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A Regulatory Affair AndContribution Of Total Quality Management Towards Quality Assurance In Healthcare Management

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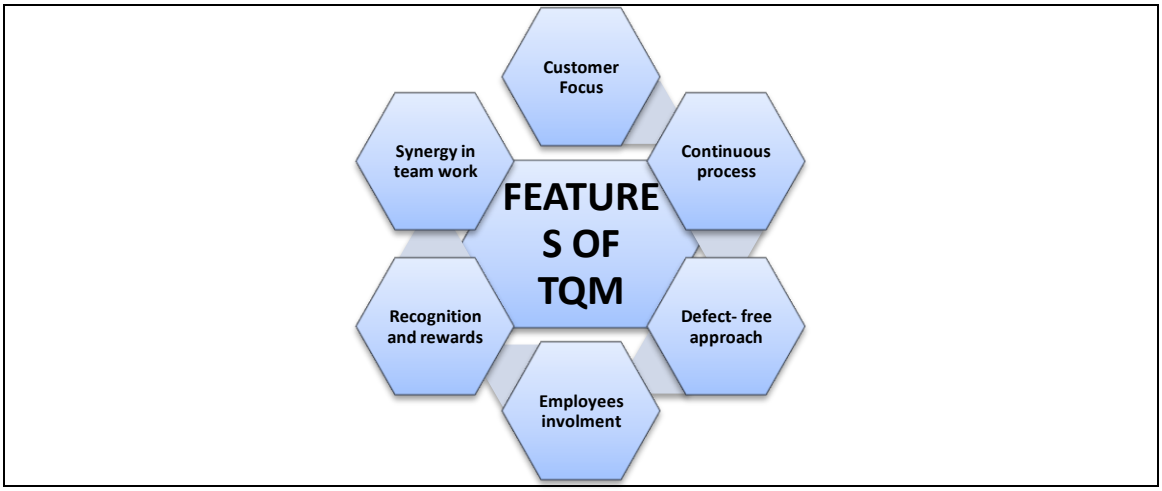
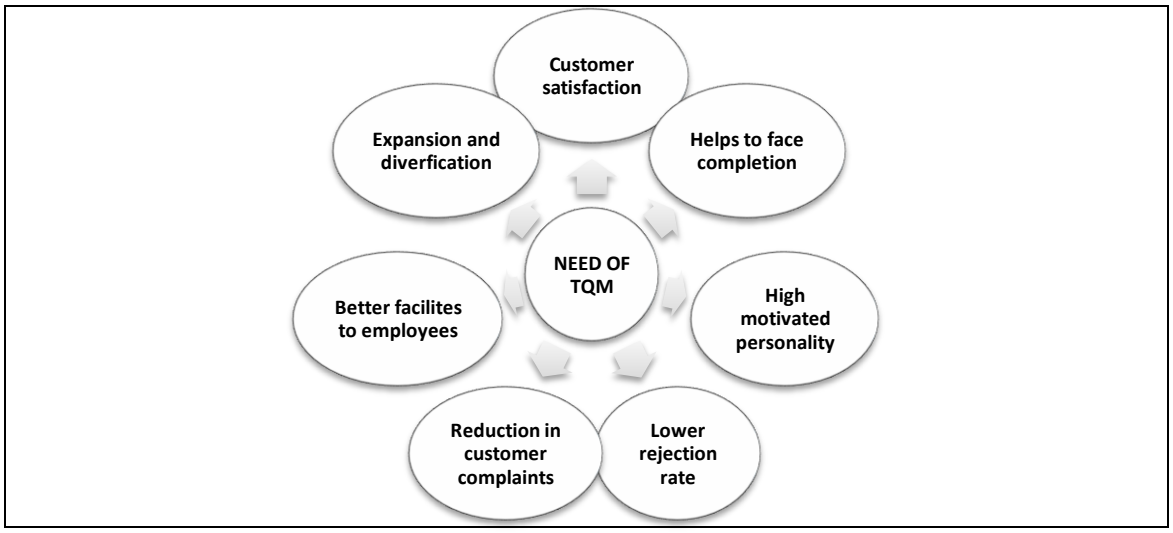
INTRODUCTION:

WHAT IS TQM?

It consists of organization-wide efforts to install and make permanent a climate in which an organization continuously its ability to deliver high-quality products and services to customers. While there is no widely agreed-upon approach, TQM efforts typically draw heavily on the previously developed tools and techniques of quality control. Total quality refers not only to the product but also to the way the product is made as well as presented to the customer. Total quality for customer orientation, process orientation, people management and leadership. All these are continuous processes

TQM is a people driven process. It involves changes in people's attitudes primarily. In addition, it deals with process orientation and continuous improvement of the process. It strives for empowerment and autonomy of the people involved in using process of production. It asks people to continuously look for new ways to adapt to the changing environment. It is continuous improvement plan. With an effort to bring the best for the stakeholders as well as for the institute.

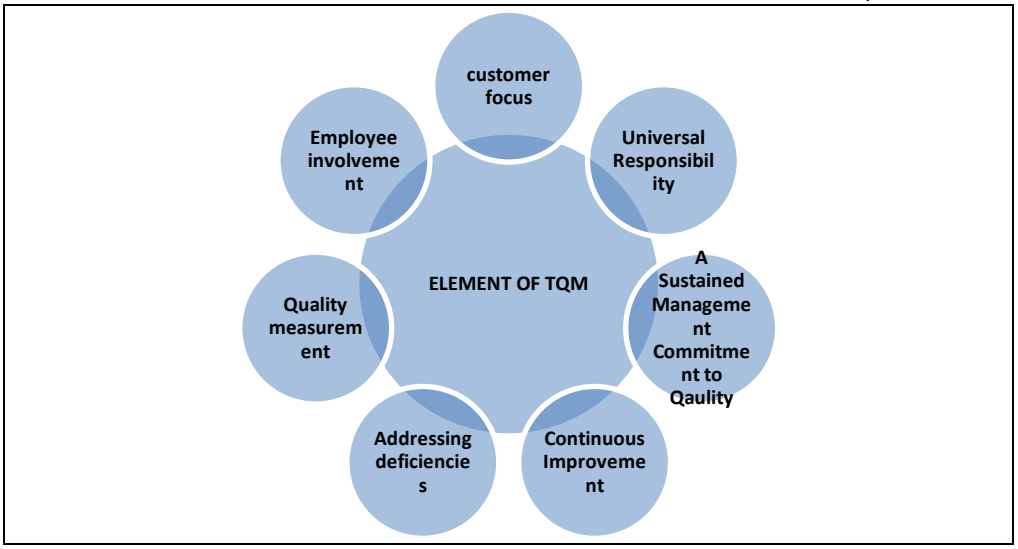




Direct benefits of TQM are as follows:

1. Increased pride of workmanship among individual workers.
2. Increased readiness
3. Improved sustainability caused by extended time between equipment failures.

