

The Necessity of Evaluation of Training that Calls for the Development of the Technical Knowledge and Skills Required for Freshers and Associates Working in Different Departments of Pharmaceutical Industry

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ABSTRACT

This thesis is dedicated to my dear pharmacist and professionals working in pharmaceutical industry in different departments like R and D, Formulation, Analytical, QA, RA, Clinical research and others. A Pharma graduate (B.Pharm) or post graduate (M.Pharm) who is having a desire to make his/ her career in Pharma industry in different departments as mentioned above, who wishes to enhance their knowledge and Technical skills, but having no idea or little knowledge about the industry and current job requirements which comes as a part and parcel of the Development of Technical knowledge and skills by different Training methodology. The purpose of this research study was fivefold. First, to describe selected successful models of training and development of Technical knowledge and skills through various courses and Seminars/workshops as they may apply to colleges and Pharma industry in India. Second, to describe selected methods of needs assessment for training and development programs for fresher's and working employees and employers. Third, to identify selected managerial techniques those contribute to lost productivity and morale and build the confidence in employees. Also to identify learning and teaching methodology for college students. Fourth, to selectively assess what types of on job skills and knowledge are most essential for career success. Fifth, the results of this study suggest recommendations for developing a comprehensive plan (model) for the creation of effective employee training and development programs for Fresher's and working professionals in different departments like R and D, Production, RA, QA, Clinical, Patents and so on. This study was conducted by engaging in comprehensive review and critique of the existing literature on different training and development models used in industry.

Keywords: Training and Development in Pharma industry, RA, QA, Clinical, Analytical.

INTRODUCTION

In Pharmaceuticals the fresher's and associates working in various departments like Analytical, Formulation, Quality Assurance, Regulatory Affairs (RA), Production, Clinical Research and others contribute towards the Product Development pathway till the market launch of various products in different countries of interest. Hence the most critical task for small scale Pharmaceutical/Biotech industry is to develop technical skills in these departments.

It has been seen that professionals often feel stuck up in a career after some period of time and eventually decide to leave an employer or the organization if their fundamental career requirements do not get fulfilled. Surprisingly, it has been also noticed by author that, there is always a demand gap for the talent supply for the pharmaceutical industry. The demand gap

is mainly because of the tremendous gap between the industrial demands for job oriented skills and personals ready with professional knowledge and the academic supply. Academic supply becomes useless either as a result of outdated educational curriculum or unawareness or lack of training for on-job skills and failure in updating with new science and technologies developing in the field of Pharma sectors.

The advancement in the technical skills is of the paramount importance in influencing the performance of the employee and hence the development of the training strategies. Indisputably, the need of the analysis or evaluation of training is quite inevitable with the aim of achieving the entailed fallouts. There can be many altered approaches towards the evaluation of the training such as the Training Needs Analysis, nonetheless, the

qualitative and quantitative research, being a motivator the employer's approach of assessment can be most fruitful in evaluation of the training and eventually on the way to the development of technical skills. The purpose, the process and objectives of the same have been delineated in this thesis of which the advantage can be taken in the submission and/or registration of dossiers in regulated or semi-regulated market.

MATERIALS AND METHODS

Chapter 1, Introduction, covers various pre-emptive concepts. It is a preamble to the Pharma world elaborating the ways and means of how the knowledge is enhanced by taking proper training at different stages of career right from the fresher's till Pharma professionals. This chapter also talks about how the research was conducted previously by different people.

Chapter 2, Review of Literature, as the name suggests give a list of authors and the message they have given to the world. Enough literature is not available on the growth of Indian Pharmaceutical industry taking many parameters simultaneously. Whatever literature is available is in the form of papers/articles published in Pharma magazines and studies showing growth of Indian pharmaceutical industry by taking a few parameters only.

Chapter 3, Objective

The main objectives of the research study are:

- To find out the gap between training methodology in MNC and Indian

organizations for development of Technical skills and Knowledge.

- To evaluate the need for training of fresher's and associates working in Pharma R & D especially in Analytical, Formulation, RA and QA departments.
- To evaluate current methodology of training and development program fresher's looking for job in small scale Pharma R & D especially in Analytical, Formulation, and RA/ QA departments.
- To develop new methodology of Effective training using good, basic training techniques.
- To evaluate the effectiveness of training before and after training Methodology applied in Indian Pharma, R & D and related departments like Analytical, Formulation, RA and QA.

Chapter 4, Research Methodology, gives the scientific and statistical base to the observations made. CSF/KPI (Critical Success Factor / Key Performance Indicator) method was used. Several types of seminars were conducted, hundreds of participants were served with a questionnaire and primary data was collected. Since the data collected was of the type "before training or course" and "after training or course", paired t-test was used for judging the significance or effectiveness of training. Another method used was ADDIE model (i.e. Analysis, Design, Development, Implementation and Evaluation).

