An Investigational Study on Factors of Quality Culture in Pharmaceutical Manufacturing Sectors

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Abstract
Quality in pharmaceutical is strengthened by training of concerned employees through validated training system consistently with effective assessment mechanism. The health of Quality in the pharma industry is determined through the sites’ compliance status. Quality is maintained by the trained employees involved in the manufacture, processing, packing, or holding of the drug product in the company. Training of employees cannot be limited to company policies, standard operating procedures (SOP), standard testing procedures (STP), work instructions, or guidelines but need to be extended to those areas whose input enhances the quality approach of employees. Quality of employees enriches the way of execution and sets trends on quality. Intervention through quality culture enhances the quality of the existing system. Quality culture aligns employees to the concept of quality through a quality approach. Finally, quality culture involvement aims for better productivity.

Quality is important but criticality varies with resource allocation which was sensed by pharmaceutical companies during the Covid time. Impact of Quality Culture was studied through six factors: quality mindset, inspiration, integrity, proactivity, discipline, and accountability. An online survey was done on sixty pharmaceutical professionals from India, Switzerland, and the United States. A survey was designed to understand the strength and weaknesses of quality culture. The survey consisted of 32 questionnaires with 5-points Likert scaling and routed through online mode. The survey specifically speaks on how quality culture speaks, guides, enhances, encourages, and transforms the work environment through quality insight. Descriptive analysis was performed for the data and found quality mindset dominates the list whereas accountability is least impacted by the quality culture. Overall satisfaction level for Quality Culture was found satisfactory and recorded on the higher side.

Keywords: Pharmaceuticals, Training, Quality Culture, Factors, Covid.

Introduction
Quality Culture in the pharmaceutical industry shapes the Quality output. The quality of people working in the pharmaceutical sector is impacted through Quality Culture. The concept of Quality Culture is a new addition to the pharmaceutical industry. It has originated from Total Quality Management (TQM). Due to quality insight and the easy-to-grasp concept, pharmaceutical experts endorse quality culture.
The business of pharmaceutical industries depends on the quality of the product. The quality of pharmaceutical industries is guided by different regulations applicable as per the market authorization. The employees in the pharmaceutical industry are always scrutinized for their quality approach. Through consistent focus on training and awareness, management is keen to develop the workforce with the highest quality standard. Increment in quality standards results in a higher compliance rate and boost confidence in employees.

Training and development play a significant role in aligning employees to the core value of quality. In pharmaceutical industries training is performed through a well-designed program with proper assessment mechanisms and employees can work only after required training completion. Documented evidence of training completion of standard company policies, standard operating procedures (SOP), standard testing procedures (STP), work instructions, or guidelines are needed before task allocation in pharmaceutical manufacturing setup. Thus, quality is always on top priority in pharmaceutical industries as quality operations ensure quality output and the company must stick need for quality to excel in business. But due to the business need on the ground of quality products, pharmaceutical companies are in tough competition with each other. To scale up the standard of quality pharmaceutical companies are investing more in quality resources including investment in training. Companies know well that the enhancement of quality of manpower will enhance the compliance state of the system, process, and products. In the quality enhancement programs, the role of quality culture is endorsed more and more and hence it is introduced to pharmaceutical companies subsequently.

Due to the inclusiveness of quality, the program of quality culture has been added to the learning arena of most pharma companies. And rest will also follow the same in coming days. Quality culture has its origin in Total Quality Management (TQM). It has been used extensively in Engineering and other manufacturing sectors. For its notable quality insights have gotten importance in the pharmaceutical manufacturing sector and are implemented nowadays.

Engaging people through ‘easy to grasp’ concepts, “Quality Culture” campaigns for a better approach of quality across the industry. Quality Culture motivates and guides employees attuning quality in day-to-day activities. The synchronized approach of quality from individual to group overall enhances the quality output at the end of the day. The concept of quality culture is easily cascaded in vertical and horizontal lines.

The quality of a product depends on a series of operations executed in a validated and specified way. The companies with a more qualitative approach face fewer issues in quality output. The importance of quality culture is so significant in building quality that even during critical situations, it makes a difference.

During the Covid time importance of quality, culture was felt in pharmaceutical industries significantly. Due to lockdown and other restrictions, an unprecedented crisis was noticed in pharmaceutical industries, as resources were concerned. The availability of employees became a challenge to the manufacturing units. The said units had to continue operations to cater to the emergency need of the nation(s) with available resources only.

