

# Application of Six Sigma- DMAICDV tools to Enhance the Effectiveness of Training and Development in the Pharmaceutical Industry

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## Abstract-

Training in the pharmaceutical industry is challenging. To ensure quality, the pharmaceutical industry depends on trained employees. Training is significant and critical in the pharmaceutical industry. The pharmaceutical industry is bound by stringent regulations. Non-compliance to pharma regulations impacts credibility and trust in the said company. To ensure compliance in pharmaceutical companies, an effective training system is a must. Ineffectively trained employees are detrimental to the overall functioning of the pharmaceutical industry. Pharmaceutical industries continuously face regulatory challenges and hence a robust training model is the need of the hour. Across industries, Six Sigma tools are profoundly recognised for improving quality attributes and the applicability of the same in the existing training model can be weighed for better impact. As part of this research, literature was explored mainly on the aspects of Six Sigma and training perspectives in the pharmaceutical manufacturing sector. The literature review showed that no training model with the Six Sigma approach was used in pharmaceutical industries. This research paper aimed to develop a training model based on Six Sigma tools for the pharmaceutical industry. To cater for the very need for an enhanced training system, a six-sigma-based training model with detailed DMAIC tools was developed as part of this research. The said model was surveyed among 72 subject matter experts from selected 10 pharmaceutical-regulated companies with USFDA approvals. An overall higher rate of agreeability was recorded across the survey for the said model, which was found useful by the respondents. For further enhancement, the surveyed training model was modified with DMADV tools in addition to the existing DMAIC tools, and the new modified model can be used for future studies.

**Keywords-** Training model, DMAIC, DMADV, Six Sigma, Pharmaceutical

## 1. Introduction

A lot of challenges and changes are currently being faced by the pharmaceutical industry (ACADEMY, 2017). To meet the challenges of the pharmaceutical industry, pharmaceutical employees need to be trained (Pai et al., 2016). Training in pharmaceuticals is a regular process but as it does not use Six Sigma tools in its training structure many times it fails to control non-compliance of the system.

According to FDA 483 observations, training isn't always effective, timely, or meaningful (ACADEMY, 2017). Recent warning letters, 483s, and "observations of noncompliance" from the agency reveal the deficiencies in companies and the Gold Sheet listed "training" as an item among 10 of the 71 warning letters sent out (ACADEMY, 2017). The pharmaceutical industry benefits from training to maintain compliance, consumer safety, product quality, and development (ACADEMY, 2017). The pharma industries across the globe ponder enhancing training systems to reduce non-compliance related to training.

Nearly every quality issue, equipment failure, or accident in industrial and manufacturing facilities has human error as a significant contributing factor (ACADEMY, 2017). Companies are struggling to control human error at every level of human involvement. According to Sabtu et al. (2023), the Six Sigma approach is regarded as a fresh option for raising the calibre of staff. Six Sigma-based training models can reduce human error through effective training interventions.

Effective training can have a significant and positive impact on a company's bottom line, and all organisations are encouraged to implement employee training programmes (Grensing-Pophal, 2018). Understanding the changes and enforcing the appropriate employee training to keep everyone up to date is the only way to ensure that the company and everyone in it maintains a competitive edge (Bybee, 2017).

The Six Sigma process has become essential in an array of industries, from health care to insurance, telecommunications to software (*Six Sigma in Pharmaceutical Manufacturing Industry - Pharma Mirror Magazine*, 2015). Six Sigma can identify problems with critical quality attributes in a pharmaceutical or biotech product (FIRESTEIN, 2020). Six Sigma significantly enhances all business processes, including financial, operational, and production-related ones, to produce business excellence, greater customer satisfaction, and superior profits (*Six Sigma in Pharmaceutical Manufacturing Industry - Pharma Mirror Magazine*, 2015).

The environment of the pharmaceutical industry is subject to more dynamic changes that increase competitive constraints (Rybski & Jochem, 2016). According to Sabtu et al. (2023) "Six Sigma" describes a stage in the process that is close to perfection. The ultimate objective of Six Sigma is to transform the organization's entire mindset and culture to develop systems and processes that are as close to flawless as is humanly possible, ensuring that they are operating at the highest possible standard of performance (Jernelid et al., 2009).

Six Sigma is a powerful tool to reduce waste and encourage people to a higher goal. Linking Sigma to the training system is the need of the hour for pharma industries. Literature indicates that Six Sigma is not new to pharmaceutical companies. In addition to Quality Management System (QMS) tools, Six Sigma is also used in pharma companies to some extent. The current use of Six Sigma in the said industry is primarily focused on enhancing productivity through waste reduction. Applications related to Six Sigma were limited to process augmentation and operational excellence in the pharma industries.

There are efforts in the regulated pharma industry to make personnel aware of Six Sigma through certain programmes. Such programmes are aimed at boosting employees on how to use Six Sigma to reduce waste in the said industry. The limitation of the existing training system is that the system itself has not been considered for its upgradation through Six Sigma. Existing structures of training systems across pharma industries do not consist of Six -sigma tools but the same system is helping others to educate professionals on Six -sigma applications through various initiatives.

Currently, personnel in pharmaceutical companies are aware of Six Sigma as it is a topic of interest in most pharma to enhance operational excellence. Although training on the implementation of Six Sigma is common in pharmaceutical manufacturing companies it was never used to modify the existing training system as a whole. Through the review of the literature, it was also observed that no survey was performed on the applicability of the Six Sigma concept in pharmaceutical manufacturing training.

In pharmaceutical industries training is crucial. In pharmaceutical industries as an awareness program, Six Sigma is used in conjunction with Quality Management Tools for process excellence. In the pharmaceutical industries, no training model was used six-sigma as an operational tool for training. Chakraborty and Pant (2023) proposed a conceptual model for applications of Six Sigma. A survey of the same was performed among 72 pharmaceutical professionals spanning around 10 regulatory companies to check the applicability of the model in the pharma industry. The research paper tried to answer on DMAIC tools in the training system.

The survey echoes a strong agreement of DMAIC tools in the proposed Six Sigma-based training model, The survey also indicates the reduction of human error is possible through the application of the Six Sigma tools in the training model. Respondents advocate including DMADV tools in addition to DMAIC tools in the proposed training model and suggested the combined DMAICDV training model in the pharmaceutical industries.

The paper contributed immensely to the survey as it captures the essence of how the training system can be enhanced with the help of DMAICDV. The Six Sigma tools if used properly can diagnose the failure of the training system or rather it can suggest better ways for enhancing training effectiveness. Corrective and preventive action in response to any failure observed by the Food and Drug Administration (FDA) where human involvement is there, this training model can be proved fruitful.

## **2. Literature review**

### **2.1 Current Training trend in pharma industries**

According to Ratsimandresy (2022), pharmaceutical companies empower Quality Assurance to deliver high-quality products through eight pillars of the Performance Qualification System. Training being the first pillar of Quality Assurance directly impacts the quality of finished pharmaceuticals (Ratsimandresy, 2022) and anyone who desires to work in the manufacturing of medical devices, pharmaceuticals, or biotechnology must undergo extensive training and evaluation of their job duties (Chugh, 2020). Apart from training other pillars which are mentioned in the Performance Qualification System are Qualified Person and Responsible Person provision, Quality Management System consultancy and design, Good Manufacturing Practices (GMP) compliance, Auditing, Standard Operating Procedures (SOP) development, Inspection preparation and support, and Quality risk management (Ratsimandresy, 2022). The other pillars mentioned in the Performance Qualification System are also dependent on training for proper function. Training is the most viable function in the pharmaceutical manufacturing industry.

The pharmaceutical industry needs an error-free environment and demands an effective training system in place to minimise risk to the shop floor. Pharmaceutical companies ensure an error-free assembly line post-pharmaceutical development to increase the quality, safety, and efficiency of the product through properly trained personnel on the factory floor (Why Pharmaceutical Training Courses Are Essential in the Rapidly Evolving Pharma Industry, 2021). To guarantee employees have a complete understanding of the established procedures, the employer must offer ongoing training (Konstantinos et al., 2011). Awareness of staff to be ensured for their cGMP compliance obligations, which include ALCOA+ recordkeeping standards, Data Integrity, and other things (May, 2021). The goal of the training programme must be understood by both the trainer and the trainee (Training Programs for the Pharma Industry, n.d.). When training a worker on pharmaceutical compliance, the Learning Management System (LMS) tools can assist trainers in ensuring that all necessary steps are taken and major topics are covered (Newton, 2021). The practice of outsourcing training to

outside experts is becoming more popular today and these experts typically customise their training materials to meet the unique needs of the industry (Training Programs for the Pharma Industry, n.d.).

To ensure compliance with GMP standards, staff members must receive proper GMP training (Ratsimandresy, 2022). This cannot be accomplished without adequate GMP training because training staff in compliance is the best way to guarantee adherence to GMP standards (Ratsimandresy, 2022). According to Ratsimandresy (2022), for a complete understanding of their roles and responsibilities throughout the drug manufacturing process, every employee involved must attend GMP training. Based on McKinsey, integrating strategic workforce planning would emphasise retraining and skill enhancement with long-term objectives in mind (Dukart et al., 2022). Assessments enable management to evaluate the success of the programme as well as enable employees to comprehend the ultimate goal and concentrate their efforts on achieving it (Neendoor, 2023).

## **2.2 Current Challenges Faced by T&D in Pharma**

Training in the pharmaceutical industry is critical because the industry still faces many challenges, both established and new (Diwakar, 2023). Even under extremely challenging situations, it is crucial to maintain employee training. (Schniepp, 2020). Employees in the pharmaceutical industry need more comprehensive training to stay competitive in the age of a more specialised market (Bybee, 2017). It has been noted that a lack of qualified, talented, and capable employees has forced organisations to come up with creative solutions to keep their priceless workforce (ACADEMY, 2017). Supervisors are crucial in managing daily compliance, but without training, they won't have the information necessary to confidently lead workers (Newton, 2021).

It has been noted that a lack of qualified, talented, and capable employees has forced organisations to come up with creative solutions to keep their priceless workforce (ACADEMY, 2017).

Poor, insufficient, and ineffective training has a sneaky way of sustaining itself if those who do the training and those who receive it have never been exposed to effective training (Jones, 2000). According to Neendoor (2023), millions of people work in the pharmaceutical industry, and since each one of them is crucial to the development of the company, training is necessary to prepare them for the dynamic environment in which the industry operates.

Poor training begins with vague or completely missing objectives, i.e., the expected outcome of the training (Jones, 2000). According to Grensing-Pophal (2018), poor training can cause employees to perform their jobs worse than they did before the training, which can lower morale as well. For the manufacturer to make sure that its staff is competent and well-trained, it is also necessary to evaluate both their performance and the training methods (Ratsimandresy, 2022). Simple regulatory infractions or process errors can have serious repercussions (Newton, 2021). Manufacturing errors cause harm to its reputation and hence pharmaceutical training programmes are a wise investment to promote the success of the staff and the business. (Why Pharmaceutical Training Courses Are Essential in the Rapidly Evolving Pharma Industry, 2021). Employee efficiency or thoroughness could suffer as a result of poorly planned training (Grensing-Pophal, 2018).

