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The Importance Of Quality Management System For a Successful Health Care Industry: A Review Based on Case Studies

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ABSTRACT

The success of any health care industry depends on three important parameters i.e. quality, safety and efficacy. The quality improvement became every ones challenge and the department of quality control and quality assurance came in to the picture very recently. Due to globalization and increased competition, every health care sector focus is on to maintain quality which is an important factor and controls the other factors known as safety and efficacy which in turn produce the zero defect product. However there are many challenges or failures to produce this zero defect product and inorder to rectify these failures and challenges, the implementation of quality management is very important in every industry, The success of quality management will depends on implementation of Total Quality Management, Six Sigma, Change Management/ Change control/ Deviation Management, Out of Specifications (OOS), Out of Trend (OOT), Corrective & Preventive Actions (CAPA). Hence this current review is emphasizing on importance of implementation of above quality management principles based on the published case studies.

Keywords: TQM; Quality; Safety; Efficacy; CAPA; OOS; OOT

INTRODUCTION

Evolution of Quality in Industrial Sector

During the early days, every one focus is only to accept or reject the manufactured goods based on the specifications after inspection and not trail was made how to prevent these defects. Early in 1920' s the statistical theory was began to applied to protect the quality aspect of products and in 1924, Dr Shewart made first attempt to make quality control chart, and was later developed by Dr Deming which developed in 1940's as the theory of statistical process control (SPC). In 1950's, Quality management practices was developed and implemented by Japan industries and in 1960's the quality control and management had become a every nations choice.

In 1969, Feigenbaum presented a paper in a conference and the term total quality was used for the first time, and referred to wider issues such as planning, organization and management responsibility.

Ishikawa presented a paper explaining how total quality control in Japan was different, it meaning companywide quality control and describing how all employees, from top management to the workers, must study and participate

in quality control. In 1970, the phenomenon of quality management became compulsory in most of the Japanese companies.
In 1980, the term quality management system came in to existence by the western globe, and the part of this is total quality management which became very important phenomena in most of the health care systems or industries in order to rectify and eradicate the mistakes in attaining zero defect products.

In the 21st century, the quality management systems became mandatory in many countries to help the organization aimed at helping organizations, to achieve excellent performance and to achieve the delivery of zero defects [1,2].

Scope of QC and QA

The Quality Assurance (QA) and Quality Control (QC) are very important units of any health care industry. Their aim is not only to test but also to produce superior quality of end product. The quality of health care products have become important aspect for the World Health Organization and International conference for harmonization with a motto that the Drugs must be market as safer and efficacious form. Quality control means checking the grade of excellence of products and processes employed for manufacture of them.
QC & QA is responsible for checking of all aspects related to products. For ex, QC of aerosol involves the documentation of checking in propellant, checking of container, valve, quality and life span active concentrate etc and QA of same is checking of products which are moved by QC department. They will check all the limits and equations passed by QC.
In pharmaceutical industries, QA professionals are the high paid employees. The main quality required is knowledge of management and analytical skills on working with any pharmaceutical industry. It is highly responsible work for the production of quality, safety and efficacy products with zero deficiency. However there is a lot of confusion between quality control and quality assurance in many of the basic learners, in order to make them clear the scope of the qc & qa is represented below in the Table 1.

Table 1: The difference between quality assurance and quality control

S.NO	**Criteria**	**Quality Assurance**	**Quality Control**
1	Focus	To prevent defects with a focus on the process.	To identify defects in the finished product.
2	Goal	To improve development and test processes so that defects do not arise.	To identify defects after a product is developed and before it's released.
3	How	Establish a good quality management system &assessment of its adequacy with continuous monitoring.	Finding sources of quality problems to continually meet customer's requirement.
4	What	Prevention of quality problems through planned and systematic activities.	Analytical techniques used to maintain the product quality and process.
5	Responsibility	Everyone on the team.	Of a specific team that tests the product for defects.
6	As a tool	QA is a managerial tool	QC is a corrective tool

The evolution and scope of the quality control and quality assurance is represented in the following Figure 1, which clearly helps the basic learners in quality management system to be easily understand and the essential functions of the quality control and quality assurance is represented in Figures 2 and 3 [3].