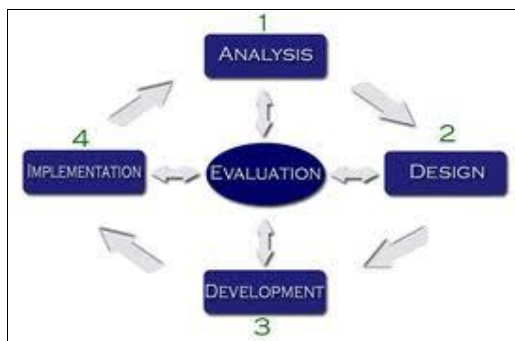


Fig. 1: The ADDIE Model

Chapter 5, Hypothesis (μ)

The author or researcher wants to show that there are some techniques, methodology for effective training and conduct short term on job relevant courses which enhance the career

of the Fresher's and working professionals. Associates working in R & D departments like Analytical, Formulation, and Quality Assurance or Regulatory Affairs perform the job better when they are trained properly with subject

knowledge. So the assumption/hypothesis made by the researcher that; existing education and training given to Fresher's and associates working in R & D and related departments does not help in improving technical knowledge and skills in respective area of job. This statement is the null hypothesis presented by the researcher.

The effectiveness factor: [KPI = Key Performance Indicator]

$$\text{The effectiveness Factor} = (\text{KPI})_{\text{after}} - (\text{KPI})_{\text{before}}$$

The null hypothesis: [H₀]

The training course seminar is NOT effective. If KPI before the training course or seminar is more than the KPI after the training course or seminar, we can conclude that it is **NOT** possible to create and disseminate knowledge through research.

The Alternate hypothesis: [H_a]

We wish to conclude that training course or seminars are effective if KPI before the training course or seminar is less than the KPI after the training course or seminar; we can conclude that it is possible to create and disseminate knowledge through research.

Chapter 6, Analysis of data; this chapter describes in details how the data was captured, entered into a database, analysed and the effective factor was calculated. Hypothesis testing was carried out. Sample size of 100 selected students and working professionals was considered suitable and practical. Some secondary data was also collected from other sources from the Internet.

Chapter 7, Finding and Suggestions; this chapter lists various findings such as Lack of awareness, Lack of proper Education and training, insufficient knowledge etc. This chapter discusses limitations of development of skills and knowledge. And also suggests remedies. Conventional remedies, future remedies, corporate remedies etc. Use of proper job relevant topics, Need Analysis, Training Methodology, Motivation, Questionnaires, Feedback, etc were suggested in this chapter.

Chapter 8 gives the conclusions. It is neither possible to acquire 100% knowledge and skills and not possible to get 100% job satisfaction

but it is indeed possible to develop technical knowledge and skills as per the industrial requirements and current job needs to a large extent. Use of proper training, different job relevant courses, attending seminars, workshop, fast track programmes can give candidate a good level of confidence that they are dealing with the current job in this competitive world.

This exploratory study has been proposed in keeping with the apparent (or potential) gap in the extant literature that addresses the issues related Training and Development in the Pharma Industry in different departments like R & D, Analytical, Formulation, Quality Assurance, Documentation, Regulatory Affairs etc. This study could serve a significant fraction to that overall responsibility, or perhaps initiate similar thoughts for future guidance. It is intended that the current theme could be raised to a more rigorous inquiry in future studies.

Chapter 9 gives the reference used in this thesis.

Appendix gives the details of how the Primary data was collected. Also gives a list of list of published articles and research papers of author, a list of national and Internationals seminars attended, participated; Survey of training methods used, Tools and Sample of Questionnaire used for a fresher's and working professionals etc.

RESULTS

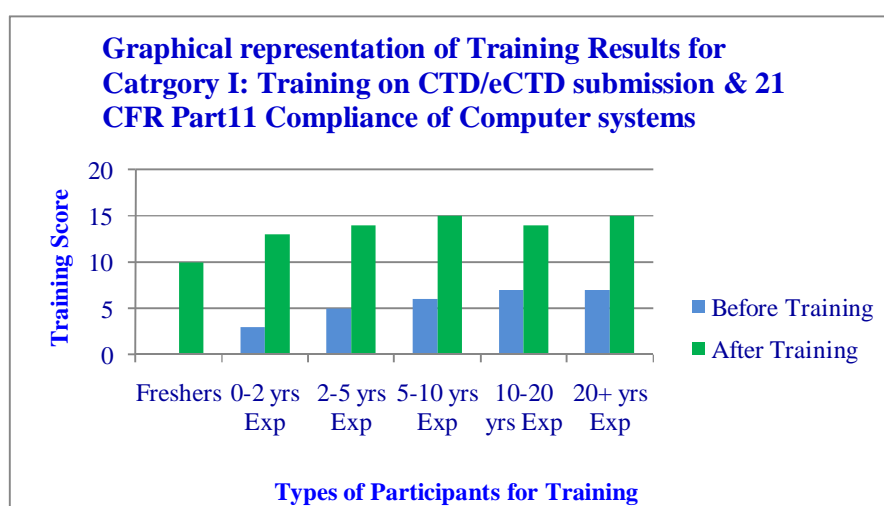
The data obtained from various training sessions, arranged for trainings and development of technical skills and knowledge, is broadly categorized into three different types as below:

