based on self experience of 25 years of the author

INTRODUCTION

The Pharmaceutical manufacturer should provide training to all the personnel employed directly or indirectly into production areas, control laboratories, quality assurance, regulatory affairs, maintenance, stores, sanitation, hygiene, safety, pest control and other areas such as R&D

Beside the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. The special attention is required on adult employees which are very hard to be trained. Further, it has been noted that the management representatives often refuse the GMP training. Infect they are the first and core people who shall be trained on priority. Training programs should be well designed and must be pre approved by Quality Assurance Department of the company. Training records should be kept.
Personnel working in special areas e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled should be given specific training.

I have been practicing as cGMP Trainer for the last 25 years. It's my hard core experience that GMP training doesn't always make a difference in attitude of trainees towards GMP compliance.

I understand this is not a fault of the trainees but it is the fault of the trainer. This article is specially written for training the trainers for effective cGMP Training which really works and makes difference in the attitude of trainees.

TRAINING THE TRAINERS

The trainers shall be trained to adopt following guidelines to ensure best results out of their training

A. TRAIN THE TRAINER TO ASSESS THE SUITABILITY OF THE TRAINING FACILITY

1	The facility must provide enough space for each trainee to spread out the materials that they will be using during the training
2	The visibility to the visual aids shall be satisfactory from all locations
3	The environmental control (temperature, humidity and supply of fresh air) shall be appropriate during all seasons. Training under adverse environmental conditions is usually ignored. Training under very comfortable conditions may induce hypnotic effect on the trainers and trainees.
4	The facility shall be sound proof. There shall be Complete barrier to outside noise and distractions. Further the sound shall not resonate.
5	The audiovisual equipments provided in the facility shall be appropriate and in good working conditions. It is not very uncommon to find disturbing noise associated with audio equipments. All the equipment shall be located in predefined position. The necessary extension cords shall be available for relocations as needed.
6	The water and refreshments facility shall be appropriate to seasonal needs.
7	There shall be an expert staff to check that the facility is in order before each training session begins.

B. TRAIN THE TRAINER TO PLAN FOLLOWING IN ACTIVITIES IN ADVADVANCE

8	Preparation of Slides/Video for training. The fact is that “The plain speech commands not even 15 % stake in learning but live discussion and audio visual presentation commands 50 to 60% stake in learning.”
9	Background Analysis of each trainee. This will help him to deliver effective talk matching to their qualification and experience.
10	Designing content, mode of delivery and effectiveness of all training activities.
11	Shortlising topic on which the trainer can impart effective training. He shall accept training assignments matching to his core competency.
12	Scheduling all training sessions with date, time and place in advance in coordination with the respective departments
13	Learning Trainer to Trainers and trainees expectations for particular training sessions.

14	Designing a scheme for distributing training documents. Normally training documents are provided 30 minutes before the training session and electronic copy at the end of the session. However, this shall not induct the trainees to abstain from the training sessions.
15	Establishing his true identity and credentials. The trainees respond quickly when they know the trainer is really experienced and knowledgeable. The trainer may be introduced by Managing director / Trainer of Trainers/QA Head
16	Identifying the key components on which he must stress during all his training sessions.
17	Designing a suitable Training manual with the help of departmental heads and TOT.
18	Designing training style by which trainees will remember maximum of what is said. The watch word of the trainer shall be "Listen, See and Rember". The training which is remembered to the extent of 50% is termed as the best
19	Selecting the most powerful ideas for training. Some trainers display recorded video of FDA officials/Company Directors on cGMP Compliance to impress upon trainees.
20	Securing approvals from QC/QA/Production department for his training materials. Nothing shall be contradictory to actual GMP/GLP followed at the site. The trainees shall not be confused with contradictory situation between what is said during the training and what is actually practiced
21	Verifying the integrity of the Training Notes. The trainer must ensure that the training notes comply with the current GMP and the latest amendments issued by regulatory authorities. There shall be proper authorization and review date on the notes.
22	To design comprehensive notes on training to be provided. The notes shall be devoid of confusing text or pictures.
23	To update the training material from time to time in terms of the contents and visual appeal.
24	To prepare annual training calendar for cGMP with due discussion with management, regulatory affairs department and QA

C. TRAIN THE TRAINER TO COMPLY WITH FOLLOWING SOP DURING TRAINING SESSIONS

25	To introduce himself before beginning the session. Unless the trainees know that he is an expert, his words will be taken very casually.
26	To be aware of adult/literate/illiterate learning theories.
27	Not to over talk. The trainer must know that just talking affects only 15 % of mind but the live discussions/visual aids/videos affect the mind to the extent 40 to 50%
28	To focus on understanding of the facts rather than memorization.

