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The significance of training and development in the Pharmaceutical Industry

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Abstract

Training and development are inherent in pharmaceutical industries. The pharmaceutical manufacturing industry is based on critical steps to ensure compliance which needs trained and qualified employees. Training shapes and empowers employees in the pharmaceutical industry. The goal of this research paper is to investigate the role of training in the pharmaceutical industry through an extensive review of the literature and propose a conceptual framework.

Keywords: Training, Investigations, QMS, Pharmaceutical Industry, Performance, DMAIC

1. Introduction

The pharmaceutical industry's survival is entirely dependent on well-trained and qualified employees. Training is important in empowering staff and workers associated with the said sector through proper enhancement of knowledge and skills.

Training is regarded as a smart investment for pharmaceutical organisations as it directly contributes to the success of the staff and the business (Why Pharmaceutical Training Courses Are Essential in the Rapidly Evolving Pharma Industry, 2021). The pharmaceutical industry's training needs are highly assessed to improve the industry's core value, which is nothing but quality. A well-trained workforce determines a company's competitiveness.

Researchers in the pharmaceutical sciences who approach their work with a mindset of education and training are always at a competitive edge (Bjerrum, 2011). Significant changes in the pharmaceutical industry are always on the horizon and to ensure that the said business can use these developments to its advantage, one must be aware of what they are (Bybee, n.d.). The only way to make sure that the business

and everyone in it maintains a competitive advantage is to understand the changes and enforce the proper staff training to assist everyone stay up-to-date (Bybee, n.d.).

Regulators are raising concerns about the occurrence of quality deviations in the pharmaceutical industry. Quality deviations occur for a variety of reasons, and training has the potential to reduce system gaps significantly. Every year, certain types of issues are recorded in most companies, affecting productivity and leaving room for training awareness. Quality issues and the resulting productivity delays pose challenges to the entire industry, and training has a clear role to play at this point. Any flaw in the quality system discovered during inspections of human performance calls into question the efficacy of training. Pharmaceutical firms are required by law and ethics to ensure that the drugs they produce are both effective and safe (Gallup et al., 2007).

When an employee's performance fails and a deviation occurs, it is commonly blamed on insufficient training on the part of the individual (Welty, 2009). The most obvious and wellresearched pieces of evidence used in some diagnostic procedures also include insufficient training as Organizational Pathogens (Reason, 1995). Esteban-Lloret et al. (2016) confirmed through their research that staff training has a favourable and significant impact on organisational performance, albeit it has a higher impact on the company's credibility both internally and externally.

McKinsey's study 2010 "Pharma Operations Benchmarking" identified three major areas of action for pharmaceutical companies to consider to ensure future corporate success, which include improving the performance of facilities and plants, interconnection and plant configuration, as well as increased quality and compliance (Rybski & Jochem, 2016). Training in a setting focused on excellent manufacturing processes requires developing the necessary abilities, imparting discrete knowledge, and instilling an ethical and responsible approach to work (Gallup et al., 2007).

Rybski & Jochem (2016) emphasized implementing a knowledge test following the training to assess the sustainability of concepts and training. Efficient employees can perform more quality jobs and the pharmaceutical industry prioritises enhancing the efficiency of employees through proper training. The pharmaceutical industry has only recently begun to prioritise efficiency over quality (Rybski & Jochem, 2016). An effective training programme will probably increase job commitment, motivation, and satisfaction, and vice versa (Sahinidis & Bouris, 2008).

The goal of this research paper is to investigate the role of training in the pharmaceutical industry through an extensive review of the literature and proposed conceptual framework.

2. Review of Literature

2.1 GxP environment in the pharma industry

The term "GxP" denotes a generic good practice and refers to the collection of rules, policies, and guidelines that control many facets of drug development, testing, manufacturing, and distribution (Good Practice - GxP, 2016). Pharmaceutical companies are entrusted with a GxP environment. A compliant GxP environment ensures the highest standards of products. Training plays a significant role in delivering the highest standard of products which is possible through the enrichment of skills, knowledge, and expertise of employees.

Training in pharmaceutical sectors is dynamic and continuously engaged to enhance employees in the challenging GxP environment. Training prerequisite in pharmaceutical companies is specific and mandatory and it is not limited only to GxP regulations, relevant standards, standard operating procedures and policies.

The letters "x" in the word GxP stand for a variety of compliance-related practices, such as Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP). Laboratories operating under GMP or GLP laws are required to adhere to rules established by organisations to safeguard scientific integrity or show quality control of manufactured goods (GxP Compliance Solutions for GMP/GLP Labs | Molecular Devices, n.d.).

Good Practices (GxP) establish themselves as the sole acceptable solutions by providing tangible responses to the set of requirements (Marinkovic et al., 2016). GxPs and the installation of various standardised management systems are now requirements for all businesses in the pharmaceutical supply chain, not only those engaged in manufacturing (Marinkovic et al., 2016). GxP compliance requires Good Documentation Practices (GDP), which is a crucial component of the pharmaceutical quality system (3. Key GxPs in Medicine: Good Documentation Practices GDocP, n.d.). In manufacturing plants, the GxP environment and its compliance are very much important to ensure the quality and integrity of the system. Through analysing tools innate to GxP requirements, the GxP environment is further investigated.