4. Greater mission survivability.
5. Better justification for budgets because of more efficient operation.
6. Streamlined maintenance and production process



QUALITYASSURANCE:-Quality Assurance popularly knwn as QA Testing, is an activity to ensure that an organization is providing the best possible product or service to customers. QA focuses on improving the processes to deliver Quality Products to the customer. An organization has to ensur ,that processes are efficient, and effective as per the quality standards defined for software products.

Quality assurance has a defined cycle called PDCA cycle or Deming cycle.The phases of this cycle are:

1. Plan 2. Do 3. Check 4. Act

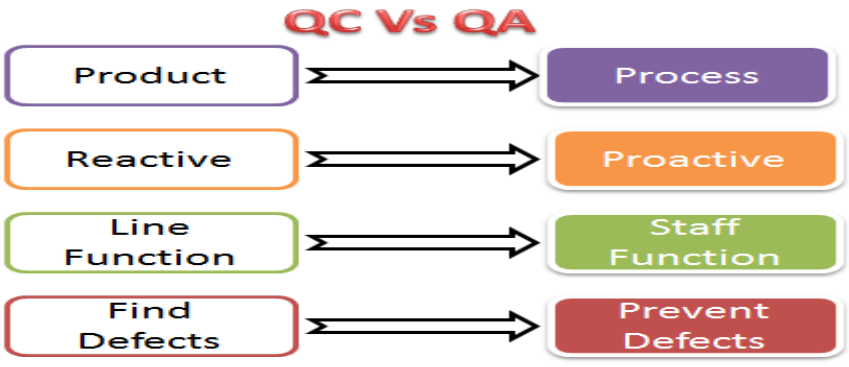
These above steps are repeated to ensure that processes followed in the organization are evaluated and improved on a periodic basis. Let's look into the above steps in detail -

1. Plan - Organization should plan and establish the process related objectives and determine the processes that are required to deliver a high Quality end product.
2. Do - Development and testing of Processes and also "do" changes in the processes
3. Check - Monitoring of processes, modify the processes, and check whether it meets the predetermined objectives
4. Act - Implement actions that are necessary to achieve improvements in the processes

WHAT IS QUALITY?

Quality is generally defined as conformance to requirements. It is also conformance to a standard that is required. However, many consider that quality need not just be conformance to requirements but should be an assurance of being the best in the world of that type.In addition, it should also keep a constancy of purpose

Quality Control:-Quality control popularly abbreviated as QC, is a process used to ensure quality in a product or a service. It does not deal with the processes used to create a product, rather It examines the quality of the "end products" and the final outcome.



Examples of QC and QA activities are as follows:

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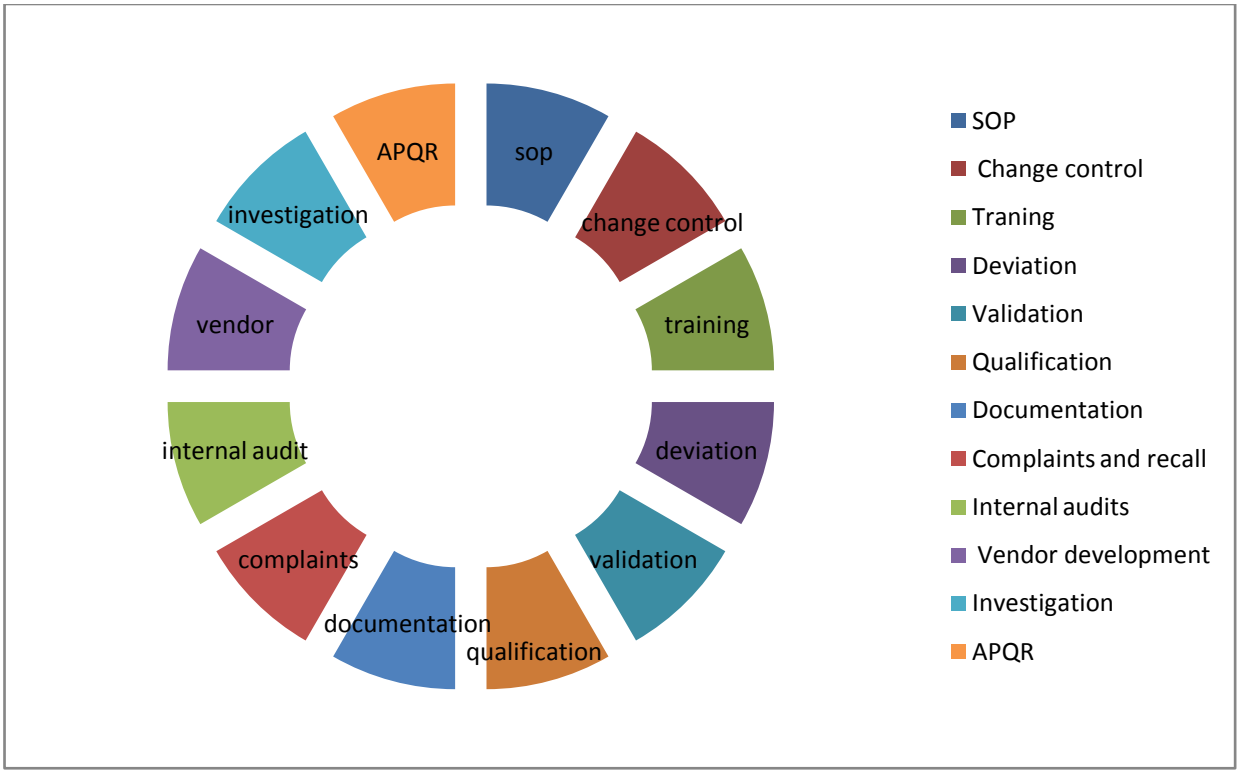
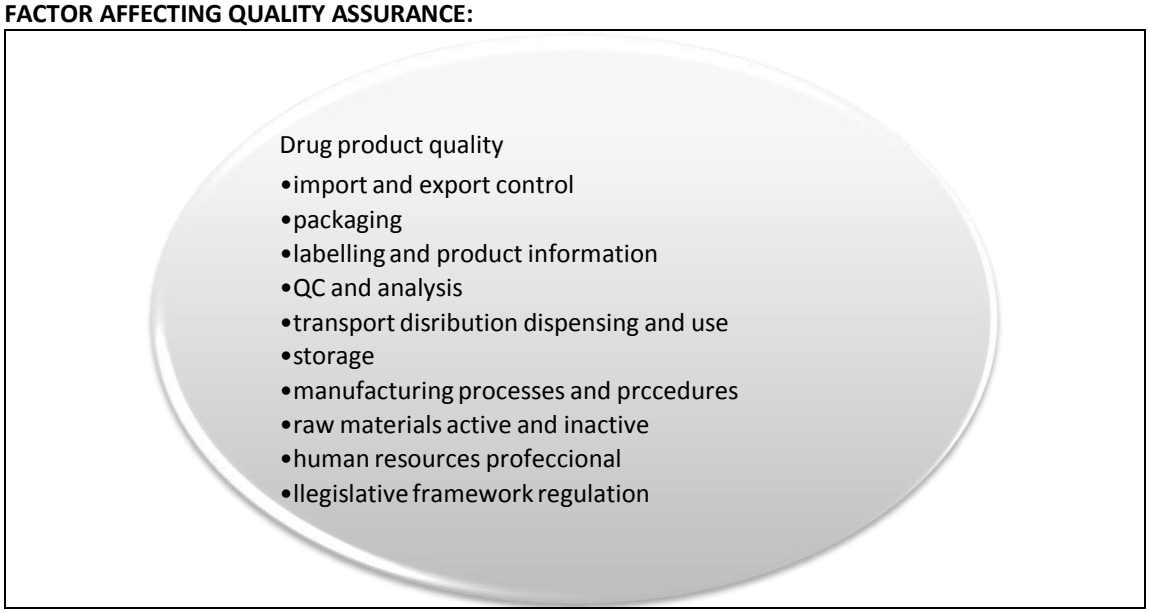
Quality Control Activities	Quality Assurance Activities
Walkthrough	Quality Audit
Testing	Defining Process
Inspection	Tool Identification and selection
Checkpoint review	Training of Quality Standards and Processes

