Insight on Management Practices in Pharmaceutical Industry

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Abstract

The search for an answer to the unknown gave rise to the beginning of the advance of human civilization. Knowledge in science and technology was of great assistance to them, but as the importance of commerce grew, their leaders needed to possess solid management abilities in order to increase the productivity of their industrial workforce. The pharmaceutical industry has its own rhythm in order to meet market demand in spite of variations in the amount of human suffering caused by differences in geography or even the changing of the seasons. This article examines the varied spectrum of management styles by classifying them into three core paradigms: authoritarian (autocratic), democratic, and free-market/laissez-faire. The article explores the unique attributes, concepts, and consequences linked to each particular style. The paper discusses the principles of Attributable, Legible, Contemporaneous, and Original and Accurate (ALCOA) in the context of smart pharmaceutical manufacturing. In addition to enhancing comprehension of the ALCOA principle, there has been a subsequent development known as ALCOA+. This article is an effort to see the core management theories through the lenses of a pharma-manager.

Keywords: Management styles, pharmaceutical manufacturing, scientific management

Introduction

There is a Latin word called "Ignoramus". This reads in English as 'Ignorance' meaning 'we do not know'. This feeling of 'not knowing' was one of the most primitive instigations for society to march towards excellence. The identical catalyst served as a "push-factor" for the advancement of ancient science, arts, and commerce as well.

After some achievements in science and arts, all noticed, commerce is the key to win the war – war of prosperity. Now, this is the era to identify 'ignorance' of consumer, educate them for product or service and to be king of that 'created' market. So, the key factor is '*know your customer'*. The mechanization of production was driven by water and steam power during the first industrial uprising. It is distinguished by convergence of expertise that obscures the distinctions between the biological, digital, and physical realms.

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Management in Productivity

The population of Homo sapiens in AD 1500 was 500 million. An estimated GDP (according to today's definition) was $ 250 billion and they consumed energy of 13 trillion calories per day in AD 1500. The same turns in present time to be a population of 7 billion with energy consumption 1500 trillion calories per day and GDP of $ 60 trillion. So, we can estimate, Homo sapiens have grown in last 500 years by 14 times, energy consumption has increased by 115 times and gross productivity has increased by 240 times [1]. This implies, productivity of humans made us moving ahead.

Productivity is the single most critical factor in determining a country's ability to grow economically and remain competitive. The ability of a nation to enhance its aggregate labor productivity, which refers to the production of more products and services per unit of labor input, is a crucial determinant of the nation's potential to improve its overall standard of living. It is believed that a company's productivity is in great part

dictated by the technologies that are currently accessible as well as the knowledge and ability of management to make process changes [2].

The knowledge of improving productivity of a job using technology is not only sufficient, but also implication of management skills stands tall at the process. The right technology with right group of workers at right time would give highest productivity, is determined by a good management. For example, the first edition of radio was patented in 1896 by Guglielmo Marconi. But this technical marvel used much lately around 1950's, in factory production floor or in mines to establish effective communication between workers and leaders for improved per/man productivity by eliminating communication gaps or delay in instructions.

Technical push for mankind

The technology revolution has brought about significant positive effects for the developing world. In the year 1990, more than forty percent of the population of the world was living in abject poverty. According to the World Bank, this number will have dropped to 16 percent by 2015. The aim of those who work in the field of global development is to eliminate all forms of extreme poverty by the year 2030. The rapid economic growth seen in China and India is among the most positive developments in the annals of human history [3].

Within the framework of industrialized nations, a particular kind of differentiation has been taking place. New technologies enable workers to generate a higher quantity of goods and services, which in turn leads to increased economic growth. Inventing new things is one of the primary drivers of economic growth. The decade beginning with the end of World War II and continuing into the middle of the 1970s saw full benefits of gradually increasing production for American households. Despite the fact that advances in productivity have occurred at a rapid pace during the past four decades, the median income of households has remained virtually unchanged, and the percentage of income that is contributed by labor has decreased. This would imply that in recent years, the advantages of creation have not been divided equitably across the United States [3].

Here the role of good management practices come into picture! Yes, in Pharmaceutical management too. Importantly, when India is the 3rd largest pharmaceutical player in the world by volume.