Fierce competition and a lack of qualified and skilled workers put businesses at risk of falling behind their competitors (Diwakar, 2023). To continue existing in the highly competitive environment, the industry must precisely increase productivity, reduce waste and costs, and do away with inefficiency (Pai et al., 2016). It should be noted that not complying with pharmaceutical-grade standards may end up in hefty fines as well as potential legal actions that could put a manufacturer's business at risk and hence it mandates to ensure individuals involved in the manufacturing process complete specific training in pharmaceuticals (Ratsimandresy, 2022).

The introduction of regulations set forth by various regulatory bodies that new pharmaceutical products prove to be safe and effective before they can be marketed and sold marks the dawn of the modern pharmaceutical industry (Pai et al., 2016). GMPs must be strictly followed by every manufacturing facility, and every employee must adhere to all rules and procedures related to manufacturing (Ratsimandresy, 2022). The importance of proper training with the necessary documentation to be conducted by the pharmaceutical industries is highlighted in specific Guidelines for Good Manufacturing Practices (GMP) that have been developed by regulatory agencies all over the world and it is important to educate those who work in GMP environments about GMP principles (ACADEMY, 2017). All employees should be taught that they are better equipped to comply with cGMPs through training to improve their performance overall (Wilson et al., 2015).

Businesses must adhere to numerous government regulations to ensure the safety and effectiveness of their products (Diwakar, 2023). Pharmaceutical industries need to maintain a proper GMP environment around the clock. All manufacturing facilities must strictly follow GMPs, and all employees must firmly abide by manufacturing procedures and regulations which can only be accomplished through effective GMP training (Ratsimandresy, 2022).

FDA Warning Letters regarding CAPA deficiencies typically result from several factors which need to be addressed before an audit by using the right tools and knowledge of GMP compliance (May, 2021). Insufficient employee training programmes also serve as examples of contributing factors to FDA audit findings (May, 2021). A comprehensive organisational strategy based on an appropriate "quality culture" at all levels of the organisation, including data governance and data integrity, is required to avoid FDA warning letters concerning cGMP breaches for deviations and CAPAs (May,

2021). For pharmaceutical workers, who are frequently subject to a large number of regulations, regulatory compliance is essential (Newton, 2021). Inadequate training can be extremely detrimental (Grensing-Pophal, 2018).

### 2.3 Six-Sigma

Six Sigma was created with the very specific intention of using statistical analysis to lower variation and defect rates in production processes. Six Sigma accomplishes this using one of two 5-step approaches, the DMAIC method or the DMADV method (Purdue University, 2019). The Deming PDCA (Plan, Do, Check, Action) cycle served as the basis for the systematic Six Sigma project management technique known as DMAIC (Aditama, 2020).

The DMAIC model consists of five stages which are Define, Measure, Analyse, Improve, and Control (S, 2020). The DMADV model consists of five stages which are Define, Measure, Analyze, Design, and Validate/Verify aims to create a brand-new process or product or to redesign an existing one that isn't working well (Feldman, 2018).

Manufacturers optimise their current workflow using the DMAIC approach, which they use to continuously implement improvement with increasing accuracy over time (Mengo, 2021). DMADV approach emphasises creating new services, products, or processes rather than enhancing ones that already exist. The initial stages i.e., 'Define', 'Measure' and 'Improve' of both DMAIC and DMADV processes are the same, but during the Design stage in DMADV, there is an opportunity to develop new tools to address the issue. DMADV approach initially adheres to the first three steps of DMAIC before switching to a different viewpoint in the Design/Redesign and 'Validate/Verify' stages (Feldman, 2018).

The goal of the Verify phase in DMADV is to confirm that the problem is still being solved by the new solution (Purdue University, 2019). Due to its data-based foundation, early success detection, and thorough analysis, the DMADV approach is particularly helpful when implementing new strategies and initiatives.

In Six Sigma. DMAIC is the fundamental data-driven improvement methodology. DMAIC is used to increase the effectiveness and efficiency of an organization's current processes and is considered a choice when enhancing a process and the problem is complex or the existing risks are high (*What Is DMAIC?*, n.d.). DMAIC is a data-driven improvement cycle which can be used to analyse business processes to identify flaws or inefficiencies that could lead to output defects and take corrective action (Henshall, 2018).

Without the proper information, it is simple to become overly focused on the DMAIC process rather than finding the best solution during implementation (*What Is DMAIC?*, n.d.). Hence DMAIC method prevents teams from skipping important steps by their underlying structure and discipline in view to increase the likelihood of the process success (*What Is DMAIC?*, n.d.). The purpose of using DMAIC is to enhance, maximise, or stabilise current processes (Henshall, 2018).

The goal of the Define phase is to precisely define the problem from a business standpoint followed by evaluations of the current process performance regarding the customer requirements and crucial quality attributes in the Measure phase (Boiser, n.d.). In the next phase, the primary cause for the problem is found through qualitative and quantitative analysis followed by the development of solutions and application of the proposed solution to attain the desired outcome in the last two phases of the DMAIC cycle (Boiser, n.d.).

The DMAIC control stage requires the team to create a thorough solution monitoring plan, monitor the effectiveness of changes that have been made, keep track of the plan's progress, and maintain an effective employee training programme (Terra, 2023). The control phase makes sure that DMAIC project management is implemented by ensuring that requirements for project definition, organisation, planning, necessary resources, budget, risk management, communication, and training are met (*DMAIC Model: What Is It?*, n.d.).

The manufacturing sector has benefitted from the DMAIC process which is best known for removing inefficiencies from projects and thus it has become a favourite among engineers for its stringent approach to productivity with almost zero defects (*The Ultimate Guide to the DMAIC Process*, 2017). DMAIC is an effective tool for enhancing business operations and raising standards by systematically fixing process flaws (*DMAIC – Improving Business Processes*, n.d.).

Thus, through the DMAIC stages, Six Sigma serves as a comprehensive approach that focuses on lowering defects and enhancing quality and hence it emphasises reducing waste and quality costs in the production process (Aditama, 2020). The lean concept offers industry and science a promising chance to achieve an optimised and continuous quality while increasing effectiveness (Rybski & Jochem, 2016).

The DMAIC process is an approach for processes that are currently operating below the desired level and are looking to improve them gradually whereas DMADV, on the other hand, is a different approach to improvement that aims to implement new procedures or goods at Six Sigma quality levels (S, 2022). According to Jena (2021), DMAIC defines the business process and talks about the process of improvement and control. DMAIC always offers a better solution after identifying the issue through the target-setting process (Jena, 2021). In DMADV, the design and verification process entails a complete process redesign to meet the customer requirements (Jena, 2021).

A DMAIC project is a Lean Six Sigma project that is designed to solve a problem within an organisation (Marmol, 2017). When the proposed solution is fully put into practice the desired outcome is attained (Boiser, n.d.). DMAIC is considered a simple and effective improvement process which assists teams in quickly exploring potential solutions, deciding on a course of action, and implementing process controls (Sussman, 2023). The problem-solving framework of DMAIC can assist businesses in strengthening and better organising their problem-solving methodologies (Reagan, 2020).

According to Henshall (2018), when determining whether DMAIC would be appropriate in a given circumstance, three key factors which need to be considered are-

- i) An existing process or set of processes has a problem of some kind,
- ii) There is the potential to decrease factors like lead times or defects while enhancing factors like cost-effectiveness or productivity.

The situation can be measured; the method itself uses quantifiable data, and the outcomes can be appropriately understood using quantifiable methods

The DMAIC model which is a key component of the Six Sigma methodology (Ferraro, 2016) is important for process improvement due to its data-driven technique (Sussman, 2023). Initiatives such as Lean even can be implemented as a stand-alone improvement method or as part of other processes (Sussman, 2023).

The quality management system (QMS) of an organisation must be designed, put into place, and kept up to date by quality assurance (Waddill, 2020). Six Sigma is the most effective method of lowering product error (FIRESTEIN, 2020). Demanding that product quality be tracked, measured, and continually improved is a best practice for QMSs (Waddill, 2020). This requirement typically manifests itself as a standard operating procedure (SOP) (Waddill, 2020) and the SOP for Training Management in Pharmaceutical Training specifically outlines the requirements for training employees who are operating in a cGMP environment (Pharmabeginners, 2020).

The DMAIC problem-solving framework encourages everyone to take a more methodical approach so that we don't rush things and potentially miss the best solution or implement the incorrect one (Reagen, 2020). Manufacturers can make the necessary improvements to their processes, make accurate assessments of the situation, and easily control the results by doing these things in this order (ACADEMY, 2017).

The DMAIC model can assist in working through waste or inefficiencies in a process and identifying solutions (Ferraro, 2016). A team can identify the main causes of issues, suggest solutions and then have those solutions into action for long-term improvements using the standardised set of steps or phases. This procedure directs the detection of issues, examines the root causes, and introduces best practices inside the factory (Mengo, 2021).

## 2.4 Six-Sigma in Pharma

Today's pharmaceutical industry is a veritable gold mine of possibilities (Neendoor, 2023). The estimated \$935 billion global pharmaceutical market in 2017 was expected to increase to \$1170 billion by 2021 and science and technology are constantly pushing the limits of what humans can comprehend (Neendoor, 2023). The industry is precise in its pursuit of quality improvement, productivity growth, cost reduction, and inefficiency eradication to survive in the current highly competitive environment (ACADEMY, 2017). For the same, Six Sigma is a must.

Some of the most profitable companies in the world have used Six Sigma, which has resulted in billions of dollars in cost savings, significant speed and capacity gains, and improved customer relationships (Jernelid et al., 2009). According to Jernelid et al. (2009), Klefsjö and Bergman (2004) mentioned GE, Siemens, Nokia, American Express, and Volvo are a few examples of businesses that have adopted Six Sigma. In recent years, a few pharmaceutical enterprises have begun to implement Six Sigma, primarily to reduce cycle time and cost (Charde et al., 2013). According to Haleem et al. (2015) even though Six Sigma became prevalent in non-pharmaceutical industries it has recently been adopted by the pharmaceutical industry.

This is especially useful in pharmaceutical and biotech research because biological systems frequently exhibit variations that must be considered and quantified in drug discovery and development (FIRESTEIN, 2020). The adoption of Quality by Design (QbD) and Six Sigma in the pharmaceutical sector has highlighted the significance of businesses creating a strong operational control strategy (OCS) to guide the management of product manufacturing processes (First Principles to Improve Pharma Manufacturing Operations Training Course, n.d.). The DMAIC principles were taught to the operations and quality staff, who now use cross-functional "continuous improvement" (CI) teams to track performance and make improvements (Shanley, 2005).