Figure no.1.13:-Elemnet of QA



FACTOR AFFECTING QUALITY ASSURANCE:



Need of the quality assurance department in pharmaceutical industry

The surge of substandard, fake and adulterated medicine is global threat. The pharmaceutical industry saw an increase in regulation after the 1957 thalidomide disaster. The stringent, scientific, systematic and sustainable approach to commercial drug production ensures protection of public health.

The system of specifications as well as practice control measures in the industry, which is also referred to as standard operating procedures (SOPs) that are designed by regulatory authorities and scientific community to ensure good manufacturing practice.

OBJECTIVES OF THE STUDY:

a) To study and match guideline of accrediting agency, for achieving total quality of product for entering into market.
b) To Comparative study of global Immunobiological product and product of Serum institute.
c) To evaluate the production of product standard with respect to particular country pharmacopeia's standard as per the requirement of particular country.

LITRETURE REVIEW:

Before the concepts and ideas of TQM were formalised, much work had taken place over the centuries to reach this stage. During the early days of manufacturing, an operative's work was inspected and a decision made whether to accept or reject it. As businesses became larger, so too did this role and full time inspection jobs were created. Accompanying the creation of inspection functions, other problems arose:

1. More technical problems occurred, requiring specialised skills, often not possessed by Production workers
2. The inspectors lacked training
3. Inspectors were ordered to accept defective goods, to increase output
4. Skilled workers were promoted into other roles, leaving less skilled workers to perform the Operational jobs, such as manufacturing

These changes led to the birth of the separate inspection department with a "chief inspector", reporting to either the person in charge of manufacturing or the works manager. With the creation of this new department, there came new services and issues, e.g. standards, training, recording of data and the accuracy of measuring equipment. Hence a need of the quality control department evolved.

In the 1920's statistical theory began to be applied effectively to quality control, and in 1924 Shewhart made the first sketch of a modern control chart. His work was later developed by Deming and the early work of Shewhart, Deming, Dodge and Romig constitutes much of what today comprises the theory of statistical process control (SPC). However, there was little use of these techniques in manufacturing companies until the late 1940's. At that time, Japan's industrial system was virtually destroyed, and it had a reputation for cheap imitation products and an illiterate workforce. The Japanese recognised these problems and set about solving them with the help of some notable quality gurus – Juran, Deming and Feigenbaum. In the early 1950's, quality management practices developed rapidly in Japanese plants, and become a major theme in Japanese management philosophy, such that, by 1960, quality control and management had become a national preoccupation. In 1969 the first international conference on quality control, sponsored by Japan, America and Europe, was held in Tokyo. In a paper given by Feigenbaum, the term "total quality" was used for the first time, and referred to wider issues such as planning, organisation and management .responsibility. Ishikawa gave 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. Companywide quality management was common in Japanese companies by the late 1970's. The quality revolution in the West was slow to follow, and did not begin until the early 1980's, when companies introduced their own quality programmes and initiatives to counter the Japanese success. Total quality management (TQM) became the centre of these drives in most cases. In a Department of Trade & Industry publication in 1982 it was stated that Britain's world trade share was declining and this was having a dramatic effect on the standard of living in the country. There was intense global competition and any country's economic performance and reputation for quality was made up of the reputations and performances of its individual companies and products/services.

The British Standard (BS) 5750 for quality systems had been published in 1979, and in 1983 the National Quality Campaign was launched, using BS5750 as its main theme. The aim was to bring to the attention of industry the importance of quality

for competitiveness and survival in the world market place. Since then the International Standardisation Organisation (ISO) 9000 has
become the internationally recognised standard for quality management systems. It comprises a number of standards that specify the requirements for the documentation, implementation and maintenance of a quality system. TQM is now part of a much wider concept that addresses overall organisational performance and recognises the importance of processes. There is also extensive research evidence that demonstrates the benefits from the approach. As we move into the 21st century, TQM has developed in many countries into holistic frameworks, aimed at helping organisations achieve excellent performance, particularly in customer and business results. In Europe, a widely adopted framework is the so-called "Business Excellence" or "Excellence" Model, promoted by the European Foundation for Quality Management (EFQM), and in the UK by the British Quality Foundation (BQF)."

LIMITATIONS OF THE STUDY:

1. The study conducted in serum institute, Hadapsar,Pune.
2. Due to confidentially of some information accurate response was not reveals by some of the respondents.
3. The study is limited in QA department and some of the replies of respondents may be biased.

Future Scope of the Study

1. This study is helpful for conducting further research.
2. This study is useful for understanding the regulatory guidelines given by agencies (WHO, ICH).
3. This research also helps to reduce the errors in institute.

RESEARCH METHODOLOGY:

Sampling Method for Sample Selection

Random Sampling is a part of the sampling technique in which each sample has an equal probability of being chosen. A sample chosen randomly is meant to be an unbiased representation of the total population. If for some reasons, the sample does not represent the population, the variation is called a sampling error. Random sampling is one of the simplest forms of collecting data from the total population. Under random sampling, each member of the subset carries an equal opportunity of being chosen as a part of the sampling process.