It’s a known fact that quality is always predominant and indispensably important in pharma operations. Employees working in pharmaceutical industries must endorse quality 24X7. Loss due to quality issues always stands as a point of concern in pharma industries. And the condition becomes critical more when employees are scarcely available due to some unavoidable circumstances and the company is facing high production demand now. In this situation, the condition of management is worrisome as it neither compromises on quality nor accommodates resources to compensate for the loss due to product failure.
Hence management ensures that those who are available at the site are adequately trained and qualified to operate and safeguard compliance. Employees need to be sensitized with quality awareness all the time as any sort of failure in the ground of quality puts pharma operations in trouble. And thus, quality culture plays an important role in pharmaceutical industries to sensitize people in quality aspects. It helps and guides people to practice and deliver the best in quality.

Quality culture actively builds that culture where quality overwhelms every other aspect through the voluntary participation of employees. So, quality culture has become more prevalent for pharma industries where it adds value to the overall environment and works in doing the best.

Everyone knows that medicines are prepared by a qualified workforce. The same product is looked at as quality inbuilt products due to the quality input by trained employees. A company with an existing quality culture environment empowers people to handle quality issues more effectively. Thus, quality culture has become a boon to inculcate quality and educate the mass for better output.

As a business need, to run the operation seamlessly in the pharmaceutical sector, the need for people with an effective quality approach is in high demand, and hence quality culture has evolved as a topic of interest in the pharma domain.

In this paper, I want to explore the factors impacted by Quality Culture in pharmaceutical industries in general and to study the contribution of said factors to the levels of satisfaction of Quality Culture as a whole.

**Literature Review**

Literature review enables the importance of Quality Culture in adding values to personnel working in pharmaceutical manufacturing companies. Quality Culture can be better understood through Total Quality Management (TQM).

TQM is defined as a management system made up of three interdependent components which are values, techniques, and tools (Hellsten & Klefsjö, 2000, p. 238). In a research study, Haleem et al. (2015) said total quality management (TQM) is a concept rather than a technique. TQM is a philosophy that works from an integrated, systematic, and consistent standpoint that would include everything and everyone in the organization and would enhance the competitive edge of organizations of different sectors (Issac et al., 2004, p. 8). TQM is described through Management philosophy which is composed of core values (Hellsten & Klefsjö, 2000, p. 239). Core values enhance the development of all faculties and impacts performance. Some investigators have examined the implementation of total quality management and its impact on organizational performance.

Hellsten and Klefsjö’s study done in 2000 (as cited in Hansson & Klefsjö, 2003, p. 71), states that in today’s competitive world TQM aims to increase external and internal customer satisfaction with a reduced number of resources.

Douglas and Judge (2001) surveyed the relationship between the degree of total quality management (TQM) practices adopted within organizations to the subsequent competitive benefits achieved and they got a relatively strong relationship between the two. In addition, their data showed some support for the moderating influence of organizational structure on TQM implementation effectiveness. Hendricks & Singhal, (2001, p. 283) provided evidence on the relationship between the financial performance of organizations and the effective implementation of TQM and argued that investing in broader TQM implementation is productive.

Berry (1997) said the role of leadership which starts from school should work for building a vision for the future, creating the quality policy, developing the quality culture, vowing on clear quality procedures, setting specific quality objectives, and the allocation of resources. The TQM leader ensures the formulation of strategies, policies, and techniques for achieving excellent performance,
stimulating excellence, building knowledge and capabilities among employees (Ulle & Kumar, 2014, p.152). The leaders with the TQM knowledge use the customer focus-centric vision to unite followers in common goals and demonstrate characteristics such as goal articulation, personal image building, demonstration of confidence, and motive arousal (Ulle & Kumar, 2014, p.154).

Seraph and Sebastian’s study done in 1993 and Westbrook’s study done in 1993 (as cited in Dellana & Hauser, 1999, p. 11), show that many reports claimed Quality culture as the main ingredient for TQM. Quality Culture plays a strong role to strengthen TQM.

The special character of the employees is made up of the employees’ values, attitudes, language, experience, etc., and it is not least in this complex field we are to find elements of the company’s quality culture. This is where we find the values that substantially determine the actual/manifest quality of the company’s products and services. (Hildebrandt et al., 1991, p. 9)

Quality in pharmaceutical industries is guided by in-house quality manuals, standard operating procedures, and applicable good manufacturing guidelines. Thus TQM, Quality culture along other relevant guidelines is helping pharmaceutical manufacturers to excel for consistent productivity.

Pharmaceutical management admitted the need for Quality Culture to sustain business as pharmaceutical business is based on compliance and Quality Culture can prioritize the need for compliance as through affirmative action of management culture of quality can be enhanced. (Jain & Jain, 2018, p. 3226)

Everyone knows that pharmaceutical companies depend on Quality by whole and soul, and hence the output is measured strictly in the parameters of Quality attributes. Thus, the challenge to continue quality production with a limited workforce expanded manifold. Across the country, the scenario was nearly the same.