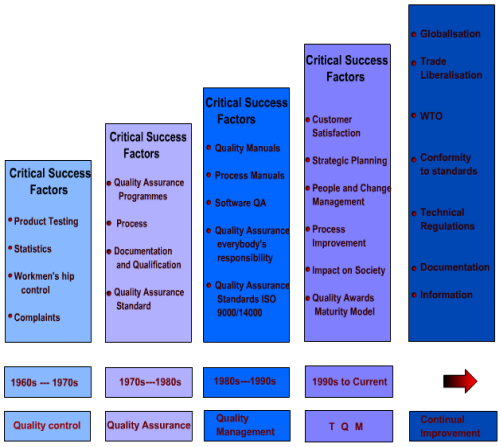

Figure 1: The evolution and scope of quality control and quality assurance

Figure 2: The functions of the quality control (QC)

Figure 3: The functions of the quality assurance (QA)

Essential Principles of Quality Management System

The quality management system and protocols are important in every organization to achieve the target of quality and safe products and this will work on the following principles i.e. Total Quality Management, Six Sigma, Change Management/ Change control, Out of Specifications (OOS), Out of Trend (OOT), Corrective & Preventive Actions (CAPA) and Deviations. This current review emphasizes on the importance of above principles with some cases as an examples and the importance of these aspect of quality management system was strictly considered by Pharmacy Council of India which lead to a new Maters of Pharmacy course named pharmaceutical quality control and quality assurance in which the course practical of I semester name Quality Assurance Practical-I (MQA 105P) in which one of the practical is case studies on quality management system , hence this review is also useful for the M Pharm students who can choose quality assurance or regulatory affairs as their platform of career interest.

Total Quality Management (TQM)

The total quality Management can be defined as philosophy and quality system to that became a need of every company to adopt and to achieve the excellence of any organization, this can be better understand by taking a case

study in to consideration and a case study can be defined as research strategy used when attempting to understand complex problems; by allowing to aim on which is manageable and can be understood in all its complexity [4].

The TQM became an important part of health care systems including pharmaceutical industries, a case study in a pharmaceutical industry at Serbia proved that TQM is a holistic approach to long term success of organization. This cross sectional study was performed with different stake holders with in the various pharmaceutical sectors of Serbia including manufacturers, distributors, big pharma representative offices, as well as national regulatory authority. This survey was carried out by giving a survey form comprising of 16 questions, in which one of the question was impact of

TQM in pharmaceutical industry and the total number of participants in this study was 121 and the results proved that the perception of TQM by the experts in pharmaceutical companies and regulatory authority is wider than the common definition of TQM, The opinion of various stake holders proved that the TQM has a great potential to address the quality problems in pharmaceutical industry or health care system inorder to improve the organizational performance, This research approved that there is a urgent positive and significant relationship between employee's perceptions, TQM and significant relationship between perceived effectiveness and quality processes. This study concluded that implementation of TQM principles is an essential for the quality and safety of the product. Even this case concluded that the medicine product quality is inseparable from the safety of the patient , hence TQM is an essential quality principle in pharmacy business which having a wider sense than for the other industrial sector [5].

Six Sigma

The six sigma can be defined as the methodology of continuous improvement aimed at reducing defects which can be used along with lean management principles. The essentiality of lean management and six sigma principles are must in a pharmaceutical company in order to provide a zero defect product which having safety and efficacy towards the customer. Today, many companies in different industries, both large and small, adopt six sigma and lean together towards improve of efficiency of design, manufacturing, business processes and intellectual property in reducing costs. This implementation of six sigma and lean management in together improves the entire quality of the pharmaceutical and medical device industry with a minimal cost. Even this will resolve the issue of unnecessary cost that limits profitable innovation.

To combat the scenario of the unstable and turbulent market in time of crisis, it is very much essential to implement the concept of six sigma along with lean management systems. The implementation of these two combined principles six sigma and lean management will play a major role in cases of challenging cases [6].

