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A Review: Quality Control

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Abstract

Quality control is a process by which entities review the quality of all factors involved in production. ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements. The results of measurements should provide reliable information and the laboratory should be able to prove the correctness of measurements with documented evidence. Analysts carry serious responsibilities to produce correct and timely analytical results, and are fully accountable for the quality of their work. The expanding national and international trade, the responsibility of national registration authorities permitting the use of various chemicals required long ago reliable test methods, which were acceptable by all parties concerned. A Quality Control Manager supervises staff and oversees product development procedures to ensure that products meet quality and efficiency standards. The Quality Control Manager will also work with clients to ensure the final products meet their needs and requirements.

Key words- Quality Control, ISO, Total Quality Management, QA/QA, Inspection.

Introduction

When the expression "Quality is use we usually think in term of an excellent product or service that fulfils or exceeds our expression". These expectation are based on the intended use & the selling price.

Quality can be defined as –

$$Q = P/T$$

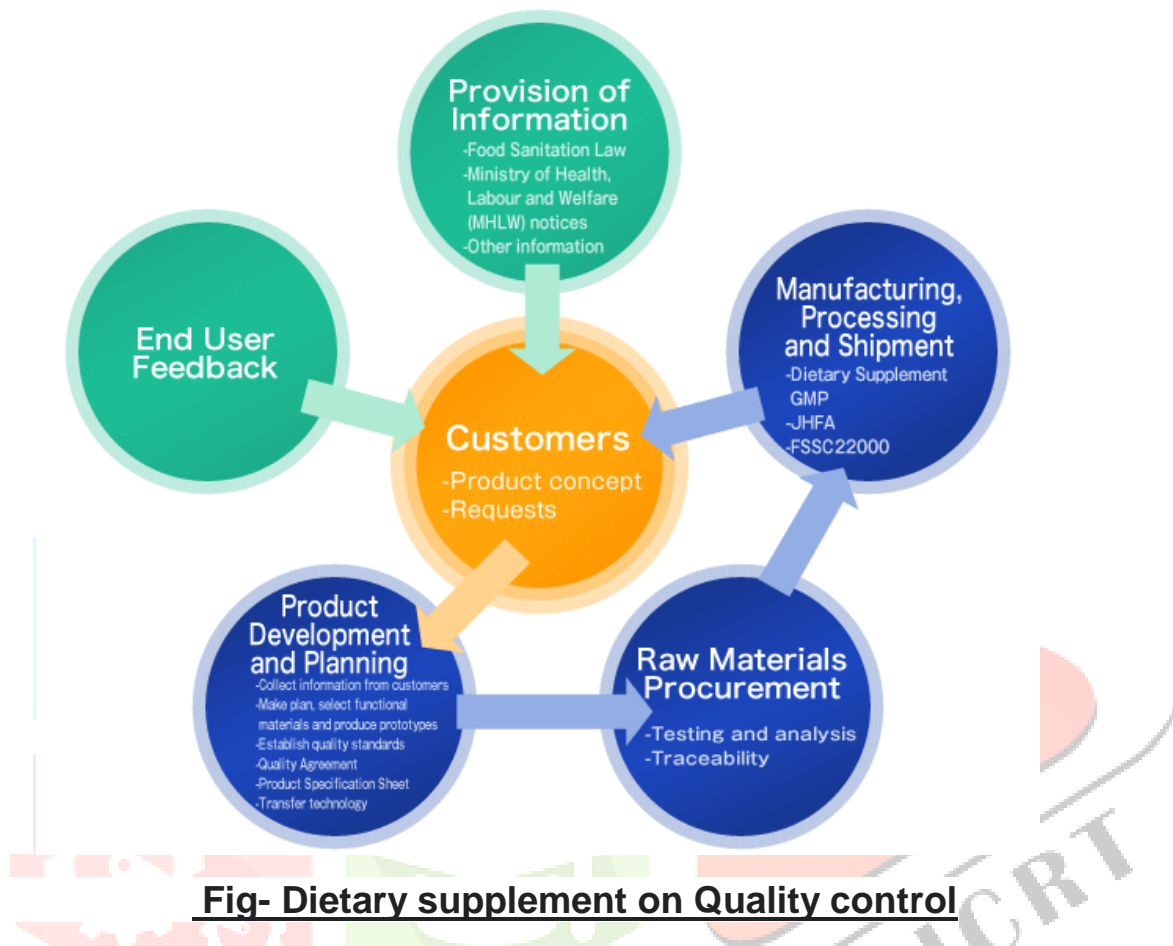
Where,

Q= Quality

P= Performance

T = Expectation[1].