The success of Six Sigma in manufacturing industries compelled pharma industries to start implementing the Six Sigma project at their end. According to admin (2018), Lean Six Sigma principles have been applied by pharmaceutical institutions like GlaxoSmithKline and it has contributed to lowering waste, increasing efficiency, and minimising error in a field where even a minor error can have grave repercussions. Six Sigma has proved effective in pharma industries. The cost increases brought on by increased investments in R&D, regulatory requirements, as well as an increased focus on environmental and workplace safety issues, are major forces behind this change (Rybski & Jochem, 2016). Wherever Six Sigma's applicability is there, industries are interested in implementing the same. Six Sigma's fitment to the pharmaceutical training system will encourage the entire pharma fraternity to improve the said system to handle variations in day-to-day operations due to various challenges.

## 2.5 Six-Sigma in Training & Development

Currently, pharmaceutical manufacturing companies are opting towards more sophisticated tools and Six Sigma can offer a better option for the training system in the pharmaceutical manufacturing sectors.

According to Terra (2023), team training in the DMAIC methodology and its use is the first step in implementing a DMAIC journey for an organisation. Writing precise and concise objectives is the logical first step in effective training (Jones, 2000). This initiates the Design phase of both DMAIC/DMADV. To ensure that each step is adequately covered in the training, it is more proactive to break each job or task down into its essential steps (Jones, 2000).

Six Sigma believes in the result and any training model effectiveness of Training builds the success story. Six Sigma-based training model can enhance training effectiveness to a higher extent. The effectiveness training must and should be conducted regularly to ensure that people understand the module requirements and follow the SOP instructions without any further deviation (Chugh, 2020). The fruitful training will also help employees for the adoption of CAPA without creating any further problems in the future (Chugh, 2020).

In the United States, the regulatory expectation for training is defined in 21 Code of Federal Regulations (CFR) 211.25 whereas in Europe similar requirements are specified in EudraLex Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Volume 4, Part 1, Chapter 2 (Schniepp, 2020).

Researchers in the pharmaceutical industry who possess an educated and trained mindset are always at a competitive advantage (Bjerrum, 2011). There are numerous ways to raise the standard of job training and education, but Six Sigma may be the most cutting-edge and powerful approach (Singh & Sharma, 2020). If the organisation needs a straightforward, continuous framework to promote growth and improvement, lean may be a good fit whereas if it needs to reduce unpredictability and boost efficiency in a more complex environment, Six Sigma might be a better option. (*What Are the Differences between Lean and Six Sigma?* | Wrike, n.d.).

Six Sigma is a method for enhancing quality while guaranteeing better customer satisfaction (Singh & Sharma, 2020). Six Sigma is applied among the world's leading corporations because it has been demonstrated to generate excellent business results (Charde et al., 2013). By reducing errors and deviations, the Six Sigma methodology helps the system perform better (Singh & Sharma, 2020). To get the best of both methodologies, Lean and Six Sigma can be combined to form the hybrid technique known as Lean Six Sigma. Lean Six Sigma is effective at helping businesses cut expenses and waste while accelerating and improving output quality (*What Are the Differences between Lean and Six Sigma?* | Wrike, n.d.).

Training expectations from various regulatory bodies are expanding and the industry is challenged on the same. Six Sigma-based training can be a better option to address training issues raised by the auditors.

In pharma industries, although certain programs are delivered on Six Sigma, but industry failed to upgrade the training system itself with Six Sigma, whereas the same Six Sigma tools have been advocated for the enhancement of the corresponding system for a long. Thus, it's high time for the pharma industry to apply Six Sigma for the upgradation of the existing training system.

Six-sigma training or to boost some processes where Six Sigma tools can be proven beneficial. But this paper is unique as first time wants to extend the phenomenon from Training in Six Sigma to Training with Six- Sigma.

One of the last sectors to embrace a quality management technique like Six Sigma is the pharmaceutical sector (*Six Sigma in Pharmaceutical Manufacturing Industry - Pharma Mirror Magazine*, 2015). Using the prior research in the non-pharmaceutical industry application, managers in the pharmaceutical industry and literature should concentrate on the adoption of such practices in the pharmaceutical industry (Haleem et al., 2015).

The current survey on the Six Sigma-based model was conducted among the pharmaceutical manufacturing industry professionals to comprehend the significance of training in the pharmaceutical industry. The survey focussed on the applicability and outcomes of the Six Sigma-based training model from the perspective of the overall training system in the pharmaceutical manufacturing sector.

## 3. Research Questions

**3.1.** How are deviation, performance and training effectiveness interrelated to each other for an effective training flow?

**3.2** How interrelations of training needs identification, job role specification and training effectiveness can enhance training compliance?

**3.3** How do DMAIC elements improve the effectiveness of training systems in pharmaceutical companies?

## 4. Research Methodology

**4.1** Research Type: Both Qualitative and Quantitative research are used in this study

**4.2** Research Design: Exploratory research design

**4.3** Population: Stakeholders from Regulated Pharma Companies in India

**4.4** Sampling: Sampling size in between 60-80 professionals attached to pharmaceutical manufacturing regulatory companies

**4.5** Sampling Technique: Purposive sampling

**4.6** Data Collection Tools: Questionnaire and Semi-structured Interviews

**4.7** Data Analysis Tools: Excel, SPSS

## 5. Findings

Survey items were sent to 75 respondents who were selected based on their experience and acquaintance with pharmaceutical regulatory sectors. Pharma manufacturing companies were selected which are USFDA approved and have high market reputations. All the organisations have established training systems and are managed by Quality Assurance or functions as a separate department. Response was received from 72 participants and the survey was open for seven days.

The said survey was responded to by 87.5% of individuals who have more than ten years' experience and the rest below that. And 86.1% of respondents are directly working as pharmaceutical manufacturing industry employees and the rest are pharmaceutical training consultants.

A total of 21 items were asked on the proposed conceptual model and the survey was designed on a five-point Likert scale on the agreement level for 19 items.

The Likert items were grouped under three categories based on Training awareness, Six Sigma knowledge and DMAIC need.

Out of 19 items under the Likert scale, 7 items are grouped under Training awareness, 3 under Six-Sigma knowledge and the rest 9 under DMAIC need.

As the paper introduced DMAIC variables to a large extent, a pilot study for the DMAIC items was checked through SPSS and Cronbach alpha was found  $>0.85$  and items can be satisfactorily accepted.

Along with the quantitative analysis, suggestions were asked from the first 25% of respondents on further improvement level/scheme for the DMAIC-induced proposed model. Approx 90% of them in this category respondents in this category strongly suggested introduction of DMADV tools along with DMAIC is required in the proposed model. As the said respondents firmly believed 'Design' and 'Validate/Verify' steps need to be introduced in the proposed model to enhance the training system.

Respondents suggested that for checking the training effectiveness of the proposed model with DMAIC, training teams need to strengthen the overall process with the necessary utilisation of the 'Design' and 'Validate/Verify' steps of DMAID in the modified model after completion of DMAIC steps.

Agreeability was noted on a higher scale for all items with the highest score in the item which speaks for the impact of Training effectiveness on overall performance of employees and organizations whereas respondents. The standard deviation for each item was checked and a normal distribution trend was noted across the result.

Agreeability for each item is presented graphically for better understanding.