Hence at this juncture of critical decision making, effective leadership with a profound insight into Quality was the need and thus the strength of Quality Culture was sensed everywhere.

Methodology
A survey method was designed to get the analytical data for this research study. The survey was done online. Questionnaires were set to understand the perception of employees working in pharmaceutical companies to the quality culture. Quality culture is a new concept in pharmaceutical industries and thus participants were put through every aspect of quality culture which impacts them in various ways.

Questionnaires were broadly divided into segments comprising of various factors like Quality Mindset, Inspiration, Integrity, Proactivity, Discipline, and Accountability. The said segments facilitated the employees to be routed through the entire quality domains or circles in their respective departments and cross-functional areas and would take them through roles, responsibilities, expectations, and deliveries. The questionnaires expanded to understand the strength of quality culture and gauged to seek weaknesses (if any) of quality culture in respect to resources and to extrapolate the perception stands to the end-users.

The survey was designed for people experienced in the pharmaceutical manufacturing sector. For a better insight into perspective, the response was asked from professionals who directly or indirectly handled various activities in the manufacturing or quality departments in the industry. Before sending the survey, a small sample was also tested, and after successful validations, the survey was done online.

The data obtained through the survey would be analyzed for descriptive analysis and consolidated average method.
Data Analysis

Analysis of data comprising of 32 questions from 60 respondents obtained from the online system and an excel sheet of the same was analyzed in detail. Approximately 87% of respondents were found to have more than ten years of experience and from the rest, 3% have less than five years’ experience. The Likert scale was converted into numeric values with a 1 to 5 rating as follows:

Table 1:

| Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
|------------------|----------|---------|-------|----------------|
| 1                | 2        | 3       | 4     | 5              |

| Response on the satisfaction level on overall quality culture in pharmaceutical manufacturing |
|-----------------------------------------------------------------------------------------------|
| Not at all satisfied | Slightly satisfied | Moderately satisfied | Very Satisfied | Extremely satisfied |
| 1 | 2 | 3 | 4 | 5 |

Individual scores were analyzed against each response. A high percentage of responses were recorded in the higher range. Questionnaires were grouped under factors and the average value of response was analyzed under each factor.

All the questions were framed under qualitative analysis but through the Likert scale, quantitative data were analyzed.

The analysis was done in three parts, which were as follows:

- Questionnaires with an overall score. (Score in higher range indicates the positive impact of quality culture on resources)
- Average scores calculation for factors prioritization.
- Scoring of quality culture satisfaction level perceived by participants.

For 31 questions, individual analysis was done for overall rating by 60 respondents and found 100% questionnaires were responded with ratings ranging from 76.7%-90.3% (considering rating 5/5 as 100%)

Table 2:

| Question No. | Overall Score % | Question No. | Overall Score % | Question No. | Overall Score % | Question No. | Overall Score % |
|--------------|-----------------|--------------|-----------------|--------------|-----------------|--------------|-----------------|
| 1            | 90.3            | 9            | 88.7            | 17           | 88.7            | 25           | 86.7            |
| 2            | 88.7            | 10           | 85.3            | 18           | 89              | 26           | 87.7            |
| 3            | 89.7            | 11           | 86.7            | 19           | 81.3            | 27           | 76.7            |
| 4            | 88              | 12           | 85.3            | 20           | 82.7            | 28           | 84.7            |
| 5            | 86              | 13           | 85.3            | 21           | 83.7            | 29           | 82.3            |
| 6            | 86.7            | 14           | 88.3            | 22           | 90              | 30           | 82              |
| 7            | 87.7            | 15           | 88.7            | 23           | 84.7            | 31           | 81              |
| 8            | 79.3            | 16           | 85.3            | 24           | 88.3            | -            | -               |
The questionnaires were grouped under six factors—quality mindset, discipline, integrity, inspiration, proactivity, and accountability. The total scores were obtained by summation of rating input done for questionnaires under each factor and the later average value was calculated to find out the dominance rating between factors. Among the factors, quality mindset recorded the highest whereas accountability scored the least. Details are as follows:

Table 3:

| Factors       | Average Score | Ranking prioritization |
|---------------|---------------|------------------------|
| Quality Mindset | 265.6         | 1                      |
| Discipline    | 262.4         | 2                      |
| Integrity     | 260.6         | 3                      |
| Inspiration   | 256.6         | 4                      |
| Proactivity   | 255.3         | 5                      |
| Accountability| 244           | 6                      |