2.2 Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

Two crucial quality control tools in the pharmaceutical sector are Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) (Marinkovic et al., 2016). GMP is primarily concerned with reducing the risk inherent in pharmaceutical production (Patel & Chotai, 2011). With proper implementation of GMP and GLP, strong quality assurance systems are established and operate to enhance reliability (Marinkovic et al., 2016).

The presence of other good practices such as GDocP or GDP (Good Documentation Practices), GEP (Good Engineering Practices), GWP (Good Warehousing Practices), and many others that are essential for the operation of pharmaceutical operations. Good Distribution Procedures are also referred to as GDP, but in this research, the acronym GDP is largely utilised to refer to Good Documentation Practices.

Topics on cGMP (of regulatory authorities and current business procedures must be covered in cGMP training (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.).
Regulatory inspections are essential to the pharmaceutical manufacturing sector. For market authorization, manufacturing units are subjected to inspections. During inspections, training plays a vital role to demonstrate compliance. Training is a very important function in the GxP environment.

The European Medicines Agency (EMA) states that Good Distribution Practice (GDP) consists of minimal requirements that a wholesale distributor must achieve to guarantee that the integrity and quality of medicines are maintained throughout the supply chain (N.V, n.d.). Although Good Distribution Processes are also referred to as GDP, in this research the term GDP is primarily used to refer to Good Documentation Practices.

As a fundamental GxP requirement, Good Documentation Practices should ensure data integrity by ensuring the accuracy, completeness, consistency, and dependability of the records and data throughout the data life

cycle. (3. Key GxPs in Medicine: Good Documentation Practices GDocP, n.d.). Every documentation must be ALCOA-plus, which adds the requirements for being comprehensive, consistent, long-lasting, and accessible where ALCOA stands for Attributable, Legible, Contemporaneously Recorded, Original, and Accurate.

Regulatory inspections are a must for the pharmaceutical manufacturing sector. During inspections, GxP tools are checked for their performance and everywhere training plays a significant role to demonstrate compliance. As compliance plays such a vigorous part in industries where mistakes can be harmful, employee training alongside assessments is essential (Walker, 2020). The Gold Sheet claims 10 of the 71 warning letters mentioned: "training" (Deeksha Ramananda Pai et al., 2016). It will be possible to scale up more quickly by clearly identifying future capability needs, investing in high-potential employees' training, and hiring workers with the new necessary skill sets with priority (Carra et al., n.d.).

2.3 Training in the pharma industry

2.3.1 Types of training

In the pharmaceutical industry, training is mainly divided into two types -Technical training and soft skill or behavioural training (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.). Technical training comprises role-based and GXP topics. The training need matrix identifies required role-based Standard Operating procedures (SOP) and Standard Testing Procedures (STP) and all applicable procedures mapped to the role. The gamut of training is always enhanced through the observations recorded during regulatory inspections.

The employer must provide ongoing training to ensure that employees have a thorough understanding of the defined procedures (Konstantinos et al., 2011). In pharmaceutical manufacturing, every employee requires job-specific training in technical skills, SOPs, and awareness of the GMP and effective training programs always enhance employees' responsibility in performing relevant tasks with utmost care and assurance (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.). Rico et al., (2017 as cited by Campaniço Cavaleiro et al., 2020) said that every organization's training programmes are created based on the types of tasks carried out to enable people to gain the necessary skills and knowledge. All employees in the pharmaceutical industry have a fixed job description and are only certified to work only after the successful completion of required training. Training is focused on the Right the First Time (RFT) approach.

GxP training is composed of Good manufacturing practices (GMP), Good documentation practices (GDP) and Data Integrity (DI) which are mandatory and needs refresher courses on an annual basis. GxP training is also extended to good laboratory Practices (GLP, Good Warehouse Practices (GWP), and Good engineering practices (GEP). Training on pharmacology, aseptic practices, contamination control, personal hygiene, and basics of microbiology is imparted to employees as per requirement in addition to the GMP.

The head of the Quality Assurance Department Head Operations must authorise the training materials to be utilised for cGMP training (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.). The objective of GMP training is to inspire all staff members to fulfil their duties in line with established procedures and GMP expectations, always keeping the patient in mind which can be accomplished by educating them on the relevant concepts of good manufacturing practices (Silverstein, 2010).

Every employee must go through GMP training once a year after joining the company at induction and following training, GMP questionnaires are used to assess performance (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.). Continuous CGMP training is required by FDA regulations (Welty, 2009).

On-the-job training shall be provided to employees in their respective areas of the operation following the protocols of individual departments (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.).

