United Journal of Quality and Validation

TRAINING MANAGEMENT IN MEDICAL DEVICE AND PHARMACEUTICAL INDUSTRIES

Aishwarya Gangadi1, Senior Supplier Quality Engineer, Medtronic, United States.

Author Biography

Aishwarya G

Biography :Aishwarya G, Senior Supplier Quality Engineer, Medtronic, United States. She is self-motivated with vast domain experience and expertise in Validation, Quality and Development Engineering disciplines. Proven ability to multitask in fast paced, competitive and high priority projects with emphasis on delivering quality results in a timely manner. She is deeply passionate to contribute towards the application of biomedical engineering in the field of life sciences - improving reliability and quality of products/ services.

*Corresponding Aurthor:
Aishwarya G, Senior Supplier Quality Engineer, Medtronic, United States, Email: agangadi12@gmail.com.

Article Information
Article Type: Review Article
Article Received: 12-21-2020
Article Accepted: 12-26-2020
Article Published: 12-28-2020
Vol:1, Issue:1

OPEN ACCESS

Keywords: Training Management; FDA, Role-Based Training, Training Matrix, Learning Management System

ABBREVIATIONS

[FDA: Food and Drug Administration; CFR: Code of Federal Regulations; ISO: International Organization for Standardization; QMS: Quality Management System; SOP: Standard Operating Procedure, LMS: Learning Management System; GxP: GxP is a general abbreviation for the "good practice" quality guidelines and regulations. The "x" stands for the various fields, including the pharmaceutical and food industries. Good Lab / Manufacturing / Laboratory Practice]

ABSTRACT

Innovation in the medical device and pharmaceutical industries is continuously emerging and evolving since the past decade, and it will only continue to grow significantly in the future. Given the complexity in manufacturing, increasing scrutiny of regulatory bodies, paramount increase in product demand along with the responsibility of the organization to deliver quality and reliable devices and drugs to the patients, the reason to provide top-notch training to the employees of these organizations becomes significantly critical by the day. This article, therefore, discusses the need for training management in the organization, the training requirements of applicable regulatory bodies, and discusses about various aspects such as creation, maintenance, and evaluation of the training to ensure the right kind of training is delivered to the personnel. The conclusion further emphasizes the role and need of training to ensure compliance, product quality as well as to prevent product liability litigation.

Introduction

Training program holds undisputed prominence in any business setup, be it manufacturing, technology industry, retail industry, construction etc., Ensuring proper training for employees help in the acquisition of new skills, sharpen existing skills, improve performance, increase productivity thereby resulting in the overall growth of the individuals as well as for the associated organization. The relevance of training only gets critical in industries that have a direct impact on patient's health and safety, like pharmaceutical and medical device companies, to ensure compliance to governing regulations (FDA, ISO), high product quality, and prevent any personnel or product allegations. Training is one of the most frequently reviewed item during inspection by the auditors as it is an easy way to establish level of general compliance of the organization [1].

Citetion: Aishwarya Gangadi / United Journal of Quality and Validation 1(2020): 1-3

This review article will discuss various aspects of the training process, including assessment, development, deployment, maintenance, and effectiveness check in relation to Medical devices and Pharmaceutical Industries. Training for employees in these industries may include programs to gain working knowledge about FDA / ISO regulations and GXP requirements, specific SOPs, company policies and QMS, execution of processes for drug or medical device production, ethics management etc., Implementation of training programs are governed by FDA and/or ISO requirements and are typically managed through the Quality Management System of an organization. This article captures key steps involved in Training Management.