Quality control (QC) is a process through which a business seeks to ensure that product quality is maintained or improved. Quality control requires the business to create an environment in which both management and employees strive for perfection. ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements"[2,3].



In GMP, quality control deals with sampling, specifications, testing, organization, and release procedures, which ensure that the necessary and relevant tests are conducted, and materials and products are not released for use, sale or supply till they are proved to be of satisfactory quality[2,4].

Basic requirement of Quality Control

1. All the batches of product should be analysed approved According to the requirement of the relevant authorizations.
2. It should be ensure that the finished product contain APIs that Comply with the qualitative & quantitative composition of the marketing authorization are of the required purity & are enclosed in properly labelled container[5,1].
3. Sample of starting material packaging material intermediates & Bulk finished product should be taken by personal & by method Approved by quality control department.

4. Sufficient facilities, trained person & approval procedure for Sampling insection & testing of starting material ,packaging Material ,intermediates, bulk & finished product and the test Method should be validated [6].

5. Record should be maintained either manually or by using Recording instrument to ensure that all the required sampling Inspection and testing procedure were conducted. If any Deviation is found it should also be recorded & further Evaluated[2,7].

6. The result of insection & testing of material,intermediates and Bulk & finished products should be recorded & formally Evaluated against standards products assument should cover a Review & evalution of relevant production documentation & an Assement or deviation from specified procedures[8].

Quality Control Tools

There are many approaches to quality control. The type you use depends on your specific product and should be determined before any quality control inspection begins. There are seven primary quality control tools which include:

- Checklists. At its most basic, quality control requires you to check off a list of items that are imperative to manufacture and sell your product.
- Fishbone diagram. This visual is helpful for determining what causes a specific problem, be it materials, machines, methods or manpower.
- Control chart. This helps you see how processes historically change using controls. The chart helps you find and correct problems as they happen, predict a range of outcomes and analyze variations [5,9].
- Stratification. Instead of looking at all factors together, stratification separates data so you can identify patterns and specific problem areas.
- Pareto chart. This type of bar chart provides a visual analysis of problems and causes so you can focus on the most significant issues.
- Histogram. A common graph that uses bars to identifies frequency distributions that indicate how often defects occur [6,10].
- Scatter Diagram. Plotting information along two axes on this graph can help visually identify relationships between variables.
- A quality control inspector uses one or more of the available tools or methods to do a complete analysis of a product or service to determine where improvements can be made. An inspector typically gets training to know what method to use and how to properly use it [11].

History of Quality control

The history of quality control is undoubtedly as old as industry itself . During the middle age Quality was to a large extent controlled by the long period of training required by the guild this training pride in workers for quality of a product. Until early 19th century ,the factory system ,with started in great Britain in the mid 1950s & grew into the industrial revolution in early 1800s. American quality practices involved in the 1800s as their was shaped by changes [11-13].