Employees will be trained in the use of equipment, various unit operations, safety norms to be followed, Quality Assurance procedures, general rules and SOPs, validation and calibration procedures, cGMP, and preventive maintenance as applicable through on-the-job training (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.).

Employee training on organisational culture reduces interpersonal conflicts and promotes positive relationships among members of the organisation (Why Pharmaceutical Training Courses Are Essential in the Rapidly Evolving Pharma Industry, 2021). Training is an indispensable part of the pharmaceutical manufacturing sector and manufacturers are keen on the development of employees through the required training.

Pharmaceutical companies must make several efforts, from research and development to production, to protect their reputation. Pharmaceutical manufacturing industries employees are categorised into – Officers and operators. Again, operators are sub-categorised as critical operation operators and non-critical operation operators. The criticality of operations varies from dosage form. Pharmaceutical operations comprising of manufacturing of injectables where aseptic operations are very critical and hence full-fledged compliance in the aseptic process is validated through the qualification process and training plays an important role during the qualification process.

Moreover, analyst qualifications in Quality Control, personnel qualification in the Microbiology department, visual qualification for packing persons, and gowning qualifications for aseptic people deserve special mention.

Qualification is comprised of on-the-job training (OJT) where an employee is assessed through demonstrations of certain activities. Certain organisations enable certain simulative studies to enhance training in manufacturing plants. Apart from OJT, classroom training in a classroom set-up is a preferential mode of training in pharmaceutical companies where a trainer imparts training

A quality system requires managers to create training programmes by analyzing the training needs and ensuring training documentation along with a proper training effectiveness measure (Gallup et al., 2007).

Breimer (2001) emphasized the requirement of pharmaceutical faculties to redefine their objectives, mission and strategy in providing high-quality training programmes in the relevant field during discussing the way forward for the training needs. Frick et al., (2018 as cited by Campaniço Cavaleiro et al., 2020) said that everyone needs to possess the necessary set of abilities to enable them and their teams to accomplish their main objective as well as the capacity to appraise the current situation using data acquired from the internal and/or external environments. Training is done through online platforms also. There is various software available to support Training Management Systems.

2.3.2 Training Effectiveness

Training effectiveness is measured in various ways. Kirkpatrick's level of effectiveness is the base for effectiveness check in pharmaceutical companies with certain combination and permutations of assessments in the industry as per the needs. A methodological strategy for determining learning outcomes is training evaluation whereas a theoretical approach to comprehending those results is training effectiveness (Alvarez et al., 2004).

In pharmaceutical companies training effectiveness starts with an assessment process where each SOP needs to be assessed after training completion. Training evaluation offers a micro view of training outcomes because it only focuses on learning outcomes (Alvarez et al., 2004). The learning system as a whole is the focus of training effectiveness, which offers a macro view of training results (Alvarez et al., 2004).

There is a fixed set(s) of approved questions for each sop and employees need to qualify the same to gain credit. Organisations need to check any incidents where human performance is under question as a training opportunity to improve the system. If any error is contributed by human beings due to inadequacy of training, then training effectiveness needs to check the same and offers a better corrective and preventive plan with timelines.

Kirkpatrick's Four-Level Training Evaluation Model, which includes Reaction, Learning, Behavior, and Results, can be used to objectively analyse the impact of training, determine how well the team members learned, and improve their learning in the future (Mind Tools Content Team, 2022). Training feedback in level 1 and level 2 as per Kirkpatrick levels are used or modified as per the need of the organisation. Mainly feedback from participants after attending the training and feedback of the same employees after a certain frequency provides objective evidence on the implementation of training on the shop floor. Feedback by employees' managers, Cross-functional teams, 360-degree feedback and many others always speak on the effectiveness measures. Training effectiveness is designed as per the need of the organisation which shows the adequacy of training, quality of trainer, suitability of training materials, and competencies of the trainee to understand the training.

All applicants for trainer certification in pharmaceutical manufacturing should be evaluated for their subject-matter expertise, educational background, and familiarity with the site's training and qualification processes and any shortcomings to be rectified through validated "train-thetrainer" courses ("If Training Is so Easy, Why Isn't Everyone in Compliance?" 2004). In all circumstances, users must receive ongoing training to advance their knowledge and competence to prevent errors (Liginlal et al., 2009). Arthur et al. (2003) emphasized on the findings imply that the chosen training evaluation criteria, the skill or task characteristic trained, and the training methodology all influence the training programmes' actual effectiveness.

Many organisations also link ROI (Return on investment) in extension to the training effectiveness check. Since proving the business' return on investment for training can be difficult, it is frequently challenging to develop and justify training budgets (Thompson, n.d.). If training is directly linked to a quantifiable aspect, such as better productivity or process improvement, the acquired monetary amount would reflect the value of the training to the bottom line of the mentioned company (Thompson, n.d.). Training effectiveness results need to be discussed with senior management for corrections if needed.

