CHAPTER 1

UNDERSTANDING QUALITY

Introduction

The moment we hear the word 'QUALITY' we think of words like quality control and quality assurance, since these two words are very widely used and very popular in pharmaceutical companies. When we think of quality control we imagine a typical chemistry laboratory where people in white coats are working on laboratory benches, some colored solutions in various glass bottles and some highly sophisticated analytical instruments like H.P.L.C., U.P.L.C., F.T.I.R. and so on. And when we think of quality assurance we imagine various square faced pharmacists lost in a heap of documents, really not knowing what they are doing.

Our minds are set to think and imagine such scenarios for years. But today I am going to take you on a journey in search of what is behind these typical scenarios. We will be looking for something we have not looked for, probably for years of our studies in our undergraduate as well as post-graduate classes of pharmacy. I am sure this is going to be a wonderful journey. Will you join me? I am sure you will not repent.

For years we have been taught to consider quality as a partly "technical issue". It was Dr. Joseph Juran who proclaimed that "Quality is no longer a technical issue, it is a business issue", and this has radically changed the thinking of business tycoons not only in the pharmaceutical industry but in the industry in general.

The business people know only the language of money and when they realized that "good quality products and services for their customers" means more business and more business means more money; in terms of net profits to them, they became serious about the quality of their products and services and started to assess and improve for their benefit, which in turn benefitted their

customers and societies in general. Thanks to the revolutionary thinker, philosopher and visionary and a social benefactor, Dr. Joseph Juran.

The first nation to take note of this revolutionary thinking was Japan. Japan decide to improve their products and services, quality and thus improve their image- "a nation producing sub-standard products to a nation producing world class products and provide similar services as well." To achieve this they took certain steps immediately. e.g.

Top level managers took personal interest in leading this concept of 'quality revolution'.

All levels (shop floor workers to board room directors) and functions (like production, engineering, finance, general administration, etc.) received training in quality disciplines.

Quality improvement projects were undertaken on a continuing basis, at a revolutionary pace (i.e. fast speed)

1.1 WORLD LEADERS OF QUALITY

As the market scenario changed from 'seller's market' to 'buyer's market', the public mind showed prominence of product and service quality. The buyers started demanding what they want rather than buy what the seller is selling. This initiated a competition in the manufacturers to attract the customers for their products and services; this in turn forced the manufacturers of the products and the provider of services to become serious about the quality of their products and services, which was a good sign.

In the 20th century along with Dr. Joseph Juran some other people also contributed in the field of quality improvement, they were;

- W. Edward Deming
- A.V. Feigenbaum
- Philip Crosby and
- Kaoru Ishikawa

These quality gurus advocated certain concepts of quality and this resulted in the progress of the quality revolution wave further in the world of business.

The main quality concepts put forward by these eminent people are as follows;

1. J.M. Juran
   (i) Quality planning
   (ii) Quality control

(iii) Quality improvement
(iv) Statistical and technological approach

2. W. Edward Deming
   (i) Systems approach
   (ii) Understanding statistical variations
   (iii) Nature and scope of knowledge
   (iv) Psychology of human behavior
3. A.V Feigenbaum
   (i) Total quality control
4. Philip Crosby
   (i) Conformance to requirements
   (ii) Zero defect
5. Kaoru Ishikawa
   (i) Use of simple tools for analyzing and solving quality problems.

1.2 DEFINITION OF QUALITY

The thought provoking quality concepts advocated by these quality gurus helped change the overall business conditions.

These changed business conditions may be summarized as:

(i) Business Competition.
(ii) Focus on customer needs and satisfaction.
(iii) Change in the mindset of customers, from accepting to demanding.
(iv) Improving performance at both technology and overall business level.
(v) Organizers changed from concept of self-sufficiency to accepting outsourcing.
(vi) Work force became more educated from no or little formal school education, certifications in various skills from industry training institutes, in pharmaceutical industry organizations started employing Diploma in Pharmacy candidates as workers / technicians on the shop floor.(e.g. Hoech St, Wockhardt employed D. Pharm as technicians)
(vii) Information flow in the organizations became easier or faster. Simple concepts like I.PQ.C. helped pharmaceutical plants to make it faster decisions on shop floor activities.
(viii) Role of central quality department is reduced because some of the central control labs were delegated down the line to the shop floor, where now you have trained people, both from production as well as quality control.