DISCUSSION

Regulations and Standards that require training as an integral aspect of Quality System Management include:

FDA 21 CFR Part 211.25 for Pharmaceutical companies

FDA 21 CFR 820.25 (b) for Medical Device manufacturers

ISO 13485: 2016 Clause 6.2 for Medical Device manufacturers

Below include few key points relevant to FDA regulations and ISO Standards:

i. Both do not have a detailed indication of how much training is considered appropriate, instead, they provide broad guidance to impart training in order to assist in required job duties. This indication serves as a basis for role-based training. Role-based training relates to training individuals on necessary topics to be compliant and in functioning capacity for their role.

ii. Both of them focus on record maintenance, which is also one of the primary areas for questioning during audits and inspections. This is due to its alignment with the common rule of thumb “If it is not documented, it was not done”.

iii. Both also focus on ensuring that relevant education, background, and experience of personnel are established. These are typically covered as pre-requisites for job descriptions and play a major role in establishing a foundation for the competence of an individual. Competence of an individual can be developed by providing required training depending on their role requirements and personnel’s profile. ISO standard also includes additional focus on maintaining competence and effectiveness evaluation based on the risk associated with the work for which training is imparted [2].

iv. Additionally, FDA focuses on the importance of personnel knowledge of the device defects that may occur due to improper performance of their job.

To align with the indications discussed above for FDA regulations and ISO standards, training management can be broadly executed through the following methods described under creation, maintenance, and effectiveness evaluation of training program.

1. Creation of Effective Training Program

An effective training program can be created by developing role-based training, choosing an appropriate delivery method, schedule of training deployment, and sourcing qualified trainers.

1.1 Creation of role-based training – The development of role-based training is a key factor to ensure personnel is trained appropriately for their job function. Conducting training needs analysis and competency analysis may also help define the training applicable to varied job roles. HR, functional managers [3], and managers of other relevant groups where the employees work to complete their responsibilities may be a part of reviewing training applicable to a certain job role. Role-based training can be defined per department, QMS, business, operation, job title, governing regulation, orientation, human resources, corporate areas etc [4].

1.2 Choose method of training delivery – The training delivery method may depend on various factors such as objective of the training, complexity of the topic, targeted audience, importance of training in adhering or excelling in job role [5]. Read & Acknowledgement of the material, eLearning, Instructor-Led sessions, On the Job training may be few options to consider for training delivery. These delivery methods can also be combined with additional techniques such as group discussions, engaging in group activities to create a greater impact for training delivery.

Example: If the goal of the training is to bring general awareness about the company policy, read and acknowledge training should suffice, but if the intention is to impart a behavioral change, then a combination of training developed by a qualified instructor along with engaging in group activities may prove beneficial.

1.3 Devise training schedule – Developing a training schedule to monitor the frequency of training deployment and time frame for training completion is key in order to ensure compliance. Re-training is relevant in order to ensure the competency of the personnel. Providing training to a larger group on a process or operation and in frequent intervals would be a key factor in reducing burden [6].

1.4 Source trainers – Identifying qualified and resourceful trainers is as important as developing a training program, if not more. Sourcing trainers will be highly dependent on the objective of the training, complexity of the topic, and impact of the personnel’s job role on the overall organization. A qualified trainer will be fruitful in motivating the employees, thus ensuring their growth and of the company’s along with helping in developing the next set of trainers.

2. Maintenance of Training Program

2.1 Create training matrix – Training Matrix is a living spreadsheet and can be used to track training by group, department, or job title. A training matrix is beneficial to get a comprehensive view of training assignments at one time and is recommended to be periodically reviewed and tracked. Role-based training documentation can also be used as a training matrix and vice versa, depending on the spread and intended use of the document. Compilation of training matrix can be as simple or complicated as desired and can be tabulated in excel, Oracle, or SQL. Typically, the left-hand column would consist of names

of the personnel, top row with the relevant procedure, policies, SOP's or procedure details, and intersecting grids can be used to include information of last training date, type of training and /or any other pertinent details [7].

2.2 Individual training records – Individual training records document training completion and are requested as a source of evidence of the training program of an organization during audits. Training completion can also be documented in the form of a group sign-in sheet, but it is recommended to use individual training records as much as possible as it provides a signal for the source of truth with in-depth details of training occurrence. Sign-off or acknowledgment by a trainee on having understood the training is also said to improve a person's accountability [8]. Training records can either be an input to LMS or are equivalent to LMS depending on the company's training management system. However, the training record at a minimum shall contain employee name, topic title, training date, training method, trainer, and signature.