The six sigma is an essential failure analysis tool to rectify the errors in most of the small medium industries and its implementation is an essential even in pharmaceutical industries to enhance the customer satisfaction and to reduce the cost, the applications of six sigma principles can be best understood by studying various case studies that happen in pharmaceutical industries, and their success after implementation which are best explained Maria Jernelid and Steven Roan, 2009; in their thesis entitled "Six Sigma strategy applied to the pharmaceutical industry how customers

Benefit". The successful cases of Aspen Medical Europe Limited (hereafter called Aspen Medical), UK., GE Healthcare/Life science (hereafter called GE), Canada and GE Healthcare/Life science (hereafter called GE), UK are the best examples that explain the need of six sigma and lean management in a pharmaceutical companies for a success and to deliver a quality product at minimized cost [7].

To understand the six sigma for basic learners , it can be best understand with the help of following Figure 4 [7,8].

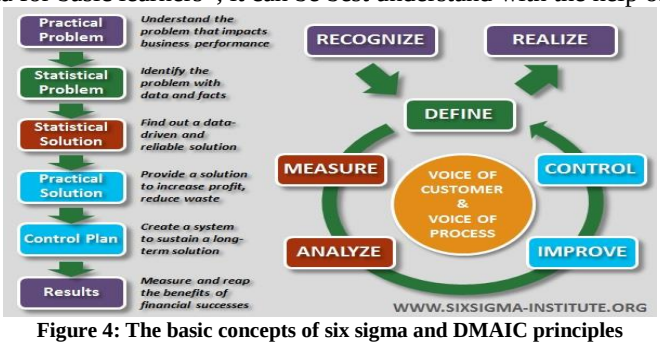

Figure 4: The basic concepts of six sigma and DMAIC principles

Change Management / Deviation Management

Change management or deviation management can be defined as a systematic approach deals with transformation of organizations objectives, manufacturing process or the protocols. The main aim of this change management also known as restructuring management is to implement strategies for effecting, controlling and the change and to help the people to adapt to the new system. This includes structured protocols to request a change and also a proper steps

to request and follow them up. Even it is a part of quality management system to eradicate the errors of failures and to make the products success. The implementation of the deviation management in many pharmaceutical companies like Astra Zeneca lead to a successful product at minimum cost with high quality Figure 4.[9].

The restructuring management can be better understood by taking an case study from AstraZeneca, which clearly explained that the success of any management is by understanding the background and challenges, the challenges faced by this pharmaceutical MNC is fewer new products from this company, expiring patents, increase in cost towards production of new products, more competition with less margin on sales and change in marketing strategies. In order to face these challenges the Astra Zeneca, Sweden implemented restructuring management skills like agreed with white collar trade unions about a compulsory redundancy package in 2006, agreed with all trade unions about a voluntary redundancy package in 2007, agreed with all unions about a check list for the reorganization & redundancy Process (aligned to our Project Management Framework) in 2008, Global process in AstraZeneca for Restructuring Selection in 2009.

These challenges can be faced successfully by Astra zeneca with the implementation of Management team with focus on change and restructuring, Project organization with people from HR and line to plan and support all activities, With planning and a change program running during four years, Developed a process to plan and manage resources internally ("resursstyrning") and continuous dialogue with trade Unions, including training in AstraZeneca processes [10]. The change management can be further understood by the following framework by a2b advisory consulting company which is represented in the following Figure 5.

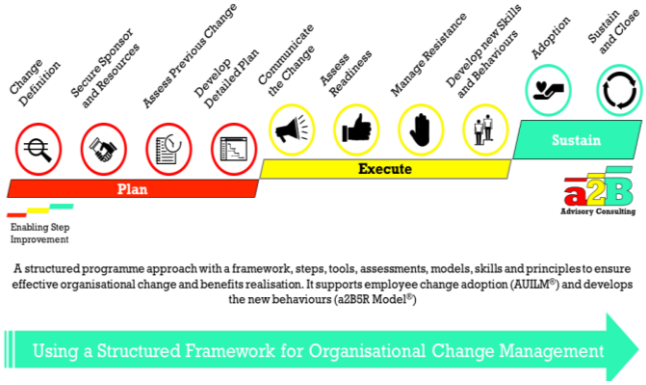

Figure 5: Change Management frame work steps

Out of specification (OOS)