Scientific management

This is a management concept that places an emphasis on the investigation and analysis of organizational procedures with the goal of boosting the effectiveness of those procedures. The goal of the scientific management theory is to conduct an in-depth analysis of the ways in which scientific, technological, and mathematical principles can be applied to boost the efficiency with which activities are carried out. The reduction of waste, improvement of manufacturing processes and procedures, and establishment of an equitable supply of products are the goals of this initiative. Taylorism is another name for scientific management, and it gets its name from the man who developed it, Frederick Winslow Taylor.

An important trend in 21st century science management has been the growth of offshore markets or third party manufacturing. Experts in scientific management conducted calculations to determine the procedures that would result in the lowest overall costs for the production of goods and services. Sometimes, as a result of the high cost of labor in the United States, businesses had to relocate or license some organizations to India, China, Korea and other nations, where labor costs and taxes are comparatively lower, to manufacture products and provide some services, being competitive in market.

India is home of young talents, fueling innovations in biological drugs at a very economical price,

highly needed by poor patients across the globe. Managerial excellence at every level may multiply this unique strength by many folds adding financial boost to the nation.

Scientific management in application

It is possible to find examples of Taylor's methods for boosting worker productivity in a wide range of modern contexts, including corporations, contemporary military, and even across all kinds of competitive sports. There are numerous companies in the business world that have incorporated fundamental elements of scientific management into their operations, while others have combined scientific management with their very own strategy [4].

McDonald's is the perfect illustration of a company that successfully applies scientific management in the production process. After it comes to this restaurant company, uniformity is of the utmost importance; regardless of which country you are in, each McDonald's location is exactly the same, beginning with the procedures used to produce meals, clean floors, promote workers, and lock up method when the store is closed. McDonald's status as the world's largest restaurant chain can be attributed in large part to the company's capacity to effectively and consistently provide high-quality food and service in every region of the world.

Timing the duration of each process step is an idea that can be credited to Taylor in order to identify the order in which they should be completed for the most effective technique of labor. The same principle is standard operating procedure at any factory floor, starting from automobile to pharmaceutical.

During the period when Taylor was engaged in his time studies, Frank and Lillian Gilbreth were concurrently contributing to the progress of scientific management through their independent endeavors in motion research. The Gilbreths employed scientific principles to develop a methodology centered on the analysis of work motions. This approach involved, among other things, photographing the particulars of a worker's activities while concurrently documenting the length of time it took to complete those activities. The films not only helped to create a visual record of how the task was completed, but they also brought attention to parts of the process that may be improved. Second, the films were utilized to teach staff members on the most effective ways to carrying out their work by demonstrating to them how to perform out their responsibilities in the appropriate manner [5].

Management styles

Management styles can be broken down into one of three basic categories [4]:

- Authoritarian (autocratic)

- Democratic

- Free-Market/ Laissez-faire

Autocratic management styles

The hallmark of this style of management is a strict chain of command in which information flows only in one way, from higher up to lower down. This is the only way information is communicated inside the organization. Employees are considered like robots, and as such, they are subject to close monitoring and control while they carry out their responsibilities within well-defined parameters. This is done so that the activities can be completed as efficiently as possible. It is not encouraged for employees to ask questions, give ideas, or express their thoughts on how to improve systems. Authoritarian, authoritarian-persuasive, and paternalistic management styles are the subcategories of autocratic management styles.

Authoritative management style

The managerial personnel within the organization effectively communicate their expectations to their subordinates and enforce disciplinary measures against employees who fail to adhere to the

prescribed guidelines. Employees are often anticipated to consistently perform their assigned tasks, refrain from challenging managerial authority, and comply with directives. These kinds of supervisors are under the impression that their personnel cannot function properly in the absence of such supervision. In point of fact, when a company is through a crisis, this management style can be successfully implemented.

Persuasive management style

This management approach involves the utilization of managers' persuasive abilities to persuade workforces that the verdicts made alone by the manager are advantageous for the team, department, or organization as a whole. Instead of only giving staff orders to complete tasks, managers who employ this approach will invite employees to ask questions and will clarify the decision-making process and the rationale for regulations. This could provide the impression to workers that they have a voice in crucial business decisions and that they are trusted and valued members of the team. It is reasonable to suppose that a pharmaceutical corporation intended to launch a relatively common medicine into a market that is quite competitive. The route of persuasive management is taken by managers in order to persuade and encourage the sales force to achieve the aim.

