

INTERNATIONAL JOURNAL OF RESEARCH IN COMMERCE, ECONOMICS & MANAGEMENT

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PERFORMANCE & SUSTAINABILITY OF QUALITY CULTURE: PHARMACEUTICAL INDUSTRY

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ABSTRACT

For decades, pharmaceutical industry rollout several initiatives for increase quality of the drug product and to exceed internal and external customer satisfaction. All pharmaceutical companies managed its business by focusing most of its resources on the next blockbuster drug and regulatory filings. The sea changes in regulations brought a shift toward developing quality drug products and compliance. Hence pharmaceutical industry started to refocus and address to improve performance and sustainability of quality culture. Performance means being able to grow rapidly while still maintaining quality. Sustainability is important because we want to touch the lives of 7+ billion people and it is very important because we want to be able to meet unmet needs for generations to come. So, we need to find ways to position our pharmaceutical industry for improving performance and sustainability of quality culture in pharmaceutical industry. Building and implementing quality culture in pharmaceutical industry effectively is essential, the best way to proceed is for us to increase performance is the degree to which we connect, collaborate and communicate to internal and external customers. Quality culture challenges continue to be visible in external failures such as non-compliances to written approved procedures, data integrity, adulteration, deviations, out of specifications, out of trends, recalls, manual errors, warning letters, 483's and import alerts. Recent trends are alarming i.e. lack of quality culture in pharmaceutical industry, which attracted attention resulting erosion of trust by regulatory bodies and investors. Why quality culture is a challenge in pharmaceutical industry? Empirical research findings found certain human behaviors in our business and regulatory practices needs improve. Additionally, quality culture concept and procedure after this study shall be useful to pharmaceutical industry progress and sustainability.

KEYWORDS

performance, pharmaceutical industry, quality culture, sustainability.

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INTRODUCTION

No pharmaceutical regulatory guideline or procedure is available/adequate to quantify or qualitative analysis of quality culture. Of the 42 warning letters sent out by its office of manufacturing quality in 2016, around one-fifth were addressed to Indian facilities (1). There is a mandate to better utilize science and research to advance public health by improving access to safe, effective, and high-quality drugs. From the product quality perspective, the FDA needs science and research to keep pace with rapid advances in technology and increasing complexity of FDA-regulated products (2). The existing quality culture in pharmaceutical industry focus on meeting organization business objectives and believe everything is fair in business to meet growth without patient centric approach and knowing the importance of 'Quality Culture' approach.

Why are we doing this? - in quality culture, quality is everybody responsibility, quality starts with you, to advance quality along with evolving quality science, quality best practices and regulatory expectations.

How are we going to execute? - by systematically driving initiatives that advance pharmaceutical quality processes through a plan of quality initiatives and deliverables, with clear expectations and accountabilities, throughout the organization.

What do we hope to accomplish? - continue to ensure pharmaceutical industry cater 7+ billion people needs to high quality drug products.

LITERATURE REVIEW

The research by Pradeep Y Sarode (2017) focuses on the change in quality concepts. The study reveals that quality departments should move away from their old "policeman" role of inspection and should play a more integrated role in the design, process improver and quality promoter (3). A research by Ashwin Srinivasan and Bryan Kurey (2014) found and defined a "true culture of quality" as an environment in which employees not only follow quality guidelines but also consistently see others taking quality-focused actions, hear others talking about quality, and feel quality all around them (4). The research by Hoffman, Richard C (2007) on The Strategic Planning Process & Performance Relationship: Does Culture Matter? study found that the general planning-performance model is relevant across the cultures sampled. While there appears to be little direct relationship between culture and planning, culture did moderate the planning-performance relationship (5). An article by Harry Kraemer (2015), How Ford CEO Alan Mullaly turned a broken company into the industry's comeback kid found five bests, leaders and their organizations can put values-based leadership into action. These same steps to building a world-class enterprise also help restore what has become broken, putting it back on track as a values-based organization (6). A research by Schein, E. H. (1992) on Organizational culture and leadership found culture as a tool and demonstrates the crucial role leaders play in successfully applying the principles of culture to increase organization effectiveness (7).