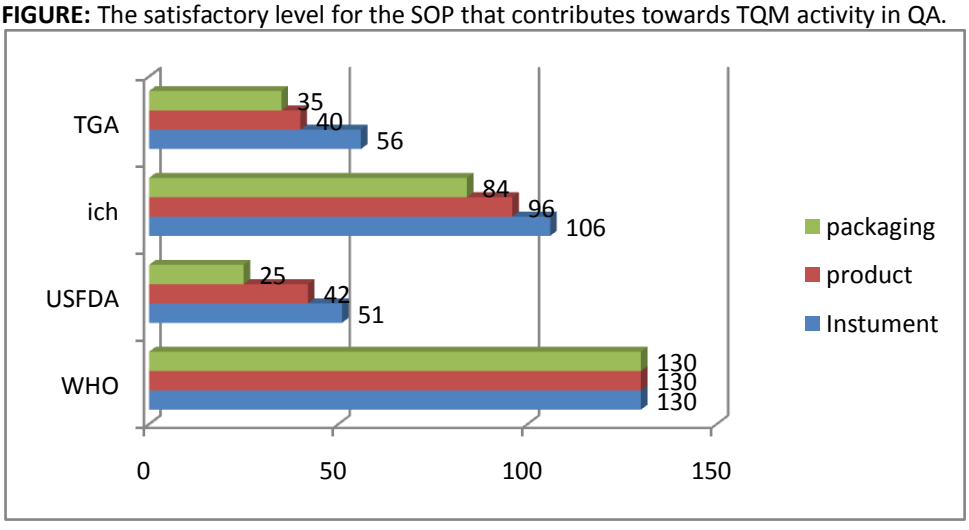
Serum Institute of India Pvt. Ltd. has total approx. 50 employees in QA

Department and 500 in QC and production department. This study targets the 130 employees of QA, QC, and production department in Serum

Institute of India in Hadapsar, Pune

DATE ANALYSIS:

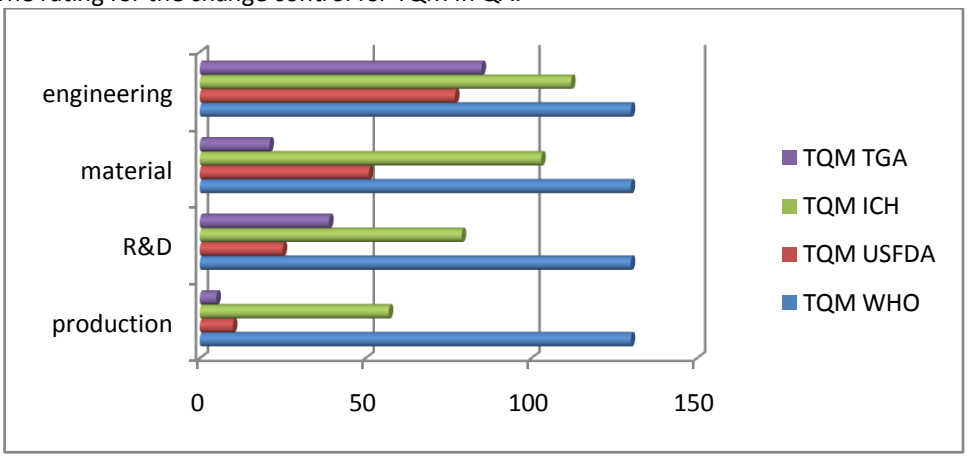
FIGURE: The satisfactory level for the SOP that contributes towards TQM activity in QA.



INTERPETATION:-instrument, production , packaging satisfy the WHO standards

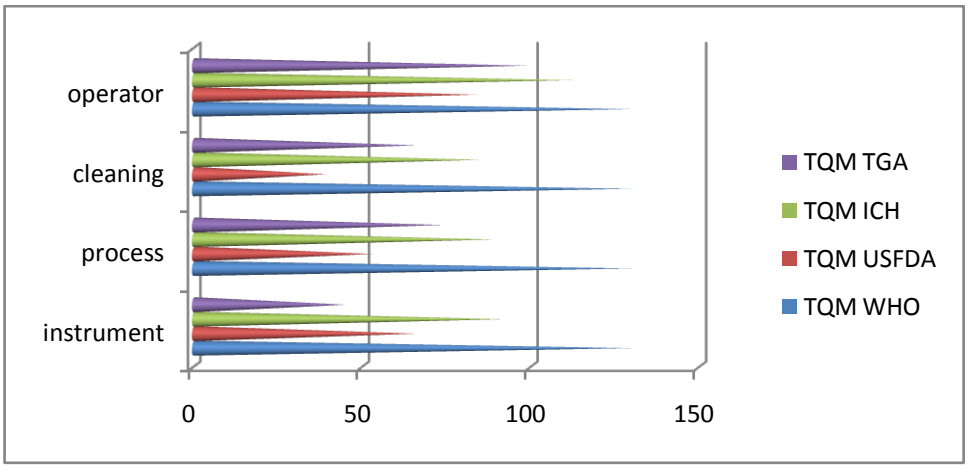
For the Sop that contributes towards TQm activity in QA

FIGURE: The rating for the change control for TQM in QA.



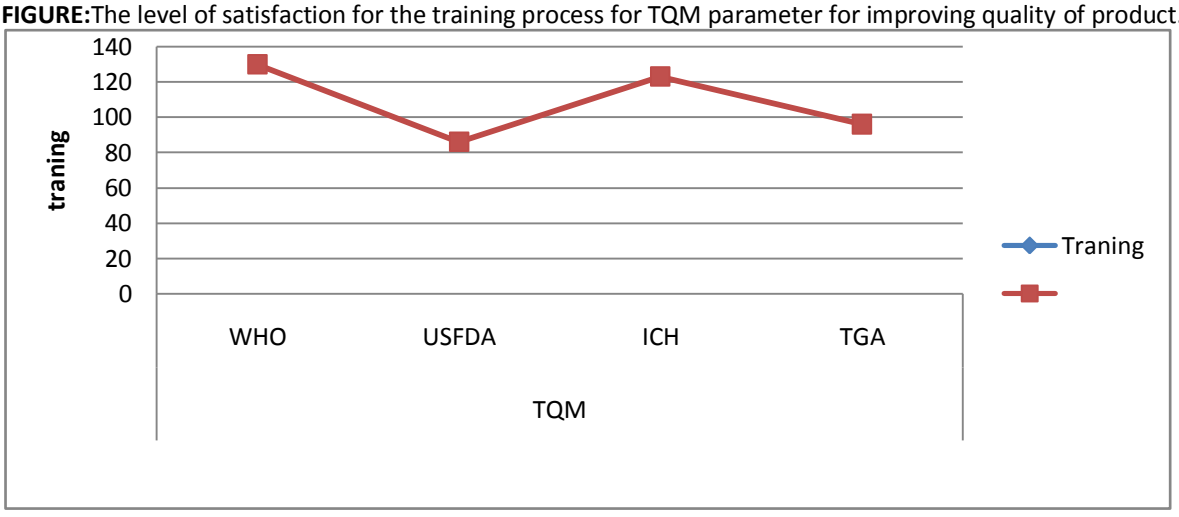
INTERPETATION:-The maximum rating for the change control in production, R&D, material and engineering is given to WHO standard for TQM in QA.