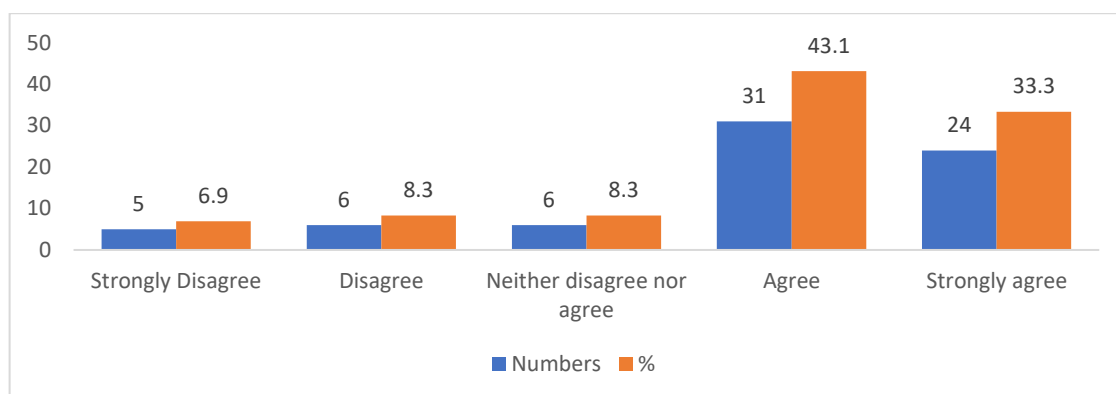


Figure-1. Deviation impacts training effectiveness

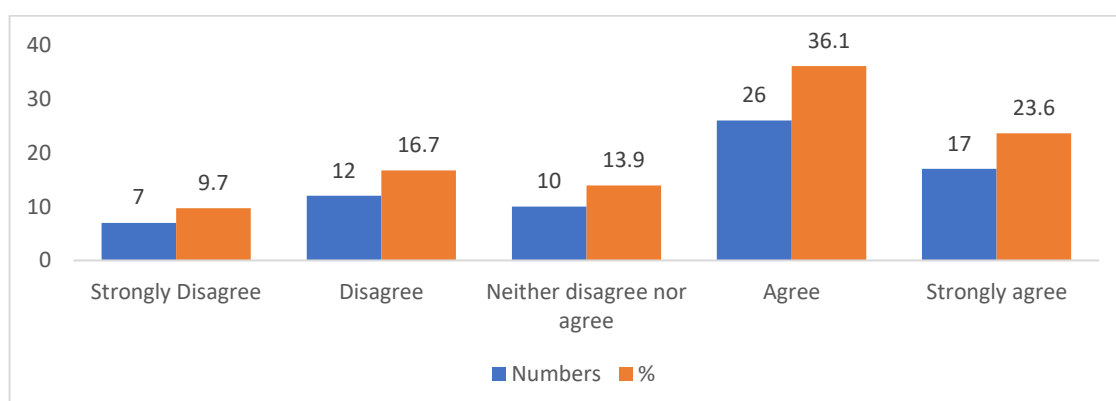


Figure-2. Deviation and performance are inversely (conversely) related

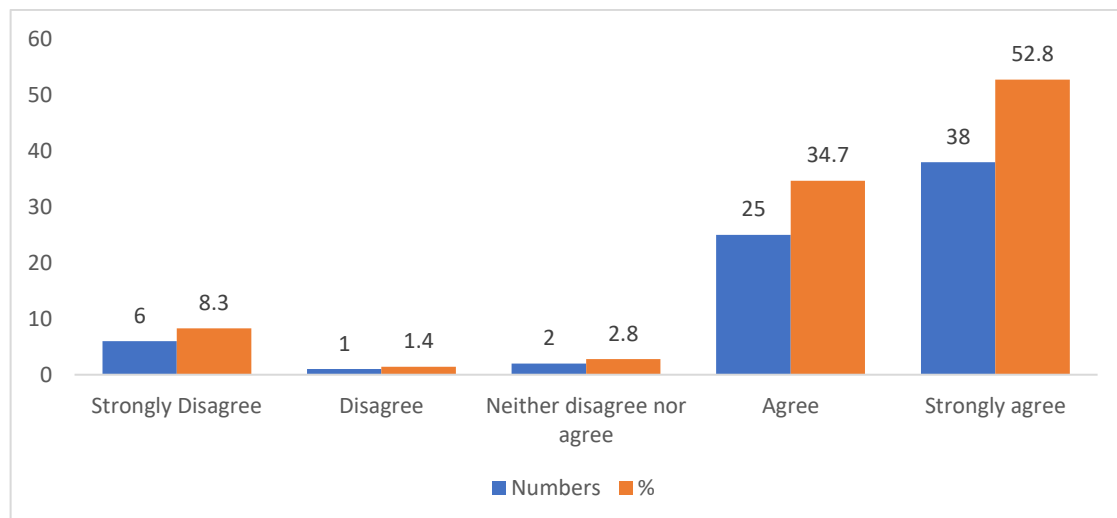


Figure-3. Training impacts performance

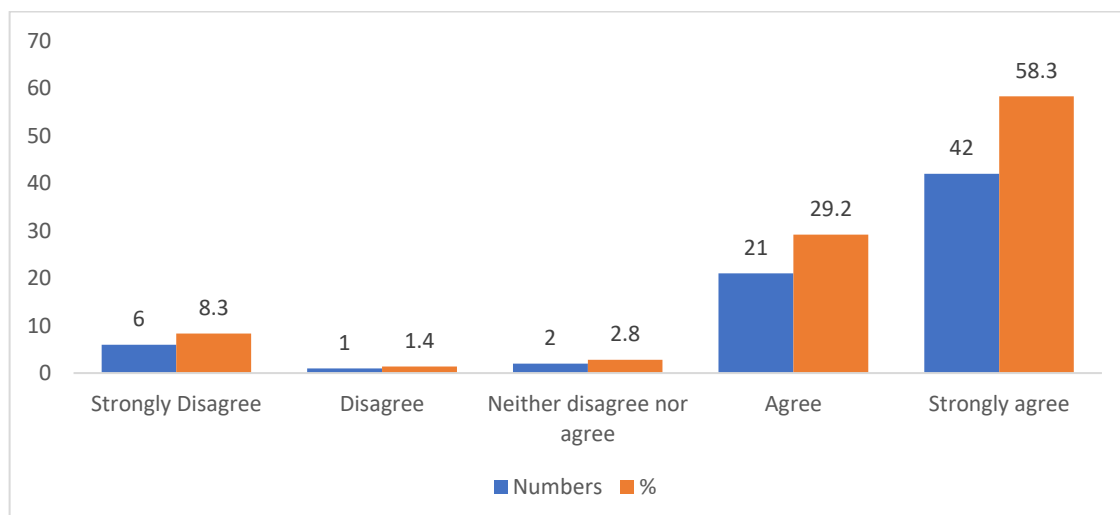


Figure-4. Training Need Identification should be 100% mapped to the role of the employee

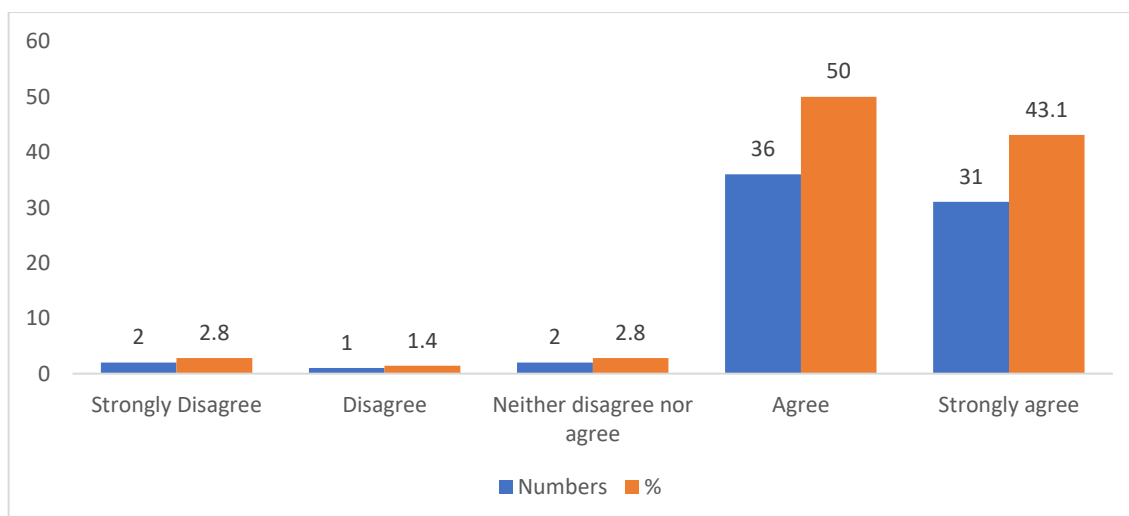


Figure-5. Training Need Identification (TNI) impacts training effectiveness



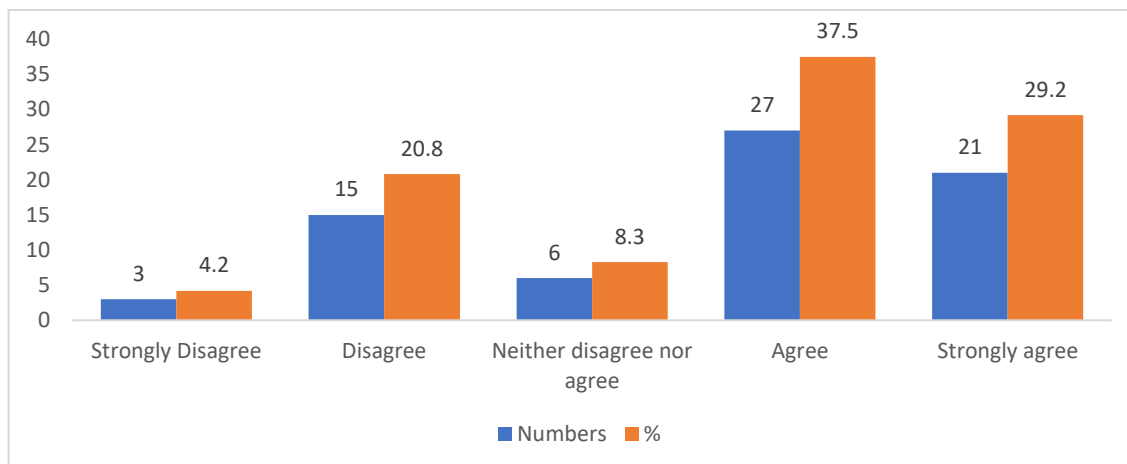


Figure-6. Pharmaceutical employees in general are aware of the 'Define, Measure, Analyze, Improve, and Control' (DMAIC) concept of Six Sigma

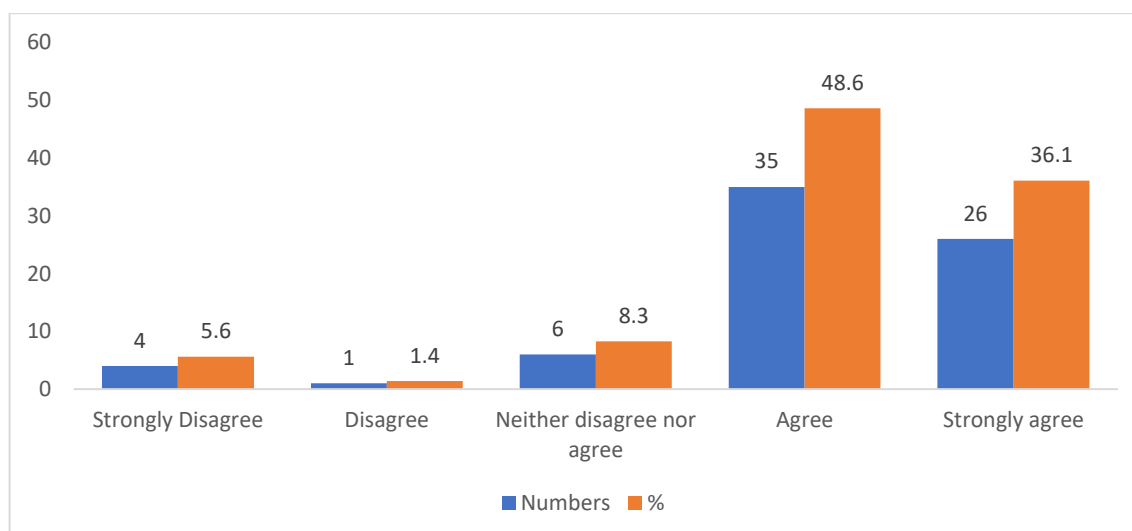


Figure-7. The Six Sigma concept enhances the training system

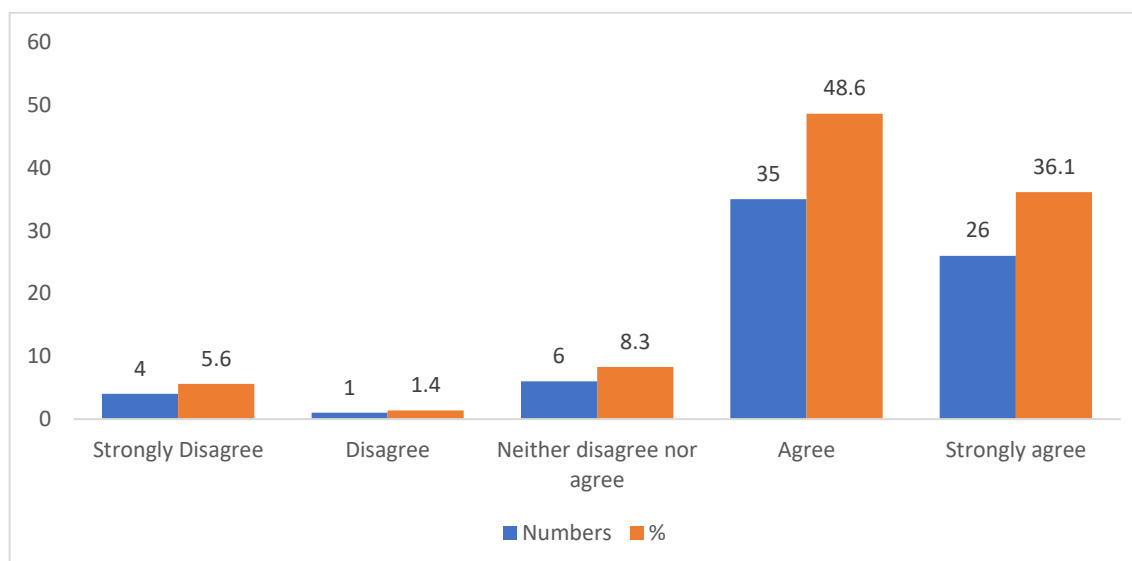


Figure-8. Six Sigma principles can be proposed for the better implementation of the training management system