In short the whole quality management scenario has started taking new shape all together.

With this brief introduction to the quality environment now let us go in a little more depth of the subject on quality by defining the word "QUALITY."

The word 'Quality' has been defined in many ways in literature. Let us look at some of the common and well accepted definitions and make an effort to understand them.

(i) Quality is customer satisfaction and loyalty.

(ii) Quality is fitness for use.

(iii) Quality is compliance to specifications.

(iv) International Standards Organization (ISO) defines quality as the "totality of characteristics of an entity that bears on its ability to satisfy stated and implied needs (of customers)."

If we look at these definitions we see some of the key words in these are:

- Customer
- Satisfaction (satisfy)
- Fitness (fit)
- Loyalty
- Compliance (comply) and
- Specification

To clearly understand the definition we need to understand the meaning of the above key words in our present context of quality. Let us look at these meanings.

(i) 'Customer' is one who is affected by the service, product or process. The customer can be internal (from within the organization) or external (outside the organization).

The internal customer may be the recipient of in-process material for further processing at his end.

Example: A tablet compression machine operator is a customer (recipient) of granulation department.

(ii) 'Satisfy' means to please someone or giving them what they want or need or meet a demand, desire or need.

In the above case the internal customer for example gets satisfied if he gets the 'granules which will run smoothly on his compression machine.'

(iii) 'Loyalty' means firm and constant in one's support for something.

If I am satisfied with a brand of a particular pharmaceutical tablet say, Calpol, I will continue to buy the Calpol tablet only in the future, any time that I need it. I will not change the brand even though there may be many other brands available in the market

eg. Crocin, Metacin, etc. This is customer's loyalty to a product.

(iv) 'Fit' means a product or service of a suitable quality or type to meet the required needs or purpose.

(v) To 'Comply' means to act in accordance with wish, rule, law or command. Here 'comply with specification' means the product must meet the stated requirements in the specification.

(vi) 'Specification' means a detailed description of design and/or materials used to make something.

In our context a specification for our product refers to a list of parameters and their limits to which the product must comply with, eg. For a compressed tablet the specification may be stated in the following fashion:

Parameters	Limits
Hardness	4 to 6 kg/cm^2
Weight variation	485 to 515 mg
Disintegration time	Not more than 15 minutes

Now if we look at these various key words and their meanings, we will be able to clearly understand the definition and the scope of the word quality. In short 'customer satisfaction or delight' is the key of the definition of 'quality'. Hence the whole process of quality should always revolve around knowing and satisfying the customer needs.

Finally we can summarize that quality is defined by the customers, and features and freedom from deficiencies are the determinants of customer satisfaction.

1.3 PRODUCT FEATURES

Now that we have understood and agreed (hopefully) upon the definition of quality, all our efforts should dove-tail to the process of knowing and satisfying our customers.

It is well known that customer satisfaction is achieved by two things:

(i) Features of the product or service and

(ii) Freedom from deficiencies.

Let us look into these two issues in a little more depth.

A. Features of the product

There is a long list of features of the product for the manufacturing industry. We shall look at these with reference to the manufacturing industry.

1. Performance

   This refers to how the product should perform at the user end.

   e.g.

   - A tablet should disintegrate in the body and release the medicine as required.
   - A simple closure of the liquid bottle must protect the content from leaking out during transport, it should be easy to open and reclose appropriately. The performance is not good if the bottle leaks out the solution during transport, or if it cannot be opened easily or it is not easy to reclose the bottle once the seal has been broken. If this happens the customer is not satisfied.
   - If a tablet in a strip is already broken within the strip pocket before reaching the customer, the customer is dissatisfied.

2. Reliability

   If I take medication for a particular ailment, it must work for that purpose every single time.

3. Durability

   The product must have the therapeutic efficacy till the stated date of product expiry.

4. Ease of use

   The product must be easy to use

   eg. Tablets or capsules should be of appropriate size and shape so that these can be easily swallowed. Too big a tablet may not be easy to swallow.

5. Esthetics

   The product should look eleganteg.