2.3 Learning management systems – A good Learning Management System makes it easier to automate and ensure compliance with training activities. An LMS can assign and control course enrollment, provide access to eLearning and virtual learning, schedule and track training, serve as a repository for training records, retrieve historical training data, ensure accessibility of training across all divisions and workforce levels, provide online training, better visibility and send email notifications. LMS can also be used to run reports easily with granularity across departments, business divisions, operating facilities [9]. Integration of LMS with Manufacturing Operating system can help in establishing poke yoke to ensure that only an operator trained to a process is able to access relevant manufacturing set up.

3. Effectiveness Evaluation of Training Program

Completion of training is not achieved until effectiveness is established. Regulators view monitoring of training effectiveness with a critical eye more so than the training itself as the effectiveness of training help in measuring the fulfillment of training objectives. Additionally, the importance of measuring effectiveness is driven home in ISO 13485:2016 with regard to risk management. There are different evaluation methods for achieving varied training objectives of which few are:

3.1 Perform surveys – Surveys are typically requested towards the end of the training session to evaluate if course content is aligned with job duties, if the training is worth the time spent and if it is helpful to improve job performance [4]. Surveys are typically used as a method of evaluation when the goal of the training is to spread awareness or capture the reaction of the trainee.

3.2 Quizzes – Quizzes are used as the method of evaluation to test knowledge and learning gained by the trainee.

3.3 Project work – Project work indicate team activity to stimulate information sharing and promote in developing a skill that can be implemented in real life.

3.4 Post training evaluation – Managers are typically able to provide this information by assessing the compliance level of the trainee and also due to performance improvement based on training provided. This is an appropriate tool to assess evaluation when the goal of the training is behavioral changes in an individual. Training Evaluation can also be provided by the trainer based on the involvement of the trainee during the training session.

3.5 Engaging in group activities – Any activities which involve a group, including group discussion, role play, sharing ideas, and information, may be used to evaluate training effectiveness, particularly when content is complicated, to establish competence and influence change in behavior or attitude regarding a certain topic.

3.6 Visual aids – Adding visual props or posters, typically with examples of commonly seen defects in manufacturing areas, may reinforce training effectiveness. Having visual defects on hand so that inspectors can view them as examples also help to assess impact of the training. This strategy also relates to ensuring compliance to 21 CFR 820. 25 (b).

CONCLUSION

Considering the number of regulatory requirements and highly specific standards placed on pharmaceutical and medical device manufacturing companies, the role of training is imperative to ensure compliance, product quality as well as to prevent product liability litigation and personnel-related allegations. Moreover, regulations are continuously evolving due to rapid changes in the industry, which further means that employee training is an ongoing process. If the training is designed to deepen an employee's understanding of process, procedures, regulations, management systems, ethics, it becomes of paramount help in ensuring independence of the personnel as well as in associated group and companies overall progress. In conclusion, implementation of appropriate training determines the maintenance of a staff of highly trained and motivated employees on hand as the industries develop, change and evolve.

Conflict of Interest:

Not Applicable

REFERENCES

1. Wheelwright S M PhD.Training: How Important Is It? Pharmaceutical Outsourcing. 2015.
2. Understanding Medical Device Regulatory Training Requirements and Determining Who Needs to Know What. Medical Device Regulatory / Quality Training & Consulting. 2019.
3. FDA Training Records - Three Risky Challenges. Complience zen. 2013.
4. Marie Dorat. Training and the FDA – What do They Require? 2014.
5. Requirements of FDA for training in Pharmaceuticals. 2017.
6. Requirements of FDA for training in Pharmaceuticals. 2017.
7. FDA Training Records - Three Risky Challenges. Complience zen.

2013.

8. [8] Understanding Medical Device Regulatory Training Requirements and Determining Who Needs to Know What. Medical Device Regulatory / Quality Training & Consulting. 2019.
9. [9] How to Develop Effective training programs for FDA Compliance. ComplianceOnline.