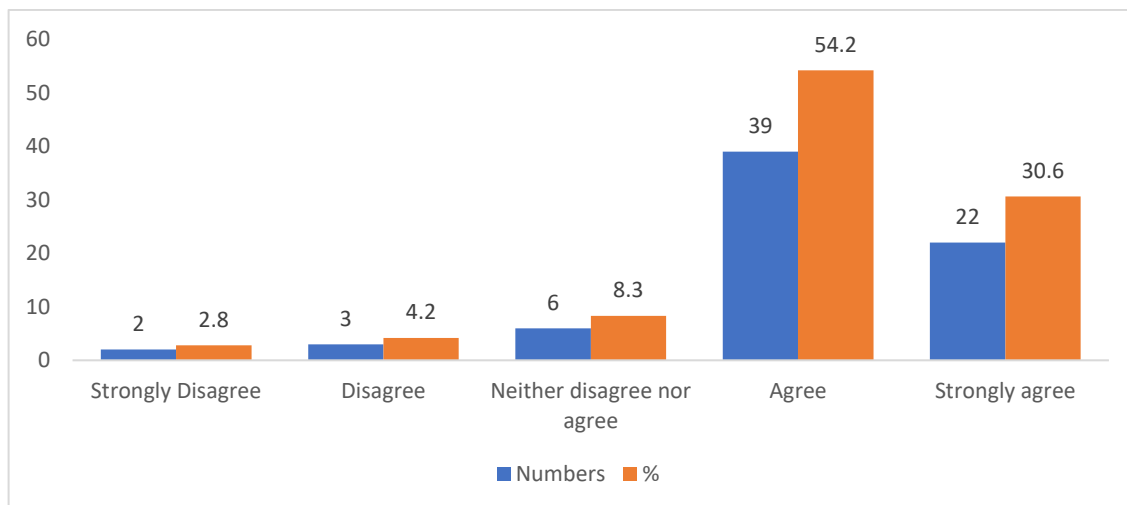


Figure-9. Training can be enhanced by focusing on the 'Define' of the DMAIC concept

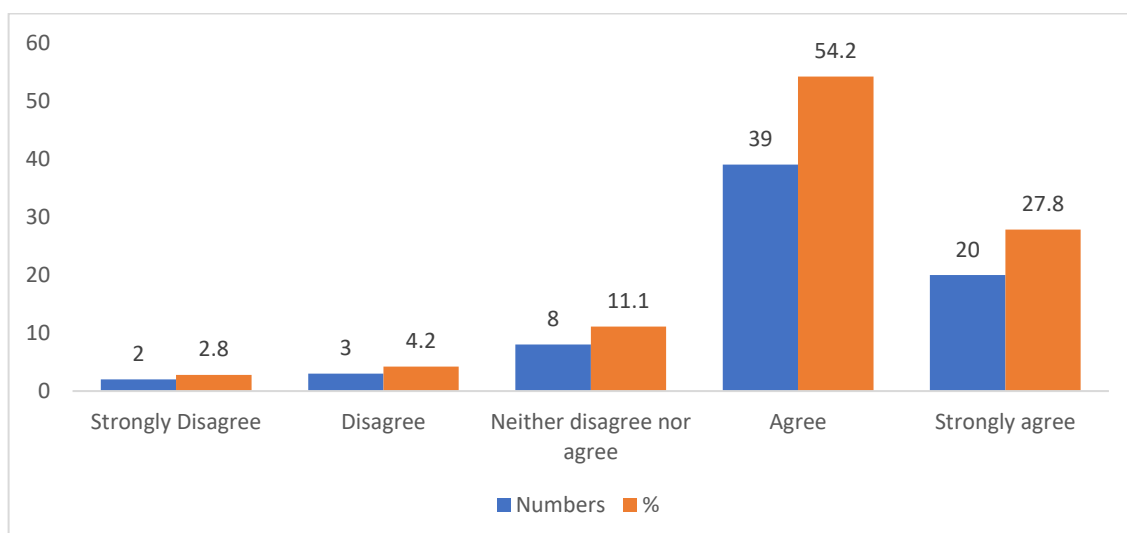


Figure-10. Training can be enhanced by focusing on the 'Measure' of the DMAIC concept

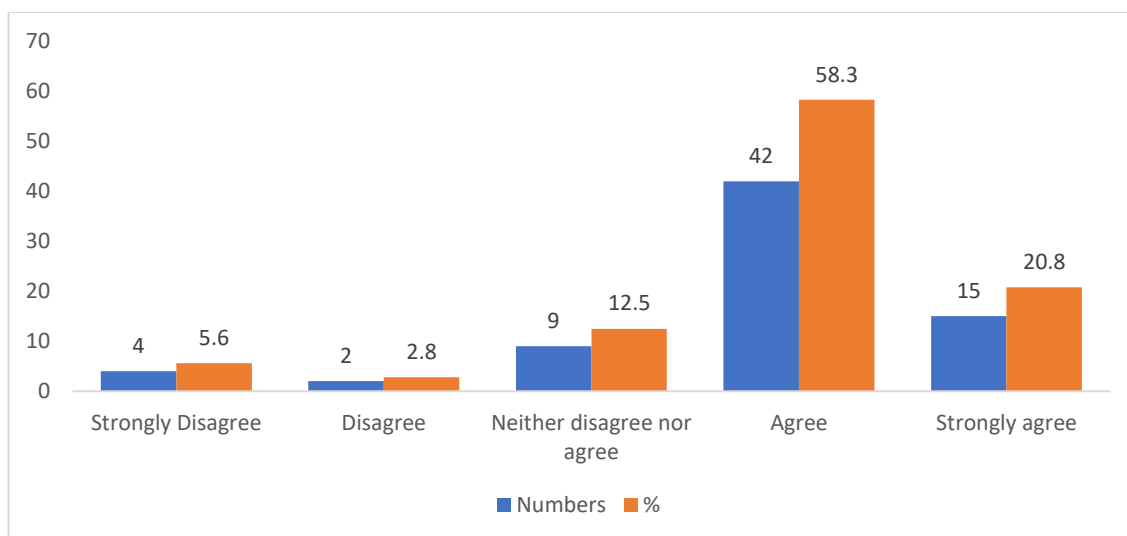


Figure-11. Training can be enhanced by focusing on 'Analysing' the DMAIC concept

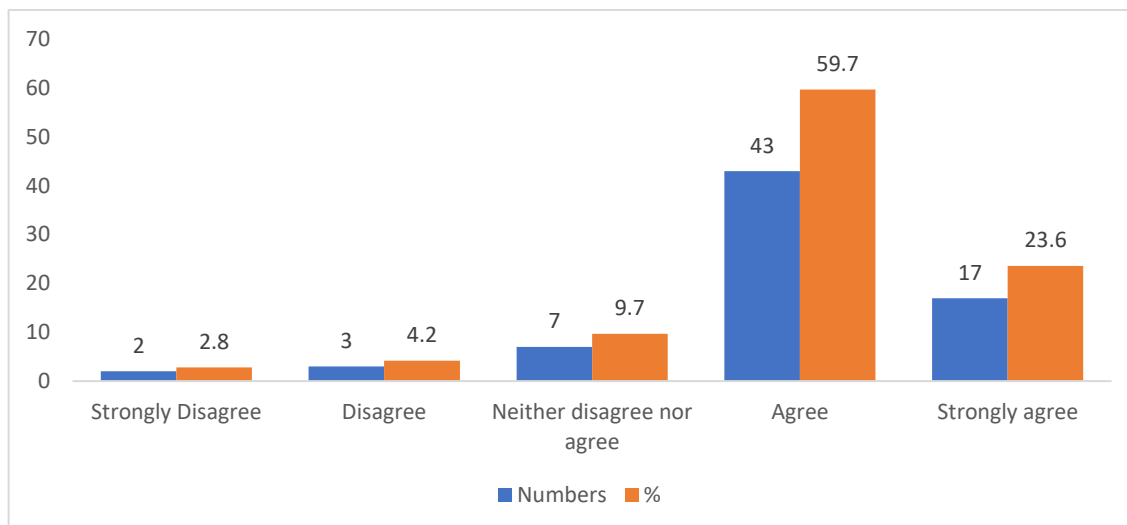


Figure-12. Training can be enhanced by focusing on 'Improve' of the DMAIC concept

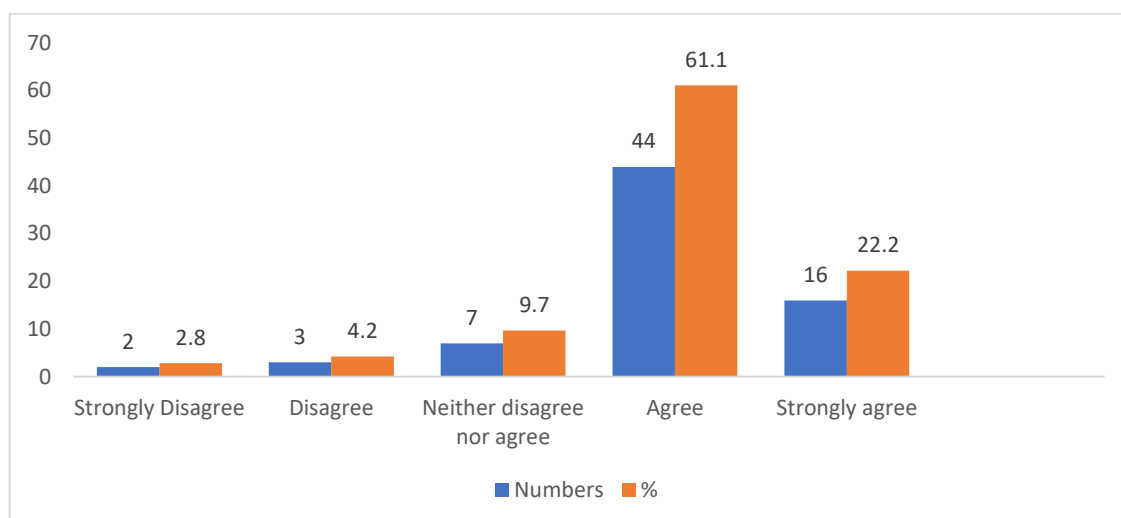


Figure-13. Training can be enhanced by focusing on the 'Control' of the DMAIC concept