NEED FOR THIS STUDY

This study proposes the strategies for enabling performance and sustainability of quality culture so interested pharmaceutical organizations can make informed decisions regarding implementation. Quality culture directly and indirectly connect-communicate-collaborate process/procedures/people/resources/ towards one quality standard throughout the organization and enables what is right and not what is easy. In nut shell encourages pharmaceutical organizations shall implement quality culture and assure in-place and in-use described in this paper expected to maintain the process in a state of control over the life of the process, even as materials, equipment, production environment, personnel, and manufacturing procedures change.

OBJECTIVES

1. To find out the strategies for enabling pharmaceutical industry quality culture performance and sustainability
2. To find out benefits of quality culture and impact on overall performance of pharmaceutical industry.

RESEARCH METHODOLOGY

The guidelines issued by various countries drug regulatory bodies, related literature and scientific search engines such as Science Direct, Elsevier, Goggle. Searching through databases was done with different keywords: pharmaceutical, quality culture, performance, sustainability. The result studies and meeting abstracts were screened at 4 steps and exclusion process was based on consensus of both the authors.

Strategies for Enabling Performance and Sustainability of Quality Culture:

DISCUSSION**1. USING QUALITY METRICS TO INCREASE PERFORMANCE AND SUSTAINABILITY OF QUALITY CULTURE**

To survive and prosper in today's economic times, companies can no longer manage using financial measures alone. Businesses have to track non-financial measures such as performance and sustainability of quality culture. Quality metrics are a company's measurable goals, typically tied to an organization's quality culture, as revealed through performance management tools such as the Balanced Scorecard. Most goals are achieved not through the efforts of a single person, but by multiple people in a variety of departments across an organization. Performance management experts agree that cascading and aligning goals across multiple owners creates a "shared accountability" that is vital to a company's success. The company then uses its quality metrics as the foundation to analyses and track performance and base key strategic decisions regarding quality culture. Implementing the quality metrics indicators of a balanced scorecard typically includes four processes:

1. The company translates its quality culture into measurable operational goals that are communicated to employees.
2. These goals are linked to individual performance goals which are assessed on an established periodic basis.
3. Internal processes are established to meet and / or exceed the strategic goals and customer expectations.
4. Finally, quality metrics indicators are analyses to evaluate and make recommendations to improve future quality culture.

Here are some of the benefits of using quality metrics Indicators through the Balanced Scorecard methodology as a measurement of a company's success:

1. Pharmaceutical industry can focus & measure the quality metrics that can help to reach an extra mile.
2. Employees and managers see the overall quality culture goal plan—and understand how their individual goals fit into the company's quality culture objectives creating a situation in which employees feel energized and engaged in the success of the company.
3. Create shared employee responsibility—by cascading his or her goals with others in the company.
4. Managers more easily stay in touch with employees' progress—during every phase of goal completion, and offer immediate reinforcement or coaching to keep performance and deadlines on track.
5. Creating an open and communicative environment including quality feedback regarding goals and progress

Cascading your quality culture strategy in organization:

Cascading quality culture goals throughout the organization lets you align your entire workforce to the overall strategy. This ensures that everyone is focused on your key quality culture objectives. Translating high-level strategic goals into clear objectives for every business unit and every employee creates a clear line-of-sight - from top down and bottom up—so everyone understands how their day-to-day actions are contributing to overall company success. This also allows employees to develop goals that link to the organization objectives, driving understanding of strategy, generating commitment and instilling personal accountability.

2. BUILDING HIGH PERFORMING LEARNING ORGANIZATION

To build high perform learning organization every employee had to empower to reach higher, achieve more and inspire others to change the world for the better.