FIGURE: The level of satisfaction for the validation for quality performance.



INTERPETATION:-More satisfactionfor the validation of operator, cleaning, process, instrument in quality performance is seen in WHO.

FIGURE: The level of satisfaction for the training process for TQM parameter for improving quality of product.



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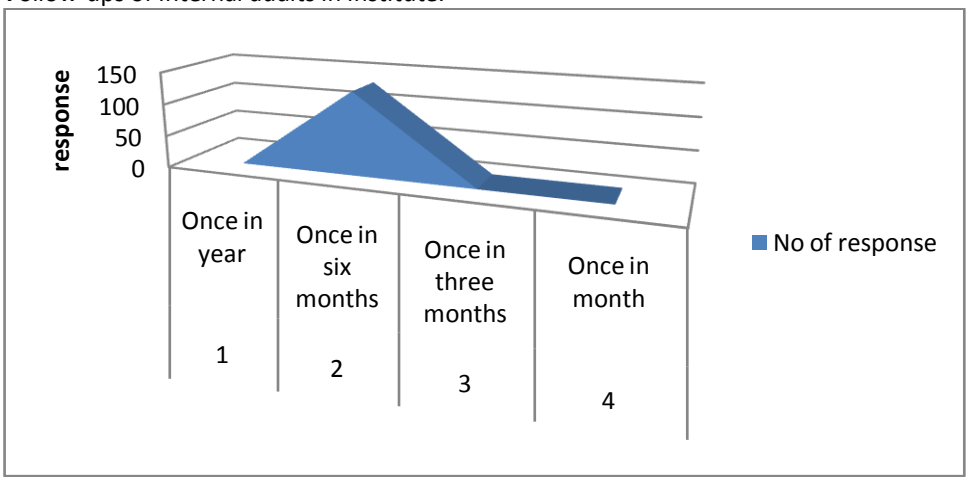
INTERPETATION:-WHO standards satisfy more for the training process of TQM parameter in improving the quality of product.

FIGURE : qualification process carried out in Institute

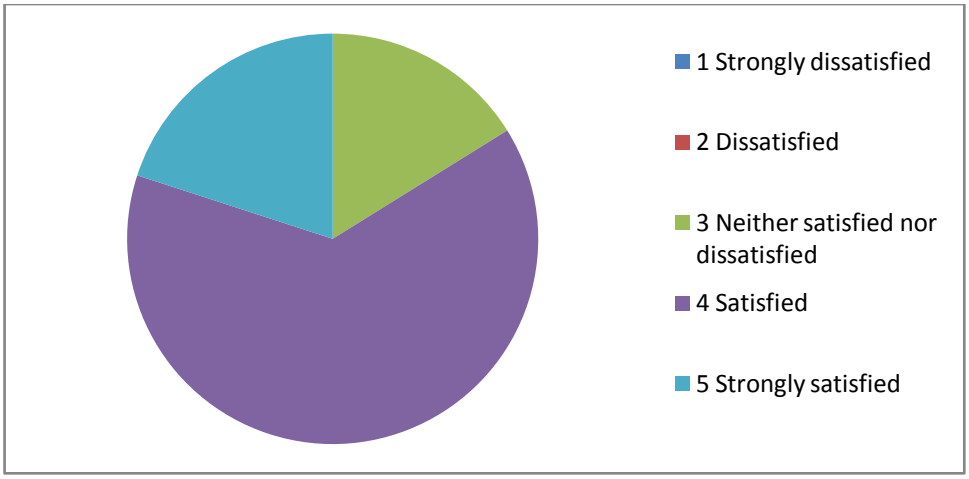
INTERPETATION:-All the qualification process carried out in institution as per WHO and ICH guidelines.

FIGURE : Follow-ups of internal audits in institute.



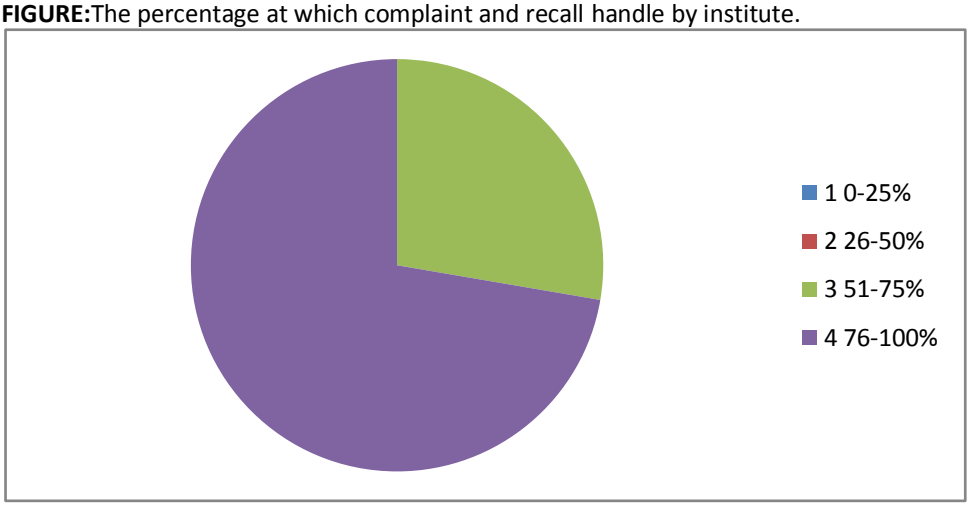
INTERPETATION:-Internal audits in institute carried out once in six month.

FIGURE : The level of satisfaction of vendor services.