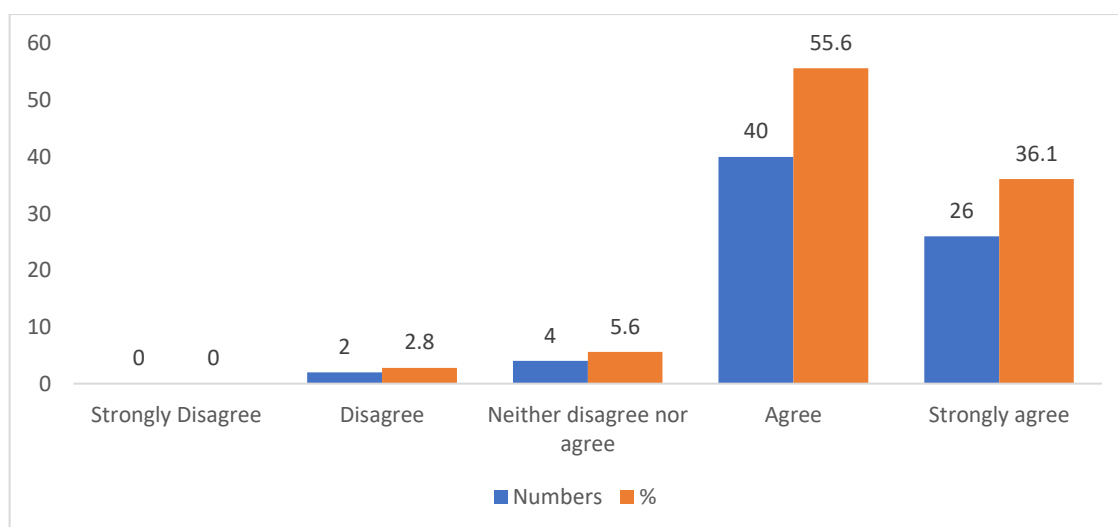


Figure-14. DMAIC can enhance the overall training system

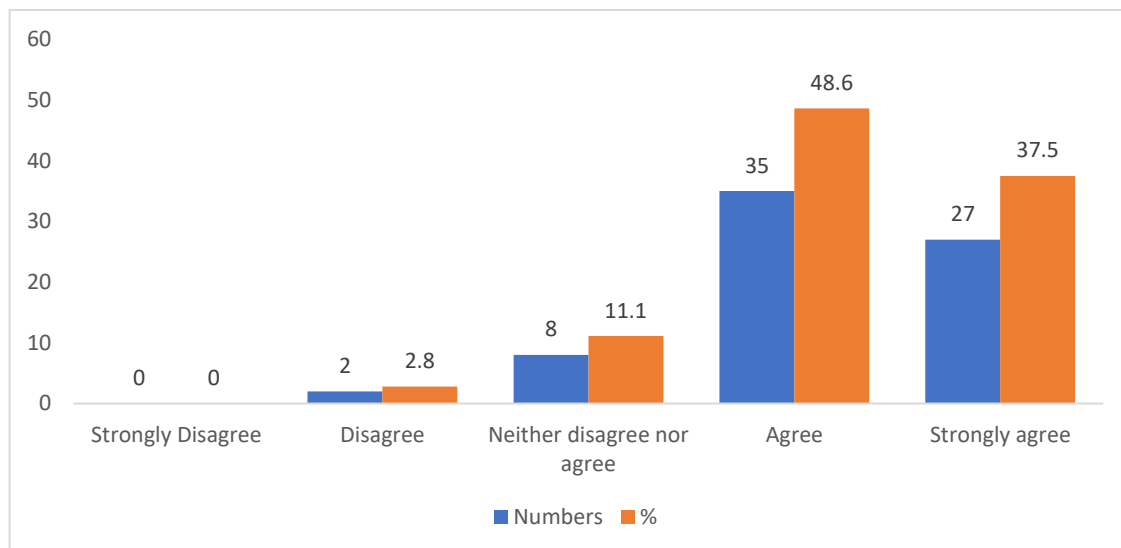


Figure-15. CAPA in the training system would be more effective if it considers the DMAIC concept

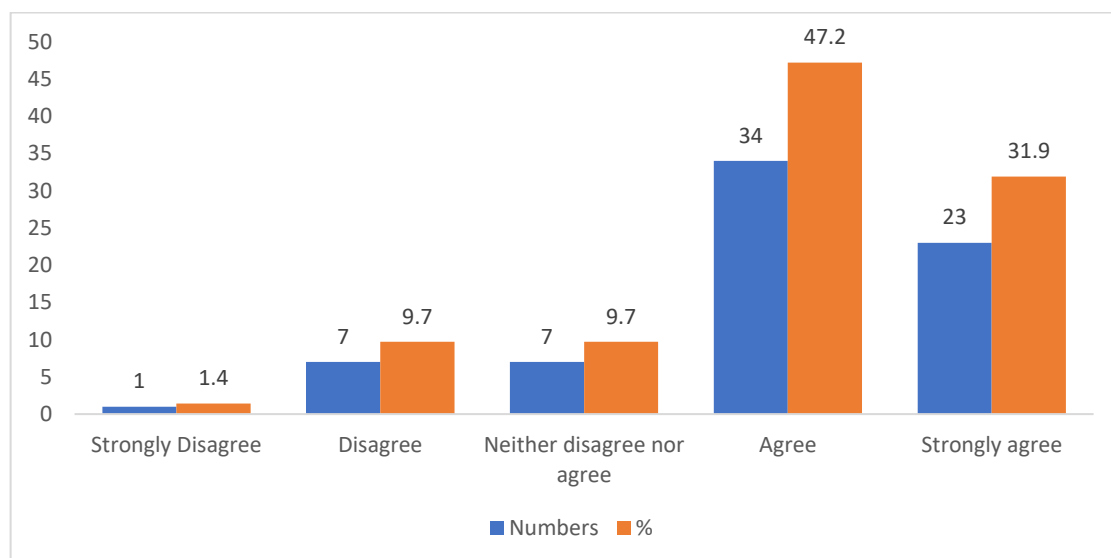


Figure-16. RCA, TNI and CAPA are interrelated

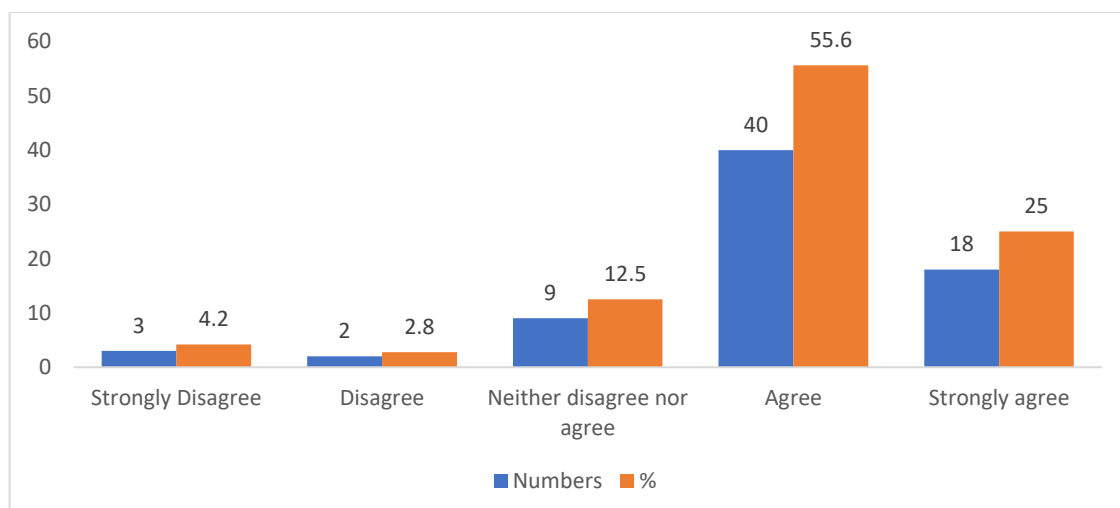


Figure-17. For training effectiveness, relations of Deviation to performance and Performance to DMAIC tools are significant

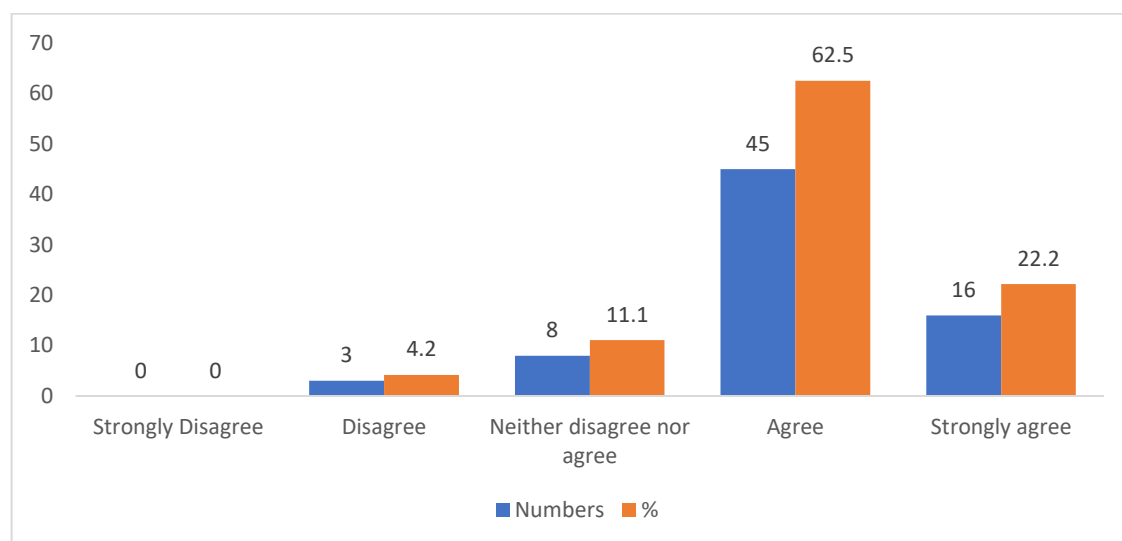


Figure-18. DMAIC would improve training feedback

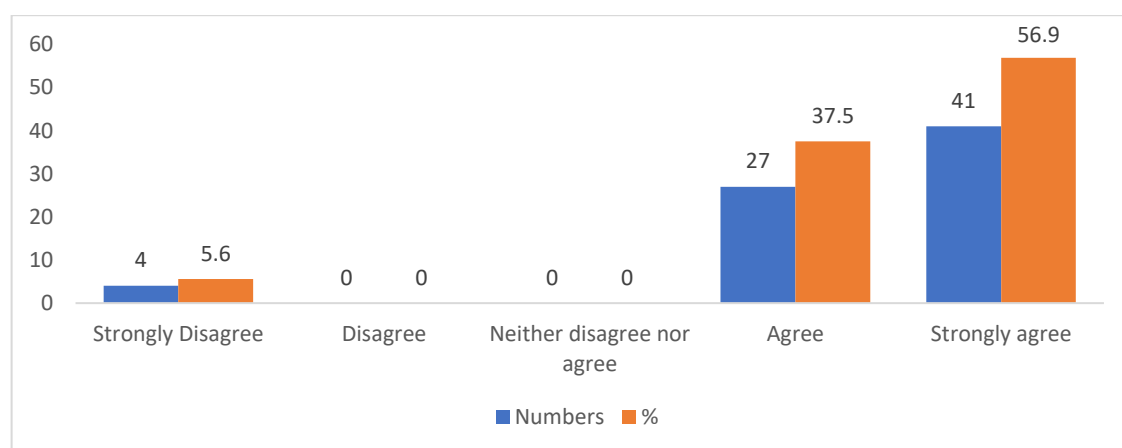


Figure-19. Training effectiveness impacts overall performance of employees and organizations