   - Tablet should have a smooth surface and uniformly colored (if color is used, especially in coated tablets).
   - The labels on the product should be pasted properly, slanted or inappropriately pasted labels give a shoddy look.

- The customer may think the product is not good, because it gives the impression that it is badly made.

6. Availability

   The product should be available to the customers where and when they need. 'Out of stock' is also not a good situation. The customer may change from one product to other competitors.

7. Reputation:

   Reputation is both, the reputation of the company and the reputation of the product.

   E.g. 'Glaxo' as a company, 'Crocin' as a product etc.

B. Freedom from deficiencies: This refers to:

1. Product free from defects (either therapeutic or otherwise) and errors at delivery, during use and during its shelf life.
   e.g.
   - 9 tablets instead of 10 in a strip or 9 strips in a carton instead of 10 etc.
   - Tablets getting discolored during shelf life at the customers end. Sometimes a pharmacist may know that the slight discoloration does not affect its therapeutic efficacy but the customer may not know that.
   - A non-calibrated measuring cup supplied along with the liquid bottle may deliver more or less medicine to the customer during its use.

2. All processes free from rework loops, redundancy and other waste.

   A validated process always eliminates reworking of the product, or recoverable rejects (redundant materials) or any other waste for that matter.

   Now-a-days many international regulatory authorities for pharmaceutical manufacturing are banning rework in pharmaceutical products as it is their opinion that it adversely affects the quality of the product.

   We must note here that, 'Features' refer to quality of design. Increasing the quality of design in general leads to higher costs.

'Freedom from deficiency' refers to quality of conformance. Increasing the quality of conformance reduces the cost.

1.4 QUALITY FUNCTION

So far we have seen that customer satisfaction is at the root of quality and the features and the freedom from deficiency are the main determinants of quality.

Now the question is who is responsible for this? Can quality be achieved single-handedly by a so called quality department? (i.e; quality control or quality assurance)

The explicit answer is a big NO!! If not then why?

The answer is simple to state but difficult to practice.

The simple statement is 'Quality is everybody's responsibility'.

Who is that 'everybody' then? Here lies the concept of 'Quality Function'.

Quality function may be defined as – the entire collection of activities through which we achieve customer satisfaction and loyalty, no matter where these activities are performed. e.g. These activities can be performed at the suppliers (eg. vendor certification), the activities carried out in the pharmaceutical manufacturers plant (eg. receiving, storage and issue of all materials, quality control, IPQC, production and distribution of finished goods, and all other plant support activities like- engineering, personnel, scrap management, factory administration and so on) and the activities done after the product is distributed in the market (eg. Product surveys from field, customer feedback etc).

This enlarged concept of quality function encompasses 3 roles of the job holder. They are:

- Customer
- Processor
- Supplier

As we accept this enlarged concept of quality management, one more modern concept enters the scenario, and that is known as 'Little-Q' and "Big-Q'.

Little-Q was the old concept which emphasizes on quality of physical products (like tablets, capsules, etc.) in manufacturing industries.

Big-Q is now emerging as the application of quality concepts to all products, all functional activities and all industries.

To summarize this we can say that Little-Q deals with manufactured goods and processes related directly to manufacture of goods in manufacturing industries. However Big-Q deals with all products, all good and all services whether or not for sale and all processes, manufacturing support and business

processes in general in all industries, manufacturing, service, government, etc. whether or not for profit.

Now we will briefly look at those triple role concept used in 'Continuous Improvement Practices' i.e. the roles played by the customer, the processor and the supplier.

Here actually we are considering 'processor' as the central or focal point for quality and how he should behave (or practice) as good customer and to a supplier and also as a good supplier to his customer.

These behavioral patterns have been summarized by Paradyne Corporation's Continuous Improvement Leadership team as follows:

1. The processor as a good customer should;
   (a) Agree on and document his requirements with the suppliers.
   (b) Return defective inputs to his suppliers promptly and tactfully (please remember that the cGMP guidelines for pharmaceuticals also say that rejected or defective materials must be returned to the supplier at the earliest possible opportunity to avoid either intentional or unintentional use of these materials in the manufacture of pharmaceutical products).
   (c) Feedback input quality data to his suppliers. This helps the supplier to take the necessary corrective action at his end to control quality.
2. The processor as a good processor himself should;
   (a) Learn and apply the tools of quality and teach others the same.
   (b) Continuously improve his processes to reduce defects, reduce cycle time and know the industry benchmarks.