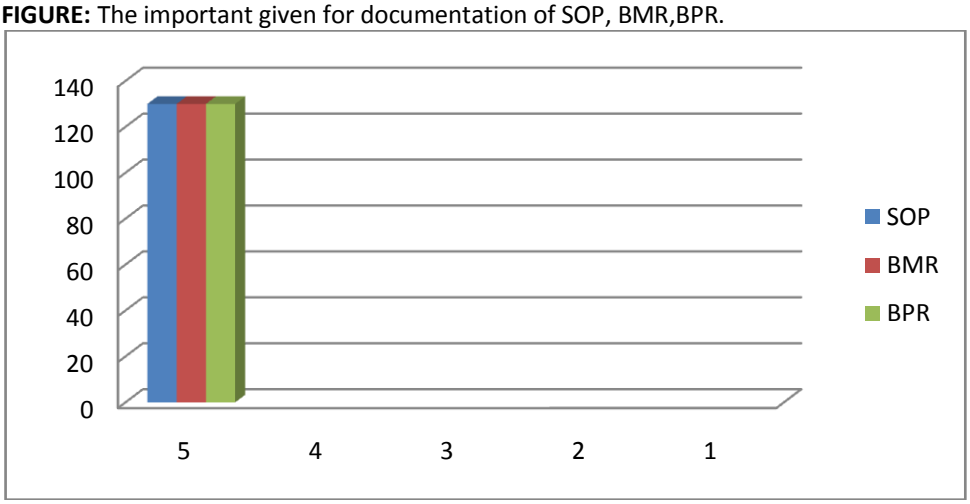
INTERPETATION:-They are satisfied with the vendor services.

FIGURE: The percentage at which complaint and recall handle by institute.



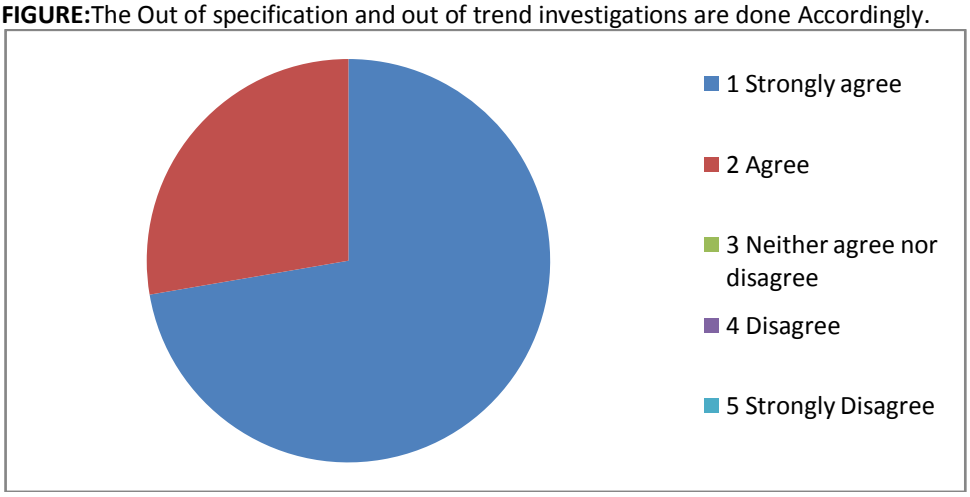
INTERPETION:-maximum complaint and recall are handle by the institute.

FIGURE: The important given for documentation of SOP, BMR,BPR.



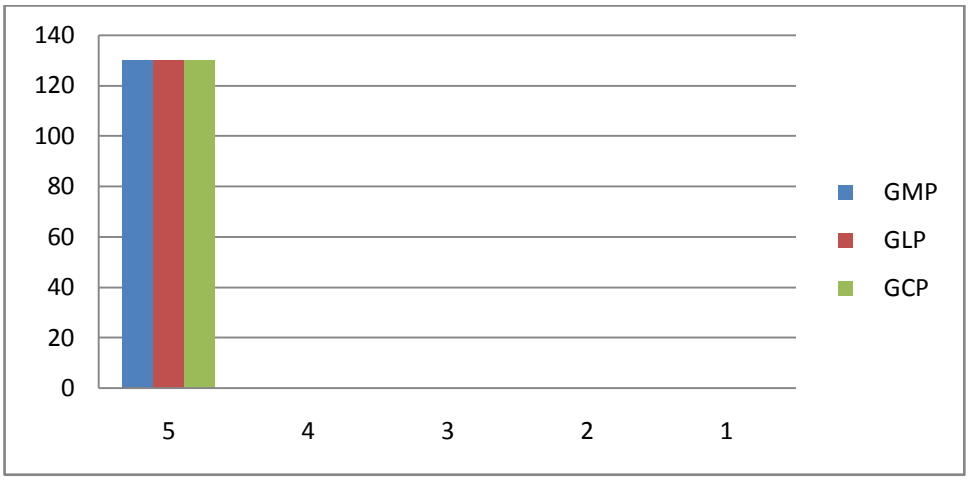
INTERPETATION:-The level of importance given is equal for documentation of SOP,BMR,BPR.

FIGURE: The Out of specification and out of trend investigations are done Accordingly.



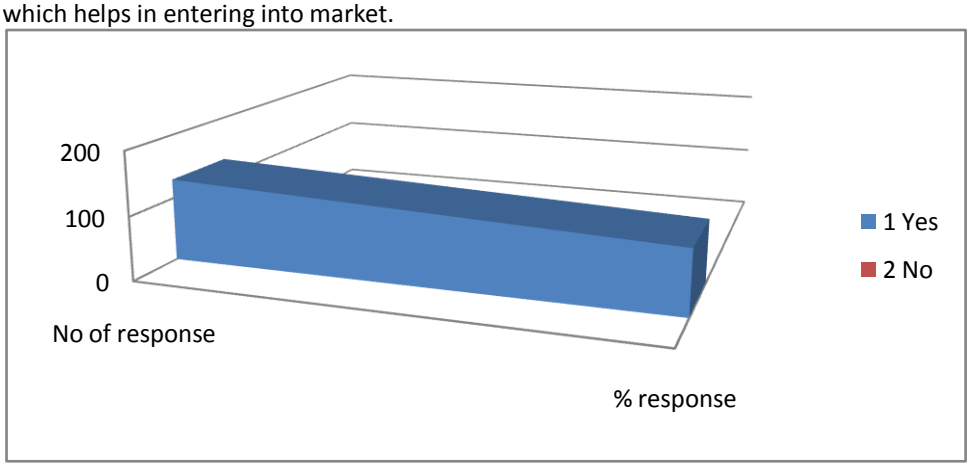
INTERPETATION:-There is strongly agreement for OOS and OOT done accordingly to WHO.