The survey speaks strongly on the use of combined tools of DMAIC and DMADV as both can affect training multi-dimensionally. A combination of DMADV and DMAIC tools, according to respondents, would be economical for handling training in the pharmaceutical manufacturing sector. As per respondents' opinions, DMADV can address the design of the training environment, and DMAIC tools can address the current training system. Respondents also added that DMAIC can handle ongoing training-related issues, whereas DMADV can manage training for a new system. With mixed tools, CAPA in the training system will be more effective because DMAIC will serve as a corrective mechanism and DMADV can serve as a better guide for the preventive mechanism. For a more efficient training solution, many respondents even indicated that the mixed uses of qualitative as well as quantitative approaches of DMAIC and DMADV tools will immensely upgrade the existing training system in the pharmaceutical manufacturing sector.

## 6. Discussion & Results

The level of agreeability in Items No.1-19 was analysed as per Table 1 and Table 2 shows the current level of agreeability for each item

Level	Strongly Disagree	Disagree	Neither disagree nor agree	Agree	Strongly Agree
Range	1.00- 1.80	1.81-2.60	2.61-3.40	3.41-4.20	4.21-5.00

Table-1. Levels and Range comparison

Sr. No.	Items	Mean	Level
Q1	Deviation impacts training effectiveness	3.88	Agree

Q2	Deviation and performance are inversely (conversely) related	3.47	Agree
Q3	Training impacts performance	4.22	Strongly agree
Q4	Training Need Identification should be 100% mapped to the role of the employee	4.28	Strongly agree
Q5	Training Need Identification (TNI) impacts training effectiveness	4.29	Strongly agree
Q6	Pharmaceutical employees in general are aware of the 'Define, Measure, Analyze, Improve, and Control' (DMAIC) concept of Six Sigma	3.67	Agree
Q7	The Six Sigma concept enhances the training system	4.08	Agree
Q8	Six Sigma principles can be proposed for the better implementation of the training management system	4.15	Agree
Q9	Training can be enhanced by focusing on the 'Define' of the DMAIC concept	4.06	Agree
Q10	Training can be enhanced by focusing on the 'Measure' of the DMAIC concept	4.00	Agree
Q11	Training can be enhanced by focusing on 'Analysing' the DMAIC concept	3.86	Agree
Q12	Training can be enhanced by focusing on 'Improve' of the DMAIC concept	3.97	Agree
Q13	Training can be enhanced by focusing on the 'Control' of the DMAIC concept	3.96	Agree
Q14	DMAIC can enhance the overall training system	4.25	Strongly agree
Q15	CAPA in the training system would be more effective if it considers the DMAIC concept	4.21	Strongly agree
Q16	RCA, TNI and CAPA are interrelated	3.99	Agree
Q17	For training effectiveness, relations of Deviation to performance and Performance to DMAIC tools are significant	3.94	Agree
Q18	DMAIC would improve training feedback	4.03	Agree
Q19	Training effectiveness impacts overall performance of employees and organizations	4.40	Strongly agree

Table-2. Items and Levels

When the same data series of the mean value was checked against the response with the range of agreement, we can see high levels of agreement in Table 2 established the alignment of responses in most of the Items to a higher extent.

The result shows that out of 21 Items, 6 were graded as **STRONGLY AGREE** and the rest 15 were marked as **AGREE**. So, a 100% response shows alignment with the theme of the paper where DMAIC was proposed in the training model for pharmaceutical manufacturing companies. Hence the level of agreeability is strengthening the need for DMAIC tools in the training model requirement in the pharmaceutical manufacturing companies.

Seven Items under the group Training Awareness focussed primarily on the roles of training systems in the pharmaceutical manufacturing industries. The very group included items covering various aspects and basics of training. The same group was aimed to understand the agreeability of respondents on how training affects deviations and also working and relationship of other elements like performance, job role, training need identification, training effectiveness, root cause analysis (RCA), and corrective and preventive action (CAPA) in pharmaceutical manufacturing set-up.

The result shows that the response on the higher scale of the agreement in the training awareness area indicates that training functions are crucial in the pharmaceutical manufacturing industry, and a connection between the relevant terminologies demonstrates the vital importance of these functions.

Moreover, to understand the opinion on the importance of reviewing training needs identification if training inadequacy was observed, 91.6% responded to the need to review the same. This shows the strong agreement among the industry on the importance of training need identification which is the base of training functions.

The other two groups - Six Sigma knowledge and DMAIC need, include 12 items. Six Sigma knowledge items are based on the understanding of the acquaintance level of the Six Sigma concept and its applicability to an existing training system. The DMAIC need items were used in the survey to understand the feasibility and applicability of DMAIC tools in the proposed training model. This group of items are critical as the concept of 'DMAIC' was used exclusively in the very items to check agreeability on the inclusion of DMAIC tools for the improvement of the training management system.

Responses show a strong alignment for the DMAIC tools in the proposed model and it can be recommended to be used in the pharmaceutical manufacturing training system exclusively. Survey results for the total score under each item is significant which shows positive response for each item and supports the inclusion of items in the survey design. A plot of the total score of the respondents under each item established the higher agreement level.

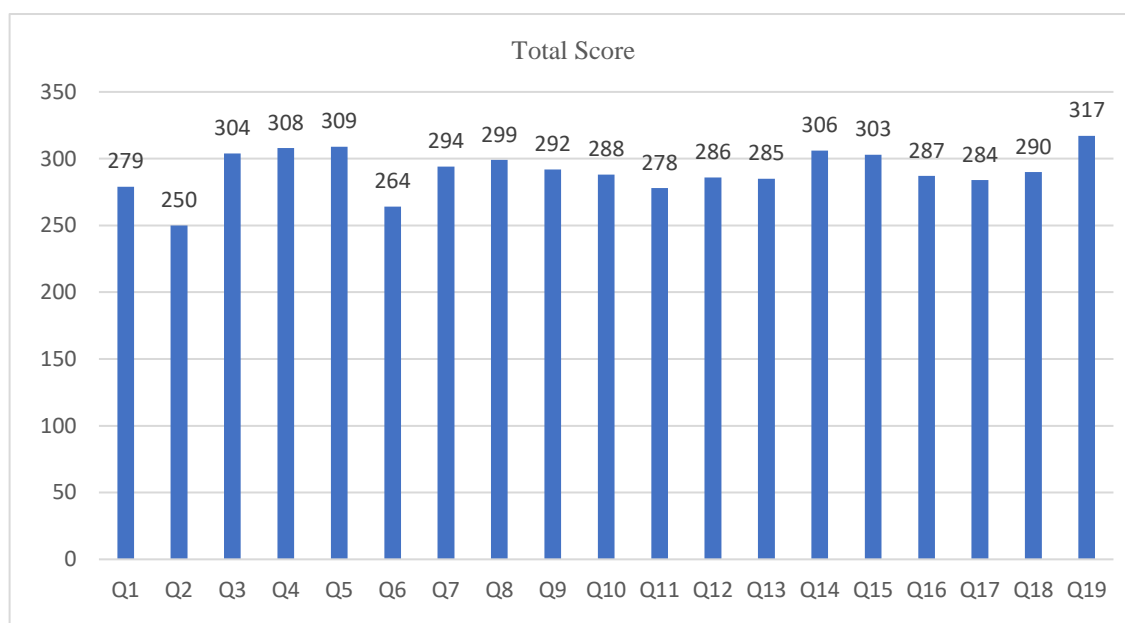


Figure-20. Total scores per Item

Similarly, a plot of mean and standard deviation among the response as a whole demonstrates strong agreement among the respondents and the distribution is also found normal. A low standard deviation value indicates that the data is grouped close to the mean. That is, a particular data point is typically close to the mean.

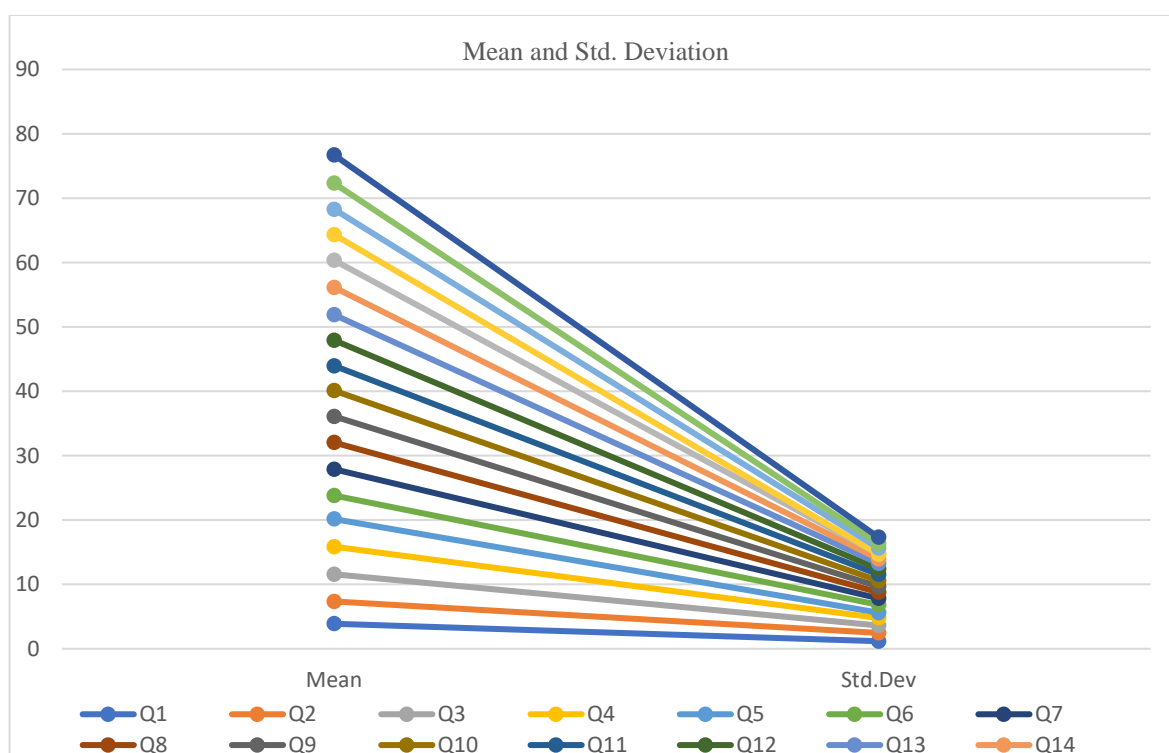


Figure-21. Mean and Standard deviation recorded per Item

Outside the scope of the Likert scale, two items were asked. One item in which an agreeability of 92% was noted for review of training need identification (TNI) if training inadequacy is revealed by root cause analysis (RCA). Similarly, 48% of respondents said that they are using DMAIC tools directly or indirectly in their existing training program in pharmaceutical manufacturing units.