   A simple survey: a tablet compression outputs in various manufacturing plants showed a variation of 25 % in standards accepted by these plants. eg. On a 27 station double rotatory compression machine the standards for the same size and shape of tablet varied between 6.0 Lakhs to 8.0 Lakhs per shift. This is a variation of 25%.

   (c) Document and display his process, defect levels and continuous improvement projects.

   In good pharmaceutical plants, the processes are displayed or at least are available at the work station but the defect levels (eg. Ampoule defects, tablet defects, etc.) and continuous improvement projects are

generally not seen displayed. This point must be noted and implemented by the manufacturing pharmacists in their plants.

3. The processor as a supplier should;
   (a) Understand his customer requirements and agree on and document his deliverables.
   (b) Reduce defects and variation (even within the prescribed limits) in his output.
   (c) Measure his outputs quality from his customer's point of view.

1.5 QUALITY RELATIONSHIP

Quality Relationships

In manufacturing industry like pharmaceutical industry, we see there is some relationship with quality of certain other concepts namely productivity, cost, production cycle time and value. These relationships can be understood as follows:

1. Quality and productivity

Productivity is the ratio of salable output divided by the resources.

Here both the terms namely, (i) Salable output and (ii) Resources used must be understood in its widest scope. Let us look at this briefly.

(a) What is the salable output of a batch produced say of an ampoule product.

- The B.P.C.R says the batch size is say 1 Lakh ampoules.

  If you look at the typical reconciliation report of such a batch of 1 Lakh ampoules the following points will come out prominently. The figures given below are approximate figures.

  - The empty ampoules used were 105,000.
  - The labels used were 104,000.
  - Ampoules filled were 92,000 (considering provision for extractable volume)
  - After visual inspection, good ampoules were 88,320. (4% rejection)
  - Samples taken at various levels say 320 ampoules. This includes the samples taken during I.P.Q.C checks, as well as those taken by the central control lab for chemical and sterility testing etc. this gives you good ampoules ready for labelling and packing 88,000.

- Considering package loss final good packed ampoules transferred for sale is 87,750.
- This means that we started with 105,000 ampoules and were left with only 87,750 salable goods i.e. a loss of 16.42% has occurred already.

(b) Now let us look at the 'resources'. The main resources are given below:

(i) Raw and packaging materials for 1.0 Lakh ampoules.

(ii) Direct Manpower used.

(iii) Equipment used.

(iv) Facility used (including cost of environment control like temperature, humidity, class 100/10,000 environment etc.)

(v) Testing of raw materials, packaging materials, in-process goods and finished goods in the quality department.

(vi) Distribution cost.

Note: Other indirect costs are not considered here.

The purpose of giving these details here is to emphasize the point that all these resources are actually a big cost to the company and one can look at these for reducing the costs incurred so that the production can be increased.

2. Quality and costs

We know that- as the "Quality of design (features)" increases so the cost also increases, and as the "Quality of conformance" increases, there is a reduction in reworks, complaints, scraps and other deficiencies which results in a significant decrease in costs.

The business look out should be savings earned from cost of compliance should be used to increase the product features and keep the price the same. This will attract the customers to your products and thus market share can be increased resulting in more profits.

3. Production cycle time

Customers want a fast response. This is possible by reduced production cycle time. If quality of process is improved, this will result in reduction of production cycle time, which will in turn increase customer satisfaction, which is our objective.

In pharmaceutical market if a product is not available the customer cannot wait for the product, and he has no other choice but to go for a substitute or alternative product of the other supplier, hence the sales lost is lost forever.

4. **Quality and value:** Value is quality divided by price and if we consider quality as customer satisfaction, then:

$$\text{Value} = \frac{\text{Quality}}{\text{Price}} = \frac{\text{Customer Satisfaction}}{\text{Price}}$$

So if we improve quality, the value will increase and increased value means more number of satisfied customers and ultimately this means more profit.

This indicates to us that quality, productivity, costs, cycle time and value are interrelated.