- ✓ **Training Category I: Training on CTD/eCTD submission & 21 CFR Part 11 Compliance of Computer systems**
- ✓ **Training Category II: Training on Technical Documentation, Writing/Review Skills**
- ✓ **Training Category III: Training on Audits, Inspections & Validations**

The obtained results for different training programs conducted are tabulated below in Table 1, 2 and 3. The results show the significant increase in skill development and knowledge.

Table 1: Results for Training Category I: Training on CTD/eCTD submission & 21 CFR Part 11 Compliance of Computer systems

Sr. No.	Description of Participants	Before Training Score (Out of 15)	After Training Score (Out of 15)	Score Difference after Training	% Difference
1	Freshers	0	10	10	100
2	Professionals with 0-2 years' experience	3	13	10	333.33
3	Professionals with 2-5 years' experience	5	14	9	180
4	Professionals with 5-10 years' experience	6	15	9	150
5	Professionals with 10-20 years' experience	7	14	7	100
6	Professionals with 20+ years of experience	7	15	8	114.29

**Fig. 2: Column Chart of Category I: Training on CTD/eCTD submission & 21 CFR Part 11 Compliance of Computer systems****Table 2: Results for Training Category II: Training on Technical Documentation, Writing/Review Skills**

Sr. No.	Description of Participants	Before Training Score (Out of 15)	After Training Score (Out of 15)	Score Difference after Training	% Difference
1	Fresher's	3	15	12	400
2	Professionals with 0-2 years experience	5	16	9	180
3	Professionals with 2-5 years experience	6	18	12	200
4	Professionals with 5-10 years experience	8	17	9	112.5
5	Professionals with 10-20 years experience	8	18	10	125
6	Professionals with 20+ years of experience	9	18	9	100

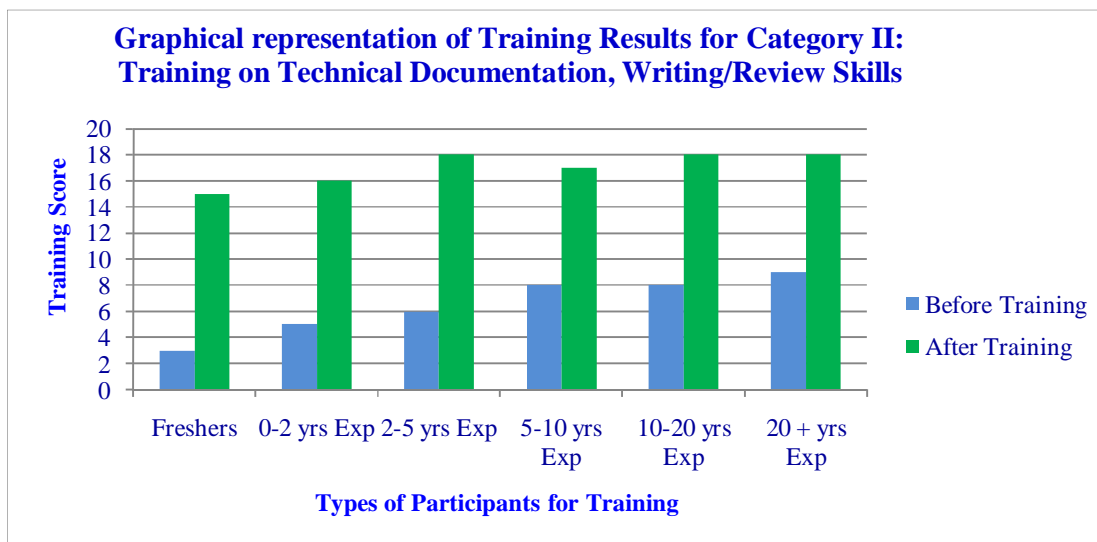


Fig. 3: Column Chart of Category II: Training on Technical Documentation, Writing/Review Skills

Table 3: Results for Training Category III: Training on Audits, Inspections & Validations

Sr. No.	Description of Participants	Before Training Score (Out of 15)	After Training Score (Out of 15)	Score Difference after Training	% Difference
1	Fresher's	3	12	9	300
2	Professionals with 0-2 years experience	4	13	9	300
3	Professionals with 2-5 years experience	6	14	8	266.67
4	Professionals with 5-10years experience	8	13	5	166.67
5	Professionals with 10-20 years experience	10	15	5	166.67
6	Professionals with 20+ years of experience	9	15	6	200