Discussing the suggestion part most respondents argue for the inclusion of DMADV tools too in the proposed model. It means the inclusion of the 'Design' and 'Validate/Verify' steps of DMAID in addition to the Define, Measure, Analyse, Improve, and Control steps of DMAIC. Although DMAIC and DMAID generally have separate approaches here the proposed model is to be modified to include all seven tools from both the approaches and it is not a replacement of DMAIC to DMAID or vice versa.

Six Sigma-based models received a high response rate when linking Training Need Identification (TNA) to Six Sigma tools in the pharmaceutical industry. Six Sigma tools, when used correctly, can use training needs analysis in a more productive way to improve overall training. This is critical for the pharmaceutical manufacturing industry. Because the response was reviewed by someone with a pharmaceutical manufacturing background, the model suggests qualitative and quantitative tools to help identify and address skill gaps in the relevant workforce. Training needs analysis using Six Sigma tools would be more successful in aligning training goals and objectives with the organization's vision and mission.

The survey respondents supported the effective interrelations among different factors of the surveyed training model and reinforced the necessity and significance of the attributes of the DMAIC elements for improving the effectiveness of the training system.

Overall, it will improve the effectiveness of the training system for both the employee and the organisation. With time, this proposed training model will become more important in anticipating future skills and needs. As per requirement, it is strongly recommended to utilise the tools of the DMAIC and DMADV as per the requirement of the organisation for the training system. The upskilling strategy gaps will have an impact on the overall effectiveness of training in the surveyed model as more and more gaps in the existing system will be discovered through the use of Six Sigma tools. Higher training effectiveness would directly influence system improvement and the development of human resources.

The effectiveness of employee training programmes, which is the most important area in the pharmaceutical manufacturing environment, is unquestionably impacted by the Six Sigma tools. Tracking the evaluation metrics of the training programme would be made easier with the proper integration of Six Sigma tools. The overall assessment of the cross-functional team's training will hasten the necessary transformation to a productive environment. Additionally, performance enhancements from Six Sigma tools will directly support the training system. As training is a dynamic process in pharmaceutical industries the training effectiveness is to be enhanced by proper utilisation of available tools from DMAIC/DMAID or both in the modified model for pharmaceutical management system. Thus, the model proposed in the original paper is modified by the proper inclusion of DMADV tools along with DMAIC tools.

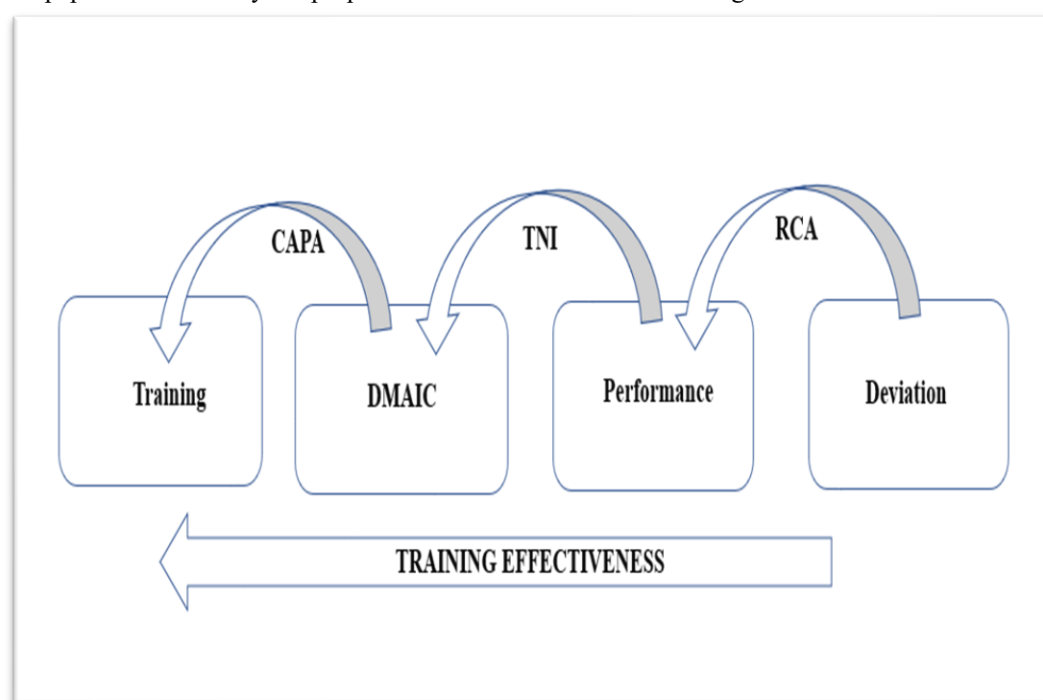


Figure-22. Proposed training model with DMAIC tools



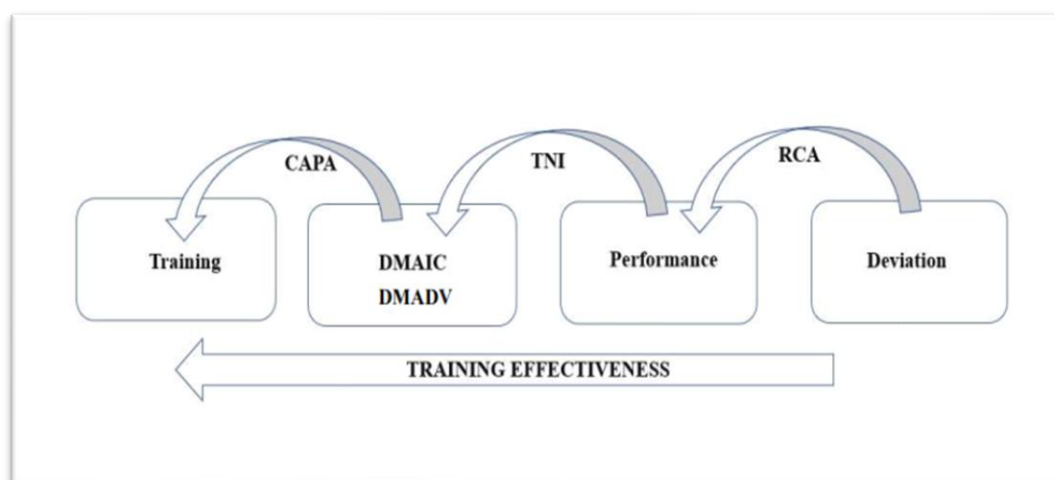


Figure-23. Modified training model with DMAIC and DMADV tools

## 7. Summary

The survey indicates a positive response to the acceptance of the Six Sigma-based training model. The Six Sigma-based training model with a combination of DMAIC and DMADV tools can serve training management in pharmaceutical manufacturing units with a better perspective. Risks of error and other challenges in pharmaceutical companies can be met properly by the proposed modified model. Pharmaceutical industries face various challenges related to training effectiveness and utilisation of proper DMAIC and DMADV tools can strengthen the overall training system.

Across the globe, consumers need better pharmaceutical products and this is the right time to invest more in the enhancement of training systems in pharmaceutical manufacturing sectors. Regulators too are concerned for the quality of medicines and a properly trained and effective workforce can deliver better products. Be it any geographical region or product dosage, enrichment is needed everywhere and an effective training system can ensure product with better Safety, Identity, Strength, Purity and Quality (SISPQ).

The proposed modified model is useful as it gives the way forward to use as much as tools from DMAIC and DMADV procedures and can check the training effectiveness of the organisation accordingly. This modified Six Sigma-based training model has the potential not only to reduce various types of errors in pharmaceutical manufacturing companies but also has similar capability to enhance productivity through proper and effective training management. Although the modified model has not been tested in this research paper and hence it is recommended for its proper testing with a higher sample size in varied geographical locations for more insights.

This modified Six Sigma base model has the potential to cater to training systems in pharmaceutical manufacturing effectively. The added tools of Six Sigma can lower the risk of errors and improve the quality of outcomes. This model will ensure training and awareness of employees to uphold the highest quality standards. A critical process in the pharmaceutical industry demands Right First Time (RFT) approaches for faster delivery of products and that can be ensured only through highly trained employees. Putting properly trained employees on the factory floor as a part of the RFT effort will enhance quality, safety, and productivity. Six Sigma tools are integrated into training models, and they can improve training systems by lowering errors across the entire organisation. The pharmaceutical industry is constantly reducing risk through trained employees. Even though pharmaceutical companies have a proper training system in place, regulatory agencies frequently point the finger at ineffective training when they find systemic flaws. To express the need for training, mentoring, and coaching to improve the industries' growth opportunities, the proposed and later modified training model can make use of the Six Sigma tools effectively.

This paper supports the development and advantages of a training model powered by Six Sigma tools in the pharmaceutical manufacturing industry. This training model is capable of reaping the benefit of training. Through proper utilisation of the model, pharmaceutical manufacturing industries would be able to improve the current skills of employees while acquiring new ones. It will impact the individual and as well the organisational performance.

In the pharmaceutical manufacturing sector, every employee needs training to enhance job-specific technical abilities required specifically in the GMP environment. Companies always invest in the best methodical strategy to develop, design, and implement training to meet the requirements. The pharmaceutical industry can benefit immensely from the Six Sigma-based training model as it will directly enhance the awareness of employees on safety, compliance, and product quality. Finally, employee effectiveness would be augmented through training, which directly advances job satisfaction while lowering employee turnover.

In today's challenging situations to safeguard pharmaceutical industries, compliance needs to be ensured 24X7 and hence industries are dependent on trained employees. Again and again, effective training is only possible when training systems

existing in pharmaceutical companies are upgraded and supported through varied QMS and Six Sigma tools and management is keen to invest in the Training and Development of people associated with the entire system.

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