2.4 Role of training

2.4.1 Role of training in improving quality at companies

To survive in today's highly competitive environment, the industry must improve quality, increase productivity, reduce waste and costs, and eliminate inefficiency (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.). Companies cannot maintain high-quality production in the difficult environment of pharmaceutical manufacturing without high-quality training ("If Training Is so Easy, Why Isn't Everyone in Compliance?" 2004). The pharmaceutical industry has only recently begun to prioritise efficiency over quality. Every individual in a pharmaceutical manufacturing facility who has a direct or indirect role in any activity involving the creation of pharmaceutical goods is subject to ongoing GMP training that is appropriate to their job (Silverstein, 2010). The GMP component of quality assurance makes ensuring that goods are consistently manufactured and controlled to the quality standards necessary for their intended application (Patel & Chotai, 2011).

It is significant to ponder the role of regulatory authorities in each country since the main goal of medicines regulation is safeguarding the safety, efficacy, quality, and balanced use of medicines that are accessible to the population (Marinkovic et al., 2016). There are various regulations apply to pharmaceutical companies. Regulations are dependent on the market. Regulatory science, as defined by the U.S. Food and Drug Administration (FDA), is the science of creating new tools, standards, and methods to evaluate the safety, effectiveness, quality, and performance of products subject to FDA regulation (Adamo et al., 2015). Regulatory compliance triggers various sorts of training which provide the opportunity for pharmaceutical employees to strengthen their job role. Ensuring that the site and processes run in a controlled manner is the primary goal of GMP training (Silverstein, 2010).

As a crucial component of the quality assurance system, documentation must be tied to every GMP component (Patel & Chotai, 2011). Training must, however, be founded on best practices rather than preconceived notions and biases (Jarvis, 2014). A greater grasp of the process will result from receiving the appropriate training, which will also increase cost-effectiveness, and performance, and reduce the likelihood of batch failure (Mankodi et al., 2019).

2.4.2 Role of training in developing employees

All personnel who complete effective training programmes are given the obligation to complete their responsibilities with the highest care and dedication (PERSONNEL TRAINING for PHARMACEUTICAL INDUSTRY 1, n.d.). The FDA is interested in knowing if you can demonstrate that your staff members are capable of carrying out the procedures in line with the SOPs and that they understand them ("If Training Is so Easy, Why Isn't Everyone in Compliance?" 2004).

Manufacturers must have well-documented training programmes that are carefully designed, successfully provided, routinely assessed, and frequently updated to be able to say "yes" with assurance ("If Training Is so Easy, Why Isn't Everyone in Compliance?" 2004). Saini et al. (2013 as cited by Obeidat et al., 2017) acknowledged that it was crucial to hire new personnel and to train and reward the appropriate staff. Workplace issues may be addressed through development, either before they become a difficulty or after

they become a clearly defined challenge (Ampoamah, 2016). Dhillon and Liu (2006) referred to Shepherd and Kraus's study, in which the need to develop pre-training job aids to address human factor issues was mentioned. The development of training programmes is recommended to improve situation awareness to enhance error prevention (Endsley & M. Robertson, 2000).

Training and development are two different processes that frequently go hand in hand (Ampoamah, 2016). The training cost is always included in the expenses of the new hires (Yaoprukchai & Kardkarnklai, 2014).

Training is also required for better awareness as audit response or some gap identified in the system or as awareness of incidents or deviations logged. Investigations into human error always led to awareness training to upgrade the system. The final discussion of the results is a critical component of the training which helps to prepare trainees to identify potential problems during implementation and what hinders the successful application of methods (Rybski & Jochem, 2016). Okumus (2003 as cited by Obeidat et al., 2017) emphasised the part that managers play in the implementation process and noted that managers need the right training to support them in implementing their best strategies.

During the implementation of a plan, organisational communication is crucial for learning, information sharing, and training (Obeidat et al., 2017). Rybski & Jochem (2016) emphasized implementing a knowledge test following the training to assess the sustainability of concepts and training.

The Learning Factory was established on the principles that lectures alone are insufficient, engaging hands-on experiences help students, and experiential, team-based learning with student, instructor, and industrial participation enriches the educational process and benefits everyone (Lamancusa et al., 2008). For training in pharmaceutical companies, the acquisition of cultural competencies needs to be strongly emphasised (Lasserre, 1982). As per the requirement, regulatory bodies are also making relevant strategic plans to strengthen the vision of regulatory functions to prioritize its trend for the industry.

Adamo et al. (2015) described FDA’s vision and priority areas for regulatory science through its 2011 strategic plan after referring to "Advancing Regulatory Science at FDA: A Strategic Plan 2011" and the opening of multiple Centers of Excellence in Regulatory Science and Innovation (CERSIs) at academic institutions for promoting regulatory science research, education, training, and professional development by referring to "Regulatory Science Special Topics 2011." The importance of regulatory science is on high tide and impacts the pharma companies heavily. Training plays an active role in streamlining regulatory requirements.