One separate question was attempted in the survey to test the overall satisfaction level of quality culture among the participants. The score gives a clear indication of the higher value of satisfaction level where 30% of participants expressed 100% satisfaction with quality culture, 46.7% expressed 80% satisfaction level, 16.7% expressed 60% satisfaction level, and the rest 16.6% expressed 40% satisfaction level.
Table 4:

| Participant Serial No. | Quality Culture Satisfaction Level | Participant Serial No. | Quality Culture Satisfaction Level | Participant Serial No. | Quality Culture Satisfaction Level | Participant Serial No. | Quality Culture Satisfaction Level |
|------------------------|-----------------------------------|------------------------|-----------------------------------|------------------------|-----------------------------------|------------------------|-----------------------------------|
| 1                      | 100                               | 16                     | 80                                | 31                     | 100                               | 46                     | 40                                |
| 2                      | 60                                | 17                     | 60                                | 32                     | 80                                | 47                     | 60                                |
| 3                      | 80                                | 18                     | 100                               | 33                     | 80                                | 48                     | 80                                |
| 4                      | 80                                | 19                     | 60                                | 34                     | 100                               | 49                     | 80                                |
| 5                      | 100                               | 20                     | 80                                | 35                     | 80                                | 50                     | 80                                |
| 6                      | 100                               | 21                     | 100                               | 36                     | 60                                | 51                     | 100                               |
| 7                      | 80                                | 22                     | 100                               | 37                     | 100                               | 52                     | 80                                |
| 8                      | 100                               | 23                     | 80                                | 38                     | 100                               | 53                     | 100                               |
| 9                      | 80                                | 24                     | 100                               | 39                     | 60                                | 54                     | 80                                |
| 10                     | 100                               | 25                     | 80                                | 40                     | 80                                | 55                     | 80                                |
| 11                     | 60                                | 26                     | 80                                | 41                     | 80                                | 56                     | 60                                |
| 12                     | 60                                | 27                     | 80                                | 42                     | 100                               | 57                     | 100                               |
| 13                     | 80                                | 28                     | 80                                | 43                     | 80                                | 58                     | 40                                |
| 14                     | 60                                | 29                     | 80                                | 44                     | 100                               | 59                     | 80                                |
| 15                     | 100                               | 30                     | 80                                | 45                     | 60                                | 60                     | 80                                |

Figure 3: Graph showing quality culture satisfaction level

Conclusion

The analysis clearly shows the need for quality culture in the pharmaceutical industry. Although pharmaceutical industries are guided through an organized training and development program where employees are trained through required standard operating procedures (SOP), guidelines, etc the requirement of quality culture has arisen due to the overall need for quality for business excellence. Current training and development programs limit the knowledge about SOP or guidelines to the working need and fulfilling the compliance status whereas quality culture will focus on the employee’s development impacting several factors.

A careful nurturing of qualities associated with quality culture can align employees to enhance the quality input everywhere and hence guides employees for a better output. Questionnaires with an impact study of quality culture in pharmaceutical industries were responded to on a higher scale and it proves respondents were perceiving the impact affecting different functions and functionalities in the said industry on the higher side. Quality culture is a new concept in pharmaceutical industries,
but its impact was welcomed by the response which solidifies the trust of quality input by quality culture.

The factors impacted through implementation of the quality culture were studied and established the same in sequential order of importance. Quality mindset tops the findings followed by discipline, integrity, inspiration, proactivity, and accountability. None of a single factor was neglected by the survey as an impact of quality culture. Quality culture shows a positive impact on strengthening training procedures and aligning employees to a learning orientation. It also guides employees on the importance of quality over quantity concepts and motivates them to set examples in quality surveillance.

Moreover, the survey also finds how it guides people to be more disciplined, and this factor links people to be more compliant in the environment under Good Manufacturing Practices. Quality culture induces a strict discipline to maintain personal hygiene, following standard operating procedures, good aseptic practices, gowning practices and strictly ensuring do’s and don’ts of guidelines. Thus, quality culture strengthens the existing training system.

Quality culture inspires employees to be empowered and adds value to company stature. It inspires people to be more productive and helps companies to do better business. Quality culture plays a significant role in transforming the quality of the workplace.

Quality culture has a definite role in inducing proactiveness in employees. It helps in embracing the right first time (RFT) approach which directly saves resources to work on error correction at a later stage. A proactive attitude initiates proactive communication which leads to proactive delivery.

Quality culture builds better accountability among employees. It helps to take ownership and guides the team for accountability stake in every task. It touches employees across levels and makes them more accountable in their attitude.

The survey also got responses on the overall satisfaction level of impact of quality culture in pharmaceutical industries. The response establishes the validity of the satisfaction level of quality culture. Quality culture enhances the quality of employees and impacts the environment positively.

Quality culture aligns people with quality principles and guides them to better delivery. Pharmaceutical company’s business is ruled by the excellence of quality and quality culture stimulates the passion of quality in each and everyone’s life.

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