29	To be patient if something goes wrong with the presentation system
30	Not to bypass or neglect any question raised by trainee. The trainer shall not raise question on question. Many of the trainers never answer questions to the point. They often drift from the question and confuse the trainees. The trainers must be strongly advised to avoid this practice.
31	To use language and a pattern of instruction to get GMP message across
32	To use simple phrases and short sentences which are easily understood by weak to weakest of trainees
33	To be cool, patient and to the point during the training sessions. Trainer shall avoid shouting/scolding/insulting/criticizing which normally demoralizes the trainees.
34	To speak in firm tone indicating confidence.
35	To appreciate an intelligent understanding and smart answering
36	Not to be too fast and monotonous during training sessions. The trainer shall smile and joke during the session to keep it alive.
37	To invite the trainees to discuss their progress and problems.
38	To use pictures, cartoons, graphs, tables, flow charts liberally to explain the GM concepts. To share interesting examples, stories , self experience and participants experience during the training
39	Not to dictate word to word notes. Further, he shall not offer explanation on matters which are simple to understand
40	To design short and readable slides. The slides with text in small fonts are unreadable especially by trainees sitting at back benches.
41	To Laugh and make the class laugh at times. It will improve attendance and provoke listening and learning.
42	To use Quotes from GMP experts/FDA officials/FDA 483 finding to stress crucial Points
43	To adjust the level of training after few sessions to match the knowledge of trainees.
44	To avoid phone calls and other distracting acts during the training.
45	Not to use any negative quotes. It distracts the participant from training.
46	To identify productivity limiting gaps and support corrective action, through training and development
47	To activate the participants before starting the training session. He may ask the participants to communicate key themes to be discussed
48	To talk in his own words rather than the lawful language of GMP
49	To ensure that the participants understand the subject. He may frequently confirm the same by asking “if they have understood or not”

50	To allow free discussion on the subject. Let the participants comment as they like. Remember that the participant's best learn through their misunderstandings Unless the misconnecpts are emptied the correct concepts may not get in the mind firmly
51	To break the training session when it gets boring or when the participants get exhausted
52	To explain the subject from all the angles which human mind can think
53	To treat all the participants with dignity and equal respect.
54	To be very punctual with the timings.
55	To anticipate likely questions from the participants and shall be ready to answer the same. The most general queries in the training are based on concepts such as: who? What? Where? Why? When? How? Which? How Much?
56	To be aware of language barriers. The trainees prefer the language in which they are most comfortable. A translator may be employed if the trainer is not experienced in the required language.
57	To emphasis on effective communication, leadership, team building, time management and performance appraisal along with the technical aspects of cGMP.
58	To deliver the training with great interest, zeal and enthusiasm
59	Not to let arguments dominate the discussion. Encourage participants to re-focus on the main topic after argument if any.
60	To avoid interruptions such as use of mobile phones during the training session. Neither the trainer nor the trainer shall use any mobile during the training
61	To restrict distracting acts e.g. nervousness, slurred speech, shouting, sluggishness, blank face, monotones speech
62	To Provide the participants with an atmosphere of trust and safety. The trainer shall help the trainee to overcome anxiety and other negative emotions that they often bring with them.
63	To provide breaks at least every 60 minutes for snacks, water, personal cleaning and important phone calls.
64	To encourage the trainees to contact him and other team members for any personal queries.
65	To use positive sentences as far as possible. The negative sentences shall be avoided
66	To involve trainees in the management of the training session. This may be done by appointing "Monitor for the day" among the trainees for each session
67	Not to be panic when a particular trainee is silent. You may wait patiently for him to think about what he want to say
68	Not to ask any personal questions which might embarrass the trainees