Good manufacturing guidelines (GMP) guidelines strongly advocate adequacy of education, training and experience in pharmaceutical industries. The said requirements accelerate the need for training in the pharma manufacturing sector. According to 21 CFR Part 211.25(a) everyone involved in the production, processing, packing, or holding of a drug product is required to possess the necessary education, training, and experience, or any combination thereof, to carry out the designated tasks (O’Keeffe, 2020).

Management needs to provide required training to all employees on required SOPs, work instructions, specifications, GxP topics, etc. Training employees make them more aligned with their job and step towards better compliance. Training records should be documented and archived properly. Employees should be supported in pursuing credentials that accurately reflect their level of education and work experience in a certain operating area (Jarvis, 2014).

A safe and effective production process depends on workers in the pharmaceutical manufacturing industry having the skills required to do their duties correctly and effectively (Gallup et al., 2007). The significance of training is emphasised in the regulations issued by regulatory agencies globally (Mankodi et al., 2019).

Employees must get training in cGMP as it relates to these job responsibilities in addition to receiving training in their assigned work duties, according to the FDA's expectations
(O'Keeffe, 2020). Training programmes are widely regarded as an effective and beneficial method for ensuring that all employees are prepared to carry out their job responsibilities and deal with any problems that may arise (Deeksha Ramananda Pai et al., 2016).

Developing required skills, providing discrete knowledge, and instilling an ethical and responsible approach to work are all critical components of training in an environment centred on good manufacturing practices (Gallup et al., 2007). Employees must receive ongoing training in current good manufacturing practices (CGMP) from certified personnel frequently enough to ensure that they stay knowledgeable about the CGMP regulations that apply to them (O'Keeffe, 2020). The primary duty of GXP trainers is to deliver training sessions on the most recent rules governing the pharmaceutical manufacturing sector (Gallup et al., 2007). Training must cover both current good manufacturing practices and the specific activities that the employee does about their job duties (O'Keeffe, 2020). Regular reminders of the impact of deviations, rework, etc. on the bottom line are given to staff members during ongoing CGMP training, which is also a legal necessity (Welty, 2009).

A combination of local problems may be the best approach to finding topics for continuing CGMP training (Welty, 2009). GMP training is ongoing and is done regularly (Silverstein, 2010). To follow the need for good documentation practices and data integrity, training on the said topics becomes a mandatory requirement in the pharmaceutical industry. Clear documentation allows for the tracing of operations carried out, and well-written instructions prevent errors brought on by verbal communication (Patel & Chotai, 2011).

To guarantee that trainees receive the right information and experience, training should adhere to national or worldwide standards (Jarvis, 2014). At the time of hiring, new employees must get induction training, which should be followed by specialised training at regular intervals (Jarvis, 2014). The trainee, the training event, or the trainer, individually or in combination, are each held responsible for the training's insufficiency (Welty, 2009). Training Each employee's training record must be preserved, and regular checks on the training's effectiveness are required (Jarvis, 2014).

In every aspect of GxP, training plays a vital role to educate the relevant employees and ensure compliance. in the GxP environment needs to be checked for training effectiveness and an investigation needs to be done for any training inadequacy if noted. Everyone who works in the pharmaceutical industry must have a fundamental understanding of the significance of GMP, put patients first, take pride in what they do, and have as their ultimate goal providing products that are of high quality, safety, and efficacy to the people they care about (Liu, 2021).

2.4.3 Role of training in improving employee performance

For required demands, training specifications should be made for both the person performing the process and the process itself, taking into account things like academic background, experience, training

specifications, and even personal traits ("If Training Is so Easy, Why Isn't Everyone in Compliance?" 2004). Schaap (2012, as cited by Obeidat et al., 2017) concluded that senior-level leaders who have received training in or studied strategic planning and implementation are more likely to meet the performance goals set for the company.

The major goals of the training are to increase knowledge and skills, as well as to alter attitudes and behaviour to improve employee performance and organisational effectiveness (Ampoamah, 2016). The contributing factors of errors in operators' performance are critical and must be dealt with effectively through training intervention.

Training can be a pre-requisite for acquiring knowledge and experience to head off issues before they arise, as well as a powerful tool for filling in any performance or skill gaps among employees (Ampoamah, 2016). Significant increases in human performance can be attained by formal training in communication and team management techniques (Reason, 1995). Training is regarded as a smart investment for pharmaceutical organisations as it directly contributes to the success of the staff and the business.

To guarantee the success of a training programme, executives in charge of employee training should incorporate concrete examples and exercises based on trainees' everyday jobs and activities into the training design process (Diamantidis & Chatzoglou, 2014). Training improves the performance of all employees, who should be taught that they are better suited to comply with cGMPs as a result of training (Wilson et al., 2015). For all employees to comprehend and accept responsibility for their activities within their field of operation, well defined policies and processes for training are essential (Jarvis, 2014).

2.4.4 Use of training in reducing non-compliance in the pharma industry

According to studies, the majority of errors are brought on by a lack of skill, knowledge and experience and to prevent the same regular training and on-the-job training will be essential (Admin, 2019).