- Learning – learning constantly transform success and failures as opportunities.
- Teaching – investing the time to share learnings and help others around me grow, effectively multiplying our collective results.
- Leading – having the courage to step out of my comfort zone, take ownership and challenge the status quo.
- Performing – demonstrating disciplined execution every day while consistently setting and exceeding new standards.

3. SUNSHINE PURIFIES

Managing quality issues before they become chronic problems. Collaborate with others to understand root causes, generate solutions and implement solutions and implement them quickly.

4. QUALITY IS EVERYONE'S RESPONSIBILITY

In Pharmaceutical industry, quality is not a department or a function, instead it's a mindset and way of life for every person who works to improve health of 7 Billion people. Be proud of what you do and give your best every day-hour-minute.

5. SPEAK UP AND LISTEN UP

If you see anything non-compliance or quality issue that isn't right or if you are unsure about something bring the issue to your manager or to another leader. You have an obligation to speak up and the right to be heard.

Top leaders had to change mindset because generally they listen and prepared what they want to listen. So, they always ready to listen when small or shop floor people speak and unpleasant or bad news to understand the quality issues.

6. INTEGRITY

Setting high standards from which organizations should never back down. This uncompromising ethical stance helps to keep pharmaceutical products pure and high-quality culture. Doing right and not what is easy even when nobody's looking.

7. INNOVATION

Connecting dots when others overlook, i.e. seeing possibilities and bring new and better ways to help people enjoy high quality life.

8. INFLUENCE OF LEADERS IN SHAPING CULTURE

Leaders can also create unhealthy cultures. An ineffective leader, a leader who is not a good fit for a desired culture, or even a good leader who makes bad decisions that impact an organization's culture can tear down or damage a culture that took decades to build (5). Although culture is often thought to be resistant to change, Alan Mulally was able to change the culture of a struggling Ford Motor Company and transform the performance of Ford in a relatively short time span (6).

9. VISIBLE AND INVISIBLE FACTORS OF QUALITY CULTURE

Culture can be viewed on two levels (7). There is a visible level that can be observed by artifacts such as dress, office layout, office design, and the emphasis on technology. Artifacts could also include leadership style, the nature of the work environment, how people are treated, and how decisions are made and get implemented. There is also an invisible level characterized by expressed values, underlying assumptions, and deep beliefs. Expressed values are consciously held convictions, clearly stated or practiced, that influence the behavior of group members. For example, the expressed values of the U.S. Army are loyalty, duty, and selfless service (8). These values influence the behavior of soldiers at all levels. Another example may be the expressed value: "It is important to take great care of our people and our customers." This sentiment will create a different culture than that of an organization with the dominant value: "What we really care about is maximizing bottom line results, no matter what it takes to get there (9).

10. GUIDELINES FOR BUILDING QUALITY CULTURE

CEOs such as Bill Gates of Microsoft, Herb Kelleher (formerly) of Southwest Airlines, and Jeff Bezos of Amazon have all been known for their emphasis on culture and willingness to take specific culture building actions. Often, other leaders mistakenly think that by talking a lot about culture, posting cultural values on walls, passing out books on culture, and placing cultural values on coffee mugs, the desired culture will happen. Following are the guidelines (10)

- ✓ Make strategy and culture important leadership priorities
- ✓ Develop a clear understanding of the present culture
- ✓ Identify, communicate, educate, and engage employees in the cultural ideals
- ✓ Role model desired behaviors
- ✓ Recruit and develop for culture
- ✓ Align for consistency between strategy and culture
- ✓ Recognize and reward desired behaviors and practices
- ✓ Use symbols, ceremonies, socialization, and stories to reinforce culture
- ✓ Appoint a culture team

- ✓ Monitor and manage the culture

11. MONITOR AND MANAGE QUALITY CULTURE

It would be wise for organizations to assess their culture at least on an annual basis. Leaders need to know if the culture is moving in the right or wrong direction and if potentially influential events are affecting the culture negatively so they can respond proactively. Organizational cultures are reasonably stable and can be difficult to change. However, as discussed previously, they can also be vulnerable to events such as downsizing, natural disasters, or changes in leadership. As pointed out above, assessing the culture can be an important function of a culture team.