OOS can be defined as those results of any procedures which may fall out of specified limits, which are represented in the official monograph or compendia, the frequent arising of oos in any procedure indicates that protocols / sops are not in control which result in rejection of final products which will be an ultimate loss for any company including pharmaceutical industries. So that it is an important criteria to address the oos results. This can be eradicate by laboratory investigation by changing the errors in the standard operating procedures and to address by quality control officer by additional laboratory testing [11]

In a deep study, the oos can be eradicated in three phases- Phase I: Laboratory investigation, Phase II: Full scale investigation and Phase III: Review of product development. This oos can be easily understand by taking the case study of apotex (Commercial Stability Program-Medicinal Products), the main aim of this program is to address the stability issues associated in the formulation with the marketed package. It is addressed in this case study that investigation of OOS is an important criteria and reporting immediately the oos results to the authorities is an important agenda by the laboratory quality control staff [12].

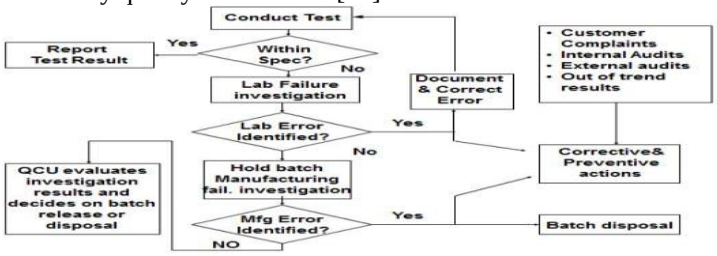

Figure 6: Flow chart of Out of specification (OOS)

Out of Trend (OOT)

The Astra Zeneca defines OOT as an out of trend is an important regulatory or quality assurance parameter that is must to be addressed in a pharma industry inorder to minise the errors and to deliver a stable pharma products. This can be defined as an out-of-trend (OOT) result is a stability result that does not follow the expected trend, either in comparison with other stability batches or with respect to old results or existed results, This a challenge in pharmaceutical companies always to identify OOT stability data and how to address this out of trend stability results. The identification of out of trend results is a very challenging task in the degradation and impurity analysis. The implementation of an OOT procedure for commercial stability batches [13,14].

The OOT can be better understood by taking a case study as an example presented by Dr Pradeep, Quality control manager, Haffkine Bio-Pharma. Corp. Ltd., Mumbai (Figure 6).

Example:

The specification limit for assay is: 95.0-105.0% w/w of label claim and the result obtained was 95.8 % w/w, even though the results are within the specified limits but it is must to compare the result with the previous data, if it found the average value of the trend is 99.05 w/w, then this batch result of 95.8 w/w is called as Out of trend (OOT). The OOT can be best understood by reading various documented literatures, however OOt issuses in most of the pharmaceutical issues like product stability, raw materials are less understood but became a hot core interest for regulatory authorities.

Corrective and Preventive actions (CAPA)

The CAPA is an important quality management principle can be defined as an corrective action to eliminate detected nonconformity and as an action to prevent the occurrence of non-conformity. The CAPA can be better understood by the help of CAPA five step process explained by Tonya White-Salters which is represented in the following Figure 7.

Figure 7: CAPA: Five step process

The CAPA can be analysed with its subsystems, The CAPA can be better understand with the help of case study of Massachusetts speciality pharmacy of Washington where a toxic fungus contaminated the steroidal injection lead to death of 25 people in various states. The FDA investigated this case and clearly expressed their opinion that implement of CAPA in every pharmaceutical MNCs is very much essential to prevent these type of mishaps and can produce zero defect and safe products to customer at economical rates [15].

CONCLUSION

The implementation of quality management systems is very much essential in pharmaceutical sector in order to deliver a quality ,safety and zero defect product at an economical rate. Inorder to minimize or eradicate the mishaps or dangerous contaminations in a pharmaceutical production these principles are very much essential, The OOS & OOT are very much essential in a pharmaceutical company to give assurance on the quality of products. The change management system plays an important role in the pharmaceutical companies to come up with innovative, safe and clinically approved drugs at cheaper cost. This review is very much useful for basic learners who are willing to choose the Quality assurance or regulatory area as their career.

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