Paternalistic management style

In this management approach, the manager makes judgements and verdicts for the well-being of their employees in mind. In most cases, the company will refer to its employees as a "family" and will appeal for their continued allegiance as well as their trust. The management team that takes this approach will make decisions without consulting their employees, but they will explain to those employees that the judgments were made from a point of abled experience, which is why the decisions may be accepted. The personnel are provided with an explanation of the decisions.

A manager in pharmaceutical sales may have a very senior and efficient worker in his team. Contribution and shouldering major responsibility by the worker may be required for a specific important project. But he needs to abide by management decision. Manager takes the route of Paternalistic management style.

Democratic management styles

The managers in charge of this management style encourage their employees to take part in the decision-making process as much as possible, but they continue to exercise final say over all of the decisions that are implemented. The cohesiveness of the team has substantially improved as a result of the increased communication that is flowing in all directions, both top down and bottom up. This procedure makes it possible for a variety of viewpoints, abilities, and ideas to come together to generate conclusions that are informed and conscious.

Consultative management style

As part of this strategy, managers will ask their staff members for their views and opinions as part of the whole process, and they will consult the ideas of each and every team member as part of the procedure. The manager will ultimately make a call, although they will consider everyone on the team's input before making a final call. This method is frequently utilized in highly specialized sectors where staff members are subject matter experts and the management requires their input in order to make educated judgments.

Very high inventory may create an acute trouble for a pharma sales team for a region. Manager calls a meeting and invites thoughts of all members. After discussing all possible solutions, manager formulates his ‘call-to-action’ with inputs from matured team members.

Participative management style

In this setup, members of both the management team and the staff participate in the decision-making process in an active capacity. Employees are given access to greater information regarding the company and its goals, and they are encouraged to come up with innovative ways to accomplish the company's goals. The management makes it a point to inquire about the thoughts, recommendations, and judgments of the employees, works in conjunction with the workforce to arrive at decisions, and then ultimately puts those choices into effect.

In annual brainstorm session for Brand Managers, Marketing Managers play integrated role as a team member and contributes equally. A brand manager concentrates more on designing of brand campaigns and messaging, when Marketing manager drives budget allocation, time frame defining for campaigns with profit & loss statement.

Collaborative management style

Before making choices based on the rule of the majority, management operates under this model by first establishing an open forum in which ideas can be discussed at length. The staff is granted the authority to assume responsibility for the outcomes, which holds the potential to augment levels of involvement, innovation, and creativity.

Transformational management style

It is generally agreed that leadership expert James MacGregor Burns, who has written biographies of several U.S. presidents and is known as an authority on the subject, was the first person to articulate the concept of transformational leadership. As an illustration of transformational leadership, Burns states that "*leaders and followers make each other advance to a higher level of moral and motivation*." [8]. In **Figure 1**, the role of the project manager is illustrated. Coupled with the "four I's" of transformational leadership, which are idealism, inspiration, intellect, and care for others. When employees are trusted with responsibility, they are more likely to put out effort and come up with novel solutions to problems.

This strategy for management is flexible and geared toward achieving growth in the organization.

Figure 1. Project manager and 4 elements of transformational Leadership

Managers ought to prioritize their endeavors towards fostering motivation among team members, urging them to surpass their current achievements, continually challenging them to step outside their comfort zones, and persistently promoting the establishment of elevated benchmarks for success. The most effective managers are those that demonstrate leadership through their own actions, so exerting a positive influence on their teams. This entails investing an equivalent level of effort as their subordinates and inspiring them to enhance their performance by emulating the manager's own standards.

Coaching management style

When operating in this manner, managers view themselves in the role of the coach, and they regard their staff as valuable members of the team. It is the responsibility of the manager to cultivate and direct their team, putting the professional growth of their team at the forefront of their list of priorities at all times. In this approach, short-term failures are given less weight than the long-term development that is prized.

Laissez-faire management styles

A hands-off attitude to leadership is taken by management under this type of management. The staff members are granted autonomy in carrying out their tasks, operating without direct supervision. They possess complete discretion in decision-making and problem-solving approaches. Management is involved in the various phases of work, including job delegation and delivery. However, beyond these stages, management has a more hands-off approach, granting staff members the autonomy to govern their own workflow and achieve desired goals. The involvement of management in the process will only occur upon the explicit request for their engagement by the staff.