12. FUTURE OF PHARMACEUTICAL INDUSTRY

The future of pharmaceutical manufacturing should be quality culture for both patient / consumer healthcare and economic reasons. On the patient side, eliminating drug shortages and recalls provides more reliability and less risk to the consumer. Equally or more importantly, quality culture can also help assure consistent performance. On the manufacturing side, significant real-life cost savings can be the result of the drive to quality culture performance. To fully realize the benefits of quality culture, the pharmaceutical sector must introduce the economic factor society needs to recognize and pay for quality. At present, public self- or independent-reporting of quality measures and marketing focused on quality is not common in the pharmaceutical industry, though it is a major focus of other industries (e.g., automobile, consumer electronics). On the regulatory side of the equation, regulators need to move from predominantly management-based to performance-based regulation to give the industry enough flexibility to manage and improve quality on its own.

13. TRANSFORMING QUALITY ASSURANCE APPROACH AND ROLE

As per CrossBy instead of setting up the world's largest smallpox hospital, we vaccinate people and then we don't need a smallpox hospital. That's the same way you have to run a company, by preventing the problems. There really isn't any system you can put in place that causes things to happen; it's a question of understanding the basic concepts. US FDA new initiatives are increasingly driving the industry toward preventive rather than the control- and audit-based approach. For an example Since then, the FDA, the International Conference on Harmonization (ICH) and the industry have been extremely active, working together to shape the new quality requirements and standards. They began to endorse a "quality by design model" that contrasts with the industry's historical "quality by test" results approach. The publication of ICH Q10, Pharmaceutical Quality System, in 2009, emphasizes the responsibility of senior management for the quality system; it is a big step in modernizing our thinking about quality.

14. ATTRIBUTES OF QUALITY CULTURE

Respected business journals, such as the Harvard Business Review (HBR), have also dedicated time and effort into identifying the key characteristics of a culture of quality. For example, in its April 2014 issue, the HBR published results of a survey it conducted that identified four essential attributes that predict a culture of quality. These attributes are as follows (4):

- ✓ Leadership Emphasis
- ✓ Message Credibility
- ✓ Peer Involvement
- ✓ Employee Ownership.

SUGGESTION

This strategies and study was done keeping in mind the views of the literature as well as regulatory perspective. It can be assumed that like the employees & management are also bound to be affected by the implementation of quality culture. Changes should be brought about only where required. Some traditional existing practices may be beneficial to the quality culture. Before introducing any major changes, the evaluation should keep in mind how it would affect the quality culture. Similarly, frequent changes in the same quality culture are not recommended by the employees of pharmaceutical industry.

DISCUSSION

Quality Culture is based on simplicity and consistency, commitment, transparency, partnership, and mindset. Quality Culture is good for pharmaceutical industry, economic development, the market, and most importantly, patients and consumers everywhere. Pharmaceutical industry and management both had to recognize that a quality culture is imperative if India is to increase productivity, reduce compliance risk, lessen rework, and minimize supply interruptions that result in lost revenue and increased risks to public health. It is important that leaders consider understanding, building, and sustaining quality culture. An abundance of research makes it clear that building strong cultures can play a significant role in the success of organizations. Making quality culture as a high priority for pharmaceutical organizations can be a high payoff investment and can have a significant influence on the success and competitive advantage of an organization. Organizational culture is directly connected with effectiveness and performance of the organization – the stronger is organizational culture, the more effective is organization. Successful integration between the quality culture and business objective drive organization performance and sustainability.

LIMITATIONS

The limitations of this study are that the point of view of the pharmaceutical industry has been considered. The reason was that the pharmaceutical industry is such a sector where heal and influence the wellbeing of society for catering quality medicines across world and other industrial sector point of view has not been considered.

CONFLICTS OF INTEREST

No current or previous support have been received from industry or organizations that might have influenced this work.

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