FIGURE: the level of importance given for GMP, GLP,GCP, in APQR



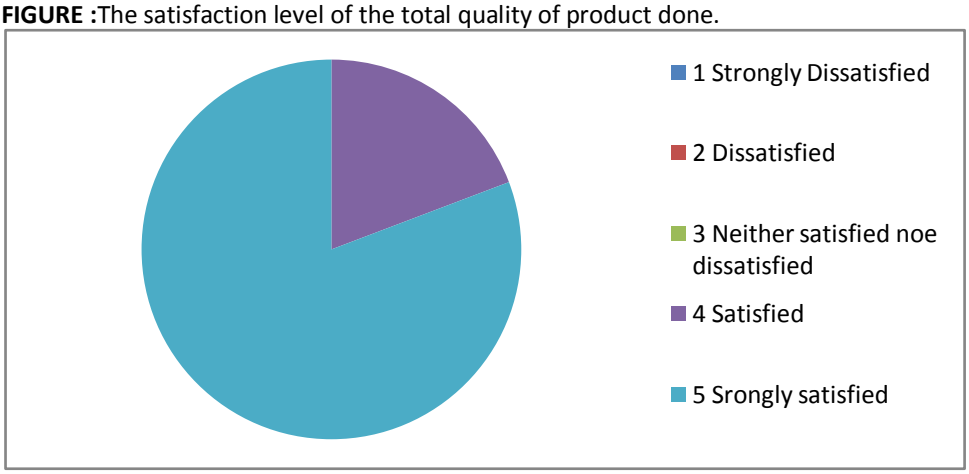
INTERPETATION:-GMP, GLP, GCP are most important in APQR.

FIGURE : All the guideline of accrediting agencies followed by company when it comes to total quality approval of product which helps in entering into market.



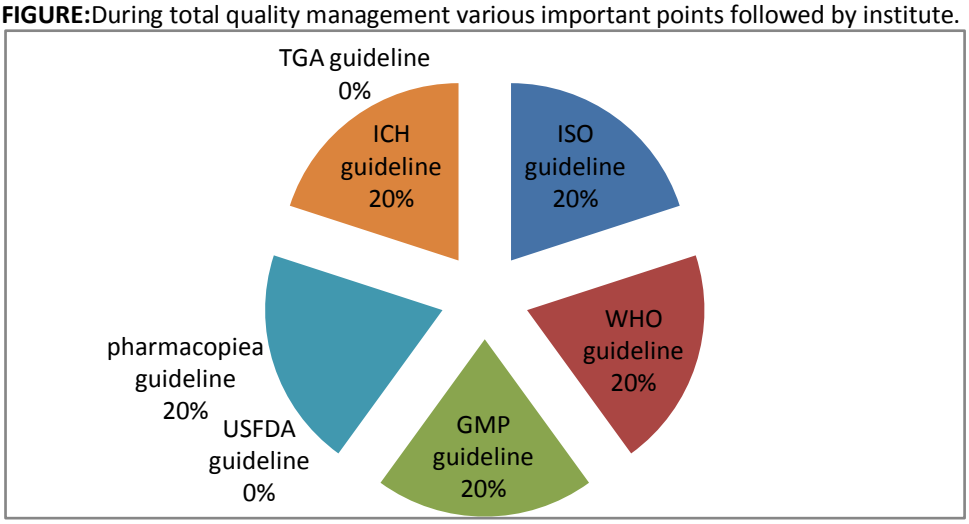
INTERPETATION:-Yes, All the guideline of accrediting agencies followed by company when it comes to tatal quality approval of product which helps in entering into market.

FIGURE : The satisfaction level of the total quality of product done.



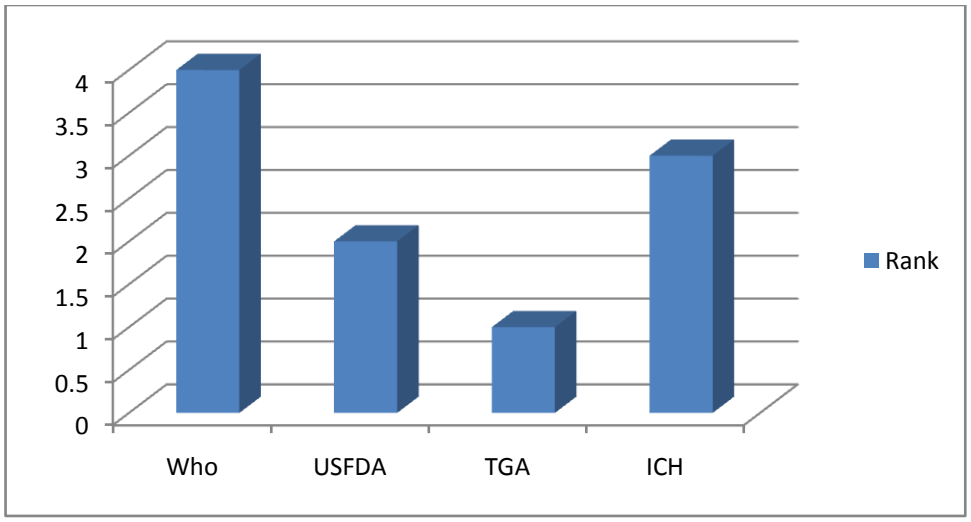
INTERPETATION:-there is strong satisfaction for the total quality of the product manufactured in the company.

FIGURE: During total quality management various important points followed by institute.



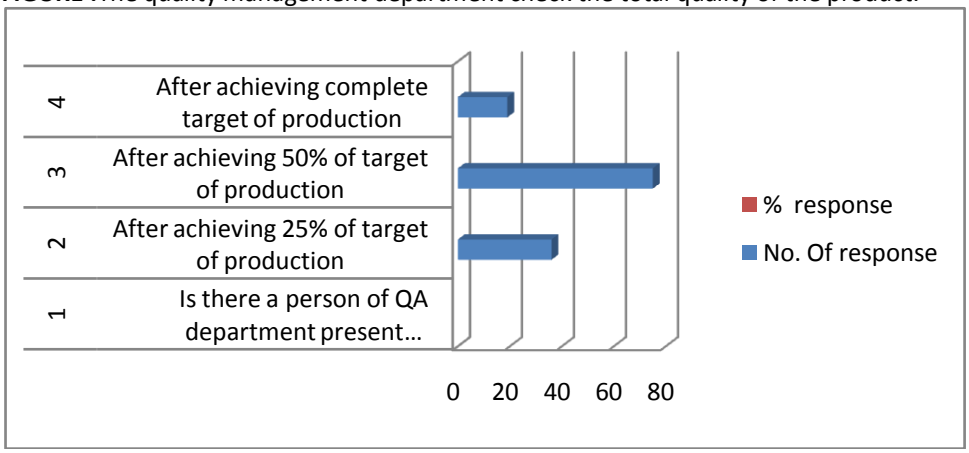
INTERPETATION:-The institute follows points of ICH,WHO,PHARMACOPIA,GMP, ISO guidelines during TQM.

FIGURE : Ranking of accrediting agencies depending on the importance given to them during total quality management of product.