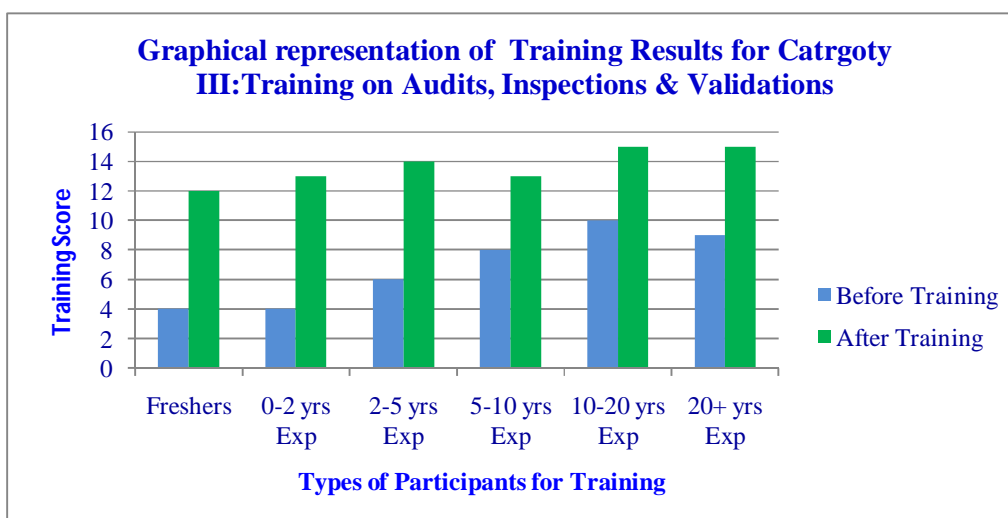


Fig. 4: Column Chart of Category III: Training on Audits, Inspections & Validations

DISCUSSION

Effectiveness of trainings was detected via few of the following direct observations such as:

- **Development of skill confidence in freshers**

Freshers who have received the trainings build up with more confidence at their workplaces after training. The technical skills and knowledge acquired by them increased their confidence levels as the utilization of the same in their routine life at the workplaces. The number of mistakes found to be reduced with increase in performance.

- **Increase in skill confidence level of working professionals**

Due to trainings, the knowledge and job skills of working professional have been polished and there were adaptations of new skills and technologies. It has been observed for the working professionals having various years of experience, the acquired knowledge and skills have increased their confidence levels resulting in better performances than the previous ones. They have much more confidence and abilities to face the newer challenges to strive through the competent world.

- **Increased Career opportunities for Freshers**

The trainings and the knowledge gained by freshers helped them to grab more number of job opportunities than past. Freshers seemed to be for confident to face the interviews related to technical skills. This ultimately resulted in getting them jobs with handsome salaries; and making them eligible to enter in the skilled pharmaceutical fields.

- **Career growth of working professionals**

The ascending graph orders of career growth for the professionals have been found. Many of the training attendees grew up in their career with higher positions and opportunities in either existing organizations or in new organizations.

- **Career gap healing of professionals especially female candidates**

It has been found that many of the female professionals have the gap in-between their career due to several reasons like marriage, change in location because of marriage, pregnancy or maternity leaves, etc. The trainings provided to such participants tend to heal the gaps in-between their careers and they can gear

up with new start towards new horizons. The trainings served the purposes like to brush up with the job skills, get acquainted with latest science and technologies, new rules and regulations, awareness of the current industry norms, etc. It helped them to face the interviews confidently and get new career opportunities and jobs with good salaries.

- **On-job awareness in different areas like QA, QC, RA, R&D, etc.**

The trainings & knowledge helped the participants to become aware of different areas of the organization. The candidates who were previously unaware of the different departments and the respective functions came to know about departments like QA, QC, RA, R&D, Formulation development, Analytical, etc. This knowledge leads to build up the thought of team, team work, intra and inter departmental and overall links and bonding of all the departments' altogether for organizational success.

- **Development of on-job skills (Analytical, Formulation, etc.)**

Trainings helped to develop and improve on-job skills for professional and workers from different departments like Research and Development, Analytical, Formulations, and Documentations, etc. The awareness of on-job skills and knowledge has been increased in the participants.

CONCLUSIONS

This exploratory study has been proposed in keeping with the apparent (or potential) gap in the extant literature that addresses the issues related Training and Development in the Pharma Industry in different departments like R & D, Analytical, Formulation, Quality Assurance, Documentation, Regulatory Affairs etc. This study could serve a significant fraction to that overall responsibility, or perhaps initiate similar thoughts for future guidance. It is intended that the current theme could be raised to a more rigorous inquiry in future studies.

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