Create a plan to bring the programme into compliance if anyone finds any flaws ("If Training Is so Easy, Why Isn't Everyone in Compliance?" 2004). McKinsey's study 2010 "Pharma Operations Benchmarking" identified three major areas of action for pharmaceutical companies to consider to ensure future corporate success, which includes improving the performance of facilities and plants, interconnection and plant configuration, as well as increased quality and compliance.

To reduce the gap between educational institutes and industries, the concept of learning factories is popular in some countries which aim to emphasise industry-partnered, active learning. The projected advantages of foreign investment in the pharmaceutical sector in the ASEAN area are sometimes limited by factors including a lack of sufficient training (Lasserre, 1982). As learning is a necessary component of technology transfer, it can be enhanced by using the right training techniques and that's the way the training activities are considered crucial in the relevant function (Lasserre, 1982).

An improvement can be made by organising training activities that take into account the kind of technology, the intended use, and the orientation of the training required to adopt the proper approaches (Lasserre, 1982). Proper training design and effectiveness testing reduce compliance issues and propel manufacturing plants toward higher productivity. Pharmaceutical companies are interested in determining the root cause

of the contribution of human beings to certain deviations and regulate the same through appropriate training intervention.

Training is an important parameter to respond to human-related deviations logged in through quality management systems (QMS). Training supports reducing error through adequate awareness in the relevant areas.

Pharmaceutical products are trusted by the distributor to the customer because of their inherent quality, and training ensures the products' quality along with safety, integrity, strength and purity. Training not only plays a significant role in developing people but builds up trust and confidence among the pharmaceutical fraternity. It is therefore important that in future the proposed model presented in this research paper is tested in the pharmaceutical industry.

Training is identified for employees as per the role concerned. Any role is fine-tuned to activities for which the employees are hired, transferred or promoted. Training needs identification starts with the area/function activities and is guided through the requirement of relevant standard operating procedures.

Initial skill training, refresher training, and management system training are some of the training methods that are most successful in lowering errors contributed by human beings (Rooney et al., 2002). Regular training as well as on-the-job training will be critical in preventing human-led errors (Admin, 2019).

Training and education enhance understanding from "nuts and bolts" to "the bigger picture" and thus contribute to avoiding simple design or procedural errors or errors of judgement (Le May & Deckker, 2009). It is well known that a new employee is more likely to make obvious mistakes than an employee who has been with the company for many years (Admin, 2019).

Thus, a proper approach to training is required during the induction training program and new employees need to be updated with proper guidelines, Standard Operating Procedures, work ethics etc. to avoid mistakes in their routine work. Repeated mistakes or errors raise questions about the credibility of the system.

Pharmaceutical firms are expected to continuously update their training needs to ensure the proper growth of pertinent workers at all levels. For continuity of learning refresher training is required and refresher training on certain procedures and Good Manufacturing Practices, Good Documentation Practices, and Data Integrity enhance the overall compliance to the system in pharmaceutical industries.

Participants must be trained and retrained if their initial training was inadequate or if the regulations require refresher training (Konstantinos et al., 2011). To assist workers in developing and maintaining a high skill level, a refresher training programme is required to address a worker's skill deterioration, improve skills beyond the initial training level and subsequently which will reduce workers' errors (Rooney et al., 2002).

The most effective tools to address errors led by workers are comprehensive training drills that provide employees with all of the necessary skills and knowledge to handle all of the plant's activities (Admin, 2019).

It is the responsibility of someone with management responsibility—a manager—to ensure that employees have the necessary skills to perform the duties of their job, and this applies throughout the organization, beginning with the most senior managers (Le May & Deckker, 2009). Managers should address the importance of training before employees attend the training to increase their general self-efficacy, learning self-efficacy, and training motivation (Tai, 2006).

3. Proposal of a conceptual model for the enhancement of training system

A conceptual model for training with a focused view on deviation in employees' performance is proposed. Training is directly impacting performance. The performance of employees in pharmaceutical manufacturing units can be enhanced through the effective monitoring of five factors: define, measure, analyse, improve, and control (DMAIC). Training improves employee performance by directly influencing the five factors -DMAIC. Proper training design and its effective implementation influence the aforementioned factors in improving employee performance, which in turn influences the occurrence of errors contributed by human beings. The proposed model (Fig.2) involves the Six sigma principle in the training management system. The need for six sigma principles along with the required Quality Management Tools (QMS) tools in the proposed model is explained subsequently.

3.1 Need of Six Sigma in the proposed model

The process of pharmaceutical industries is quality centric. Knowledge of six sigma is known through the five factors which are defined, measured, analyse, improve and controlled. The goal of Six Sigma is simple – deliver near-perfect goods and services for business transformation and optimum customer satisfaction (Aditama, 2020). Six Sigma is defined by the American Society for Quality as a method that provides organisations with tools to improve the capability of their business processes (Kidd, 2020). The underlying principle of Six Sigma is simple and involves achieving the goal by identifying the problem and solving it, through continuous improvement in finetuning processes until the desired results are achieved (Aditama, 2020).