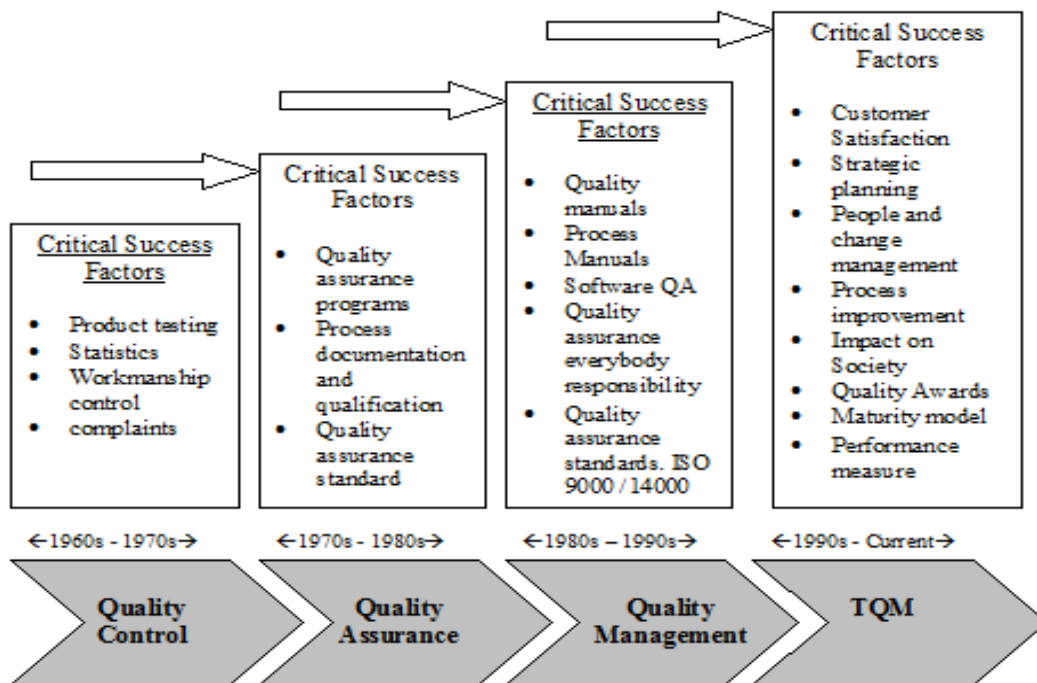


Fig- Evolution from quality control to Total Quality Management.

The simplest form of quality control was a sketch of the desired item. If the sketch did not match the item, it was rejected, in a simple Go/no go procedure. However, manufacturers soon found it was difficult and costly to make parts be exactly like their depiction; hence around 1840 tolerance limits were introduced, wherein a design would function if its parts were measured to be within the limits. Quality was thus precisely defined using devices such as plug gauges and ring gauges. However, this did not address the problem of defective items; recycling or disposing of the waste adds to the cost of production, as does trying to reduce the defect rate. Various methods have been proposed to prioritize quality control issues and determine whether to leave them unaddressed or use quality assurance techniques to improve and stabilize production [14].

In 1924, W.A Shewhart of bell telephone Laboratories developed a statistical chart for the control of product variable .This chart is considered to be the beginning of statistical quality control of product . IN 1946 the American society of quality control was formed .Walter Shewhart began to focus on controlling process in the Mid 1920 ,making quality relevant not only for the finished product but for the process that created it.In 1960, the first quality control circle as formed for the purpose of quality improvement. Simple statical technique were learned & applied by japans & other workers [15].

Importance of Quality Control

Quality control is not the responsibility of any one person or functional area. It is everyone's Job. It includes the assemblylene worker, the typist, the purchasing person & CEO of the company. The responsibility for quality start when marketing Determines the customers Quality ,requirement & continues until the product is received by a satisfied customer.

Quality is critical to satisfying your customers and retaining their loyalty so they continue to buy from you in the future. Quality products make an important contribution to long-term revenue and profitability. They also enable you to charge and maintain higher prices [7,16].

Consumers always get quality products of standard specifications to their utmost satisfaction. It is a well-known fact that some variations are bound to exist in the nature of production in spite of careful planning. The magnitude of variations depends upon the production process, namely, machines, materials, operations, etc. The techniques of quality control help in the study of these variations in quality of the product and serves as a useful tool for the solution of many manufacturing problems which cannot be solved so well by any other method.

Thus, quality control is an important technique in the hands of management to maintain the quality of the product [17].

Benefits of Quality Control

1. Consumer satisfaction

It's the consumers that benefit the most from the improved quality of the products. In other words, they get the best product from their desired company.

2. Reduction of production cost

If the production and operations go through inspection, the cost of the production comes down significantly. Aside from this, quality control also keeps tabs on wastage and the production of low-quality products. So, the cost of production can be cut down significantly.

3. Resource utilization

Quality control makes sure that the available resources are utilized to their fullest. Again this ensures that the all types of inefficiencies and wastage is brought under control.

4. Reduced inspection cost

Another benefit of control over quality is that the cost of inspection can be reduced greatly.

5. Increased goodwill

If quality products are made, customers are satisfied. As a result, the goodwill of the company goes up. As a result, the company can get financed more easily.

6. Price fixation

With quality control measures, companies can make products that have the same level of quality. As a result, the company can solve the common problem: price fixation. These are a few common benefits of quality control that a company or firm can enjoy. Hopefully, now you have a better understanding of the importance of quality [13,17,18].

Disadvantage of quality control

A major problem is that individuals are not necessarily encouraged to take responsibility for the quality of their own work. Rejected product is expensive for a firm as it has incurred the full costs of production but cannot be sold as the manufacturer does not want its name associated with substandard product. Some rejected product can be re-worked, but in many industries it has to be scrapped – either way rejects incur more costs, A quality control approach can be highly effective at preventing defective products from reaching the customer. However, if defect levels are very high, the company's profitability will suffer unless steps are taken to tackle the root causes of the failures [19,20].

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