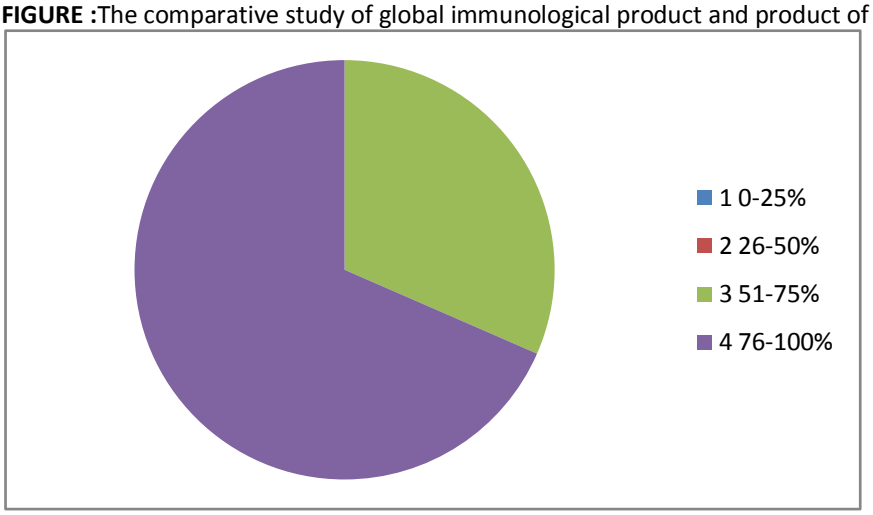
INTERPETATION:-The highest rank (1) is given to WHO guidelines during the total quality management of product.

FIGURE : The quality management department check the total quality of the product.



INTERPETATION:- It is seen that that the department of quality management checks the quality of product after completion of 25% of target of production.

FIGURE : The comparative study of global immunological product and product of serum institute.

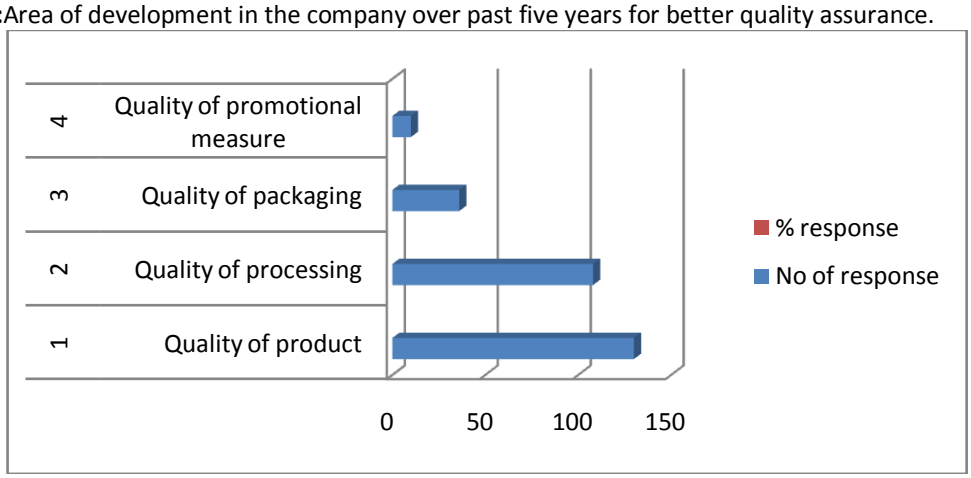


INTERPETATION:-serum institute product is comparatively more better than global immunological product.

FIGURE : The following Global Marketing strategies adopted by your firm.

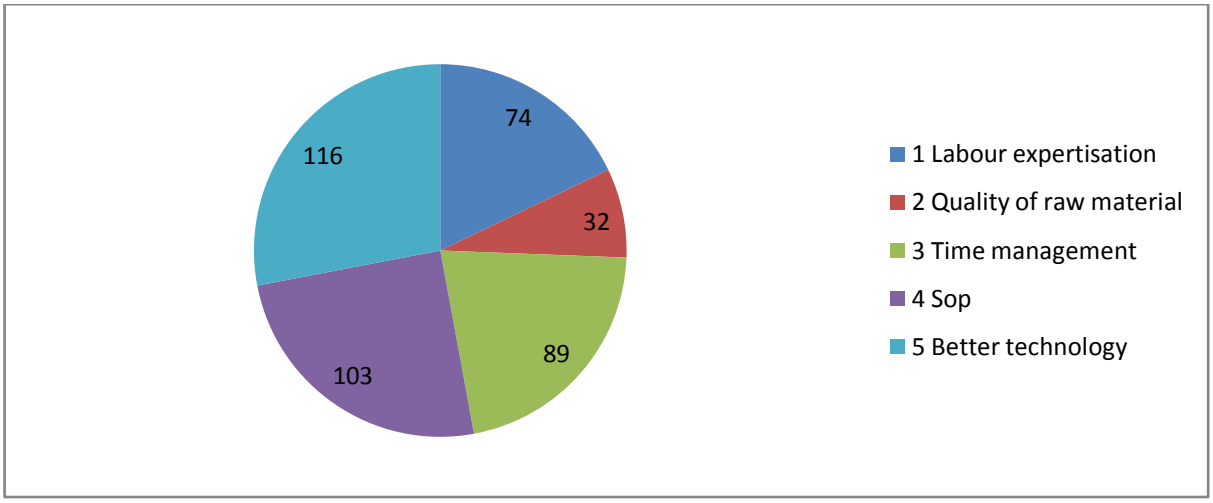
INTERPETATION:-The global marketing strategies adopted by the firm are licensing and indirect export.

FIGURE : Area of development in the company over past five years for better quality assurance.



INTERPETATION:-Department of quality of product and quality of processing were developed in past five years so as to have better quality assurance.

FIGURE : Areas in which company enjoys competitive strength when it comes to consumer satisfaction.



INTERPETATION:
The company enjoys competitive techniques in SOP and better technology areas when it comes to consumer satisfaction.
FINDINGS:
OBJECTIVES I:- To study and match guideline of accrediting agency, for achieving total quality of product for entering into global pharma market.
FINDING:- Serum Institute follows all the guideline of accrediting agency (specially WHO),for entering into global pharma market.
OBJECTIVES II:- To Comparative study of global Immunobiological product and product of Serum institute.
FINDING:- serum products are more better compared to other immunobiological company
Objectives III:- To evaluate the production of product standard with respect to particular country pharmacopeia's standard as per the requirement of particular country.
FINDING:- serum institute manufacture all product with respective to particular countries pharmacopieas.
CONCLUSION:
The main requirement of quality assurance department is to ensure that the products manufactured are of good quality and are safe to consume.The Serum institute taken for study follows all the accrediting agencies guidelines and global marketing guidelines correctly to maintain quality of the vaccine. Mainly WHO guidelines.All the parameters required for maintaining quality assurance of vaccines is carried out by giving high importance to each of them. so that TQM is achieved as is safe .
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