Analyze the frequency of problems arising in the process based on previous experience and customer feedback, and focus on solving the most significant and pressing problem first (Aditama, 2020). Analyze specific components of the problem and plug leaks to make the process self-sufficient and precise (Aditama, 2020). This improvement in performance and decrease in process variation contributes to defect reduction and improvements in profits, employee morale, and product or service quality (Kidd, 2020).

According to Diamantidis and Chatzoglou (2014), the successful outcomes for both the participant trainees and their employers depends on the design and organisation of the training process.

The conceptual model is proposed in the above lines to establish the connectivity of DMAIC tools to QMS tools used in the Training Management System (TMS) and to facilitate training effectiveness measures in a

GxP-compliant system. Detailed steps on Training requirements, root causes, and feedback are all designed and explained in the various steps.

Streamlining processes by establishing Standard Operating Procedures (SOPs) for teams to follow not only reduces the margin of error but also ensures compliance and completion of tasks on time, if not ahead of schedule (Kidd, 2020). The best part is that modern technologies and innovative methods are making the process of continuous improvement even easier (Mengo, 2021). Keeping process documentation up to date and tailored to needs is quick and easy with the ability to intelligently track Key Performance Indicators (KPIs), receive realtime worker feedback, and more (Mengo, 2021).
Manufacturers use the DMAIC approach to optimise their existing workflow and continuously implement improvements with greater accuracy over time (Mengo, 2021). DMAIC is an acronym that stands for Define, Measure, Analyze, Improve, and Control (Mengo, 2021). A Standard Operating Procedure (SOP) is a set of detailed instructions that employees can use to complete common tasks (Mengo, 2021). It is the prescribed series of steps or directives to be carried out to solve a problem or complete a task (Mengo, 2021). A collection of detailed instructions known as an SOP (Standard Operating Procedure) aids employees in doing common tasks (Kanban Zone, n.d.).

SOP is the prescribed series of steps or directives to be carried out to solve a problem or complete a task (Kanban Zone, n.d.). The greater the trainees' familiarity with the training contents, the greater their self-efficacy and willingness to attend the training programme (Tai, 2006).

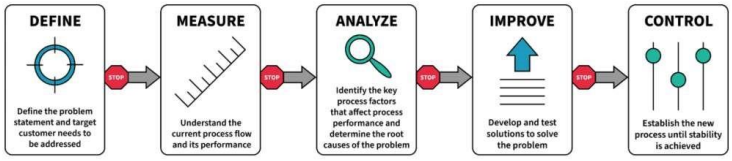

Figure 1

Depiction of application of the DMAIC process in the training content

Note- The image was created from a research article emphasizing defining Lean Six Sigma

DMAIC Process. From “Kanban Zone - Visual Collaboration for Lean and Agile Portfolio Project Management” retrieved February 5, 2023, from https://kanbanzone.com/resources/lean/lean-six-sigma/dmaic-5-phase-lean-six-sigmaprocess-improvement/

3.2 Application of six sigma in the proposed model

The proposed conceptual model for training is directly linked to six sigma principles. DMAIC tools which represent six sigma principles are proposed to link to the training matrix. This provides connectivity to the traditional training approach with a proper building of the six-sigma principles. The goal of Six Sigma is simple which is earlier mentioned as the delivery of perfect goods and services and as pharmaceutical delivery comprises Quality commitments so proper utilisation of the six-sigma principles along with other QMS tools will impact training in pharmaceutical industries with better enhancement reach.

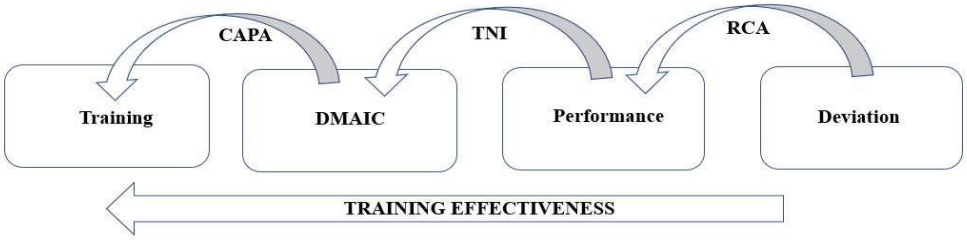

Figure-2- Proposed conceptual model of Training

The theoretical model illustrates connectivity in the training process from the logging of deviations in the Quality Management System (QMS) to the Training Need Identification (TNI), The proposed model accounts for critical steps of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) and enhance the training feedback system as QMS elements are scientific documents to provide the actual health of compliance and can provide current insight of employees' training need.
The projected model tries to establish connectivity and feedback between QMS tools for better training effectiveness measures. This model tries to empower the training effectiveness measures by accounting for each QMS deviation or any gap identified in the existing system and using the opportunity to improve human performance through enhanced training need credentials.
This conceptual model is intended to supplement the existing pharmaceutical industry training system with DMAIC principles for improved GxP compliance. During the design of the model, the relationships of important dimensions of training are taken into account.