69	To be attentionful to the whole class. The trainer may go around the whole class to pay attention on each and every trainee. However, he shall not over do the same.
70	Not to dispute and conflict with the trainees to establish his identity and supremacy. Further, not to accept over smartness/arrogance of any trainee.
71	To bridge one topic to the next. To use the topics in logical sequence and to recap at the end of each session
72	To exhibit his deep concern towards effectiveness of his training. Trainer shall frequently check whether every trainee has acquired the necessary skills and knowledge
73	To analyze the factors which inhibit the effective learning and to act on them suitably.
74	To develop relationships with the trainees so that they pay maximum attention during all sessions**.**
75	To focus on sustained learning. The initial learning is difficult. However, once there is little knowledge the brain starts demanding more and more knowledge
76	To check the knowledge, attitude and performance of trainees appropriately
77	To evaluate time effectiveness of the training. No management wants to spend long hours on training. They need quick results.
78	To invite feed backs from the management and trainees on their training.
79	To talk with the trainees and not with the black board or Visual Aids. The trainer must just show the visual aid and than explain the subject smartly while facing to the trainees.
80	Not to shout/quarrel/dispute/abuse the trainees due to their misbehaviors. He may initiate action if any through his departmental head.
81	Not to repeat the same questions, same answers and same statement again and again.
82	To be energetic and lively. Not to stay glued to one spot. To move around the trainees (but don't overdo it)
83	To be pleasant, relaxed, and sympathetic to trainees.
84	To improve training methods continuously by discovering the p[articular method which is most suitable in achieving the training objectives

D. TRAIN THE TRAINERS FOR FOLLOWING POST TRAINING FUNCTIONS

85	To self evaluate his trailing sessions via video recordings.
86	To invite feedback on his training programs from the Management and External Experts/FDA officials
87	To provide training certificates to each participant at the end of each session. The certificates enhance the interest of trainees for the next sessions.

88	To maintain all the training records for each individual and each session in a prescribed manner for audit by FDA
89	To summarize the main points at the end of each training session.
90	To assess the effectiveness of his training over a period of 6-12 months. The simplest assessment can be verifying his attitude towards GMP Compliance during routine operations.
91	To demand feedbacks from trainees. This will help in identifying if a particular trainee is getting frustrated during the session. This will also prompt the trainer to improve upon his training. Please note: most of the trainees give favorable feedback irrespective to the quality of training. Please note that true feedback can be obtained through some trusted trainees or neutral persons attending the training programs.
92	To check the impact of training on practical learning and applications during their routine functions.
93	To invite suggestions on training sessions from the trainer of trainer: What did he like about the training? What did he not like about the training? What are his ideas for follow up to the training? What are his suggestions to improve future training sessions?
94	To provide Annual Review of his Training Programs. The report shall cover the following points: No of sessions planned, no of sessions conducted successfully and no of session aborted due to miss planning. Average attendance during each session No of trainees who were dismissed from the job as they were not amenable for training Type of the updating done in training material.- Management/ToT/FDA/ Buyer/ISO comments on Training

E. TRAIN THE TRAINER TO CONTRIBUTE FOR HIGHER TRAINING FUNCTIONS

95	To assist TOT in evaluating best practices for training Pharmaceutical industry
96	To assist TOT in 'training need analysis' program conducted by Management
97	To assist TOT in designing specific training programs for new technology/new products to be launched
98	To assist TOT in identifying specific cGMP training requirements for new markets
99	To assist TOT identifying specific training needs of persons employed at different levels such as casual workmen, adult work men, trainee supervisors, shift in charges, contract employees, the sales force, physically handicapped employees, Front Line managers etc

100	To develop wide range of training program to match requirements of all the people employed at the site.

CONCLUSION

Training is an essential part of effective cGMP Compliance. However, currently it has been realized that training the trainer is still more important. All cGMP Trainers may be trained in house or through External expert.

REFERENCES

1. WHO Expert Committee on Specifications for Pharmaceutical Preparations Good Manufacturing Practices for pharmaceutical products: main principles Geneva, World Health Organization, 2003 (WHO Technical Report Series No. 908. Annex 4)
http://www.who.int/vaccines-documents/DocsPDF06/799.pdf

2. Trainer's Guide: Advance Training to Trainers, http://www2.pathfinder.org/site/DocServer/ATOT_Trainer_s_Guide.pdf?docID=9221

3. Guidelines for training of trainers, *Technical Intervention Area Summary Notes:* www.ilo.org/public/english/region/asro/bangkok/child/.../tia-f.pdf

4. Train the Trainer: Training Fundamentals
http://www.unescap.org/ttdw/common/tfs/ffmultimodaltx/tot.pdf