Delegative management style

The primary role of the manager within this framework is to assign tasks to subordinates. However, it is important to note that the manager still maintains overall accountability for the caliber of work generated by subordinates. Once the task has been assigned, it becomes the responsibility of the employees to fulfill their duties in a manner they consider to be most suitable. Once the manager has completed the assigned assignment, they will engage in a reflective process to assess the quality of the work and provide recommendations for enhancing future initiatives.

Visionary management style

In this management approach, supervisors are expected to motivate their employees. Leaders communicate their objectives and the rationale driving them to their teams in order to persuade them to work toward realizing the leaders' vision. The manager is responsible for inspiring and motivating the team members, after which they are given the autonomy to complete their assignments with as little interference as possible. Managers will check in from time to time, but they have faith that their employees will be able to stay on track and create quality outcomes because to their shared vision. This approach can be utilized by a business in order to motivate their employees into taking action in the service of driving innovation.

Data driven management

Pharmaceutical industry is completely data driven organized field of science and commerce. Management decisions are supported and groomed by various data sets giving visibility for short and long-term outcomes.

Smart Pharmaceutical Manufacturing

Manufacturing units that produce pharmaceuticals typically have production lines that continually generate a large number of disparate data sets from a variety of embedded devices. They have command over the numerous steps involved in the manufacture of medicines. These types of data sets ensure that the data's integrity, as well as its capacity to be traced, is preserved. The following criteria should be met in order for the integrity of pharmaceutical data assets to be considered satisfactory: (i) the principles of Attributable, Legible, Contemporaneous, and Original and Accurate (ALCOA); (ii) the regulations of the European Medicines Agency (EMA); and (iii) the regulations of the Food and Drug Administration (FDA).

Understanding of ALCOA to ALCOA+

Stan W. Woollen first used the ALCOA acronym in the FDA office in the early 1990s. The US-FDA first used the term ALCOA to describe data integrity in the pharmaceutical manufacturing sector. It was merely ALCOA at first, but after some time, ALCOA+ was introduced with certain potent instruments that increased its efficiency [9]. This framework's primary goal was to combine data with data security.

Complete, Consistent, Enduring, and Available are the final four components that the EMA added to complete the idea. This draws attention to demands for data management that the original five made only inferentially. This expanded notion is frequently referred to as ALCOA+ (**Figure 2**). Adopting ALCOA+ is now more important than ever to maintain FDA and GMP compliance. ALCOA+ principles are becoming more crucial for GMP and GLP compliance.

Figure 2. Impact of ALCOA+ in pharmaceutical manufacturing

ALCOA is outdated and ALCOA+ is the updated concept. It just like GMP to cGMP.

Many times, industry specialists will recommend to managers of pharmaceutical manufacturing facilities that they implement blockchain technologies on the production floor. Blockchains are distributed ledger technologies that use peer-to-peer networking to enable workers and managers to simultaneously validate transactions using decentralized peer-to-peer consensus procedures. A distributed ledger is produced by a blockchain, which is made up of a chain of "blocks," each of which contains a cryptographic sign or symbol representing the block that came before it in the chain. Given that security, authenticity, immutability, and transparency are the essential attributes that assure end-to-end verification. Blockchains are distributed ledgers that are used to record transactions digitally.

Conclusion

Before 1970, the pharmaceutical industry was virtually non-existent, but today it satisfies almost 95 percent of the nation's demand for pharmaceuticals. The pharmaceutical industry is one of a kind and has come a long way. Today, the industry holds a prominent position among India's principal science-based businesses, and it possesses extensive capabilities in the multifaceted areas of drug manufacturing and technology. India is also one of the top three nations in Global pharma manufacture and export map. The industry is mix of varying scales of productivity and volume amplitude with differentiation of high value biologics to low cost oral generics. Obviously, the industry is enriched with both highly skilled labors to common workers. This also include employees from mostly all scientific and engineering streams. This versatility demand highly efficient and trained managerial cadres to work with assured productivity. The end objective for all in this industry is to add value proposition in patients suffering. When the goal is common to solve problem of patients, all domains stands united for a better tomorrow.

Conflict of Interest

The authors declare no conflict of interest.

Disclaimer

The views, thoughts and opinions expressed in this review belong solely to the authors, and not necessarily to the author's employer, organization, committee or other group or individual.

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