4. Discussion and Result

The need for training to address issues related to human contribution is well documented in the literature review. Any compliance risk is taken seriously in the pharmaceutical industry, and the involvement of human factors, if any, is thoroughly investigated. Through awareness sessions, training plays an important role in percolating the learning from the incident. Regulatory guidelines require all employees in the pharmaceutical manufacturing domain to receive training. Training is essential throughout the domain.

Training is a regular process in pharmaceutical companies, and all employees are required to complete the required training before performing the activity associated with the role. Even though pharmaceutical companies report a certain compliance issue regarding human functions, any gaps in the system that are discovered must be investigated and controlled through a proper training system.

Pharmaceutical training is essential in all aspects and cannot be limited to gap analysis alone. Training must be used to the greatest extent possible to benefit human resources. Continuous learning in conjunction with an effective system improves training effectiveness and keeps the organisation at the forefront of regulatory compliance. Because quality is critical in the pharmaceutical industry, training plays an important role in improving overall quality in the GxP environment.

According to the findings of the preceding study, the importance of training is recognised in all types of businesses, including pharmaceuticals. Training is used everywhere to develop employees who contribute to increased productivity on the shop floor. Training has a direct impact on developing employees in all areas and roles of service in the organisation. Training is the best opportunity for management to develop human resources. People, processes and procedures, premises and equipment, and products are all influenced by training. Quality is the lifeblood of pharmaceutical companies. Quality is valued throughout the pharmaceutical industry, and training increases everyone's accountability and responsibility to improve quality.

The growth of pharmaceutical companies is dependent on the standard and commitment to quality, which is ensured by the effective performance of trained employees. A review of the literature reveals that training plays a significant role in quality enhancement in pharmaceutical companies. Currently, training is thought to be the best way to increase employee awareness, which not only protects the products but also reduces the possibility of human error in the pharmaceutical sector. Globally, many improvements have been made in the pharmaceutical sectors, with notable investments in training initiatives aimed at improving GxP compliance.

Pharmaceutical companies emphasized quality. Quality is all around us, and it is everyone's responsibility. Training plays a significant role in improving quality in pharmaceutical companies.

To support the training system, this paper proposed a conceptual model based on the DMAIC concept. DMAIC is a well-known six sigma concept that can be used to improve the pharmaceutical training system. A significant contribution of DMAIC is noted in the literature review, but no opportunity to use DMAIC tools in the training management system in the pharmaceutical sector was utilised. Because there is no direct link between DMAIC tools in the training system in the pharmaceutical sector, this conceptual model with DMAIC tools is proposed. DMAIC is useful for improving quality, so it is incorporated into the conceptual model by incorporating DMAIC into training and its performance.

This model, which includes a direct link between TNI and CAPA, will aid in improving employee performance. Furthermore, this model can be proven progressive because it links training effectiveness even to the point of deviations, which eventually represents the training insight to improve overall system quality. Every step in this model can be thoroughly documented and monitored for improved results.

5. Summary and Conclusion

The proposed conceptual model is based on improved training. According to the literature review, training is important in improving employee performance. It also demonstrates that the pharmaceutical industry is based on quality. The GxP environment governs the requirement for quality. Six sigma is well-known in the engineering industry, and it is an essential component in ensuring quality. DMAIC is a data-driven improvement cycle for improving, optimising, and stabilising business processes and designs.

The primary tool for driving Six Sigma projects is the DMAIC improvement cycle. DMAIC, on the other hand, is not limited to Six Sigma and can be applied to other types of improvement applications. As a result, a model is built to incorporate DMAIC and other training parameters. The conceptual model will improve the quality of pharmaceutical products through trained employees by implementing QMS tools following

the DMAIC features. Employees who have been trained are always an asset in the GxP environment. Training is always a significant impetus in improving overall compliance in pharmaceuticals.

Pharmaceutical industries must implement ongoing training and required awareness programmes to increase GMP compliance in the business. Following regulatory requirements and a well-established quality management system protects the product's safety, identity, strength, purity, and quality.

Developing people to improve compliance is an important milestone for training functions around the world. Because the pharmaceutical manufacturing sector is experiencing global growth, any problems impeding productivity are critical to the entire business. The company's ability to compete is seriously impacted by productivity losses caused by certain types of human errors.
The conceptual model can be studied further in the future through a survey of the pharmaceutical industry. Through insights from pharmaceutical employees, the survey will improve the model's effectiveness.

The conceptual model proposed in the research study has enormous potential for improving employee performance through the training of identified employees. DMAIC concept always adds value to six sigma approaches to improve pharmaceutical company quality by effectively focusing on "define, measure, analyse, improve, and control" process and system parameters.

Training and development play an important role in the pharmaceutical industry, and the conceptual model discussed in depth can be used to improve the current training system in the domain.

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