1.6 QUALITY TRILOGY

Dr. Juran has advocated the concept of 'Quality trilogy'. He has promoted this as a universal process for managing quality. This has 3 components namely;

(i) Quality planning
(ii) Quality control and
(iii) Quality improvement.

Each of these has some specific activities which can be summarized as follows;

(i) Quality planning: It involves,

- Establishing the project
- Identifying the customers
- Discovering the customer needs
- Developing the product
- Developing process controls and transferring to the operators

(ii) Quality control: This involves,

- Choosing control subjects i.e. what to control. e.g. weight variation of tablets
- Establishing measurements weight in milligram
- Establishing standards of performance ± 5% of the target weight.
- Measuring the actual performance, use suitable sensitive balance.
- Comparing to the standards
- Taking action on the difference

(iii) Quality improvement: This involves,

- Proving the need for improvement
- Identifying the projects for improvement
- Organizing team projects
- Diagnosing the causes of quality problems
- Providing remedies and proving that the remedies are effective
- Dealing with resistance to change and controlling to hold the gains

For achieving success for this trilogy, the organization leadership should be inspirational and there should be a quality culture in the organization.

1.7 CONTRIBUTION OF OTHER DISCIPLINES TO QUALITY

In a business environment many management functions contribute to each other and so for quality function also.

In modern competitive business environment, the quality function or discipline cannot work in isolation. Here quality discipline is the term used to denote the body of quality related knowledge. The knowledge from other disciplines is sometimes unique and sometimes overlap the quality disciplines.

Let us briefly look at the various disciplines which contribute to quality.

1. **Finance: Measuring the cost of poor quality.**

   This helps in understanding the gravity of financial i.e. monetary losses the organization is incurring. This leads us to identify and select as priority the projects for quality improvement.

2. **Industrial Engineering: Design of integrated systems, measurement, problem solving and work analysis.**

   The discipline of industrial engineering deals with motion and time studies, this knowledge helps us in clubbing similar activities and splitting complex activities to get the operational benefit.

3. **Information Technology: Measurement, analysis and reporting on quality.**

   In the modern high speed manufacturing activities, speed of information on quality is important. You need to get timely and fast feedback on the production that is being carried out on the shop floor. I.P.Q.C. is helping in this regard by collecting samples from the process, measuring various parameters and reporting on quality parameters being tested, so that if needed corrective actions can be taken immediately.

4. **Market Research: Competitive standing on quality and understanding customer desire.**

   Market research gives continuous feedback on the company's competitive products in the market. These products then can be analyzed for what is better in the products as compared to our product in terms of product features and deficiencies. The best example we can see is the innovative toothpaste products coming out in the market every day.

   Similarly the trend of peoples liking also gives us a clue to develop innovative products or modify our own existing products.

5. **Operations Management: Management of integrated systems.**

   Operations management is a job to manage the process of converting inputs into 'desired outputs' and when we say desired outputs, it covers quality of the product. This means operations management helps in integrating the resources like men, machine, materials and money to make an output which is desired.

6. **Operations Research: Analyzing product design alternatives for optimization.**

   Optimization refers to identifying bottle neck work centers and carefully managing the materials and resources related to those bottle necks to maximize outputs and reduce inventories while producing a quality output. Hence operations research can be of help in meeting customer satisfaction by producing a desired product at low cost.

7. **Organization Behavior: Understanding quality culture.**

   This will be discussed in the next chapter - which discusses making teams effective for organizational benefit.

8. **Organizational effectiveness: This helps in satisfying the needs of both the internal and the external customer.**

   Effectiveness deals with completing of a job in targeted time and of a desired quality, while efficiency deals with doing the above things more economically or with more productivity.

9. **Strategic Planning: Quality as a means of achieving an unique competitive advantage.**

   Business organizations always try to achieve an advantage over their competitors. For doing this, product and service quality is a very useful tool.

10. **Systems engineering:** This helps in counting customer's needs into a product with customer decided features and at the same time process features for producing the desired goods.
11. **Value engineering:** This deals with analysis of essential functions needed by the customer in the product.

1.8 LITTLE Q & BIG Q

To summarize we can say that both internal (Little-Q) and external (Big-Q) views of quality are essential.

We can very briefly look into this at this stage.

(a) Internal View (Little-Q)

The objective of the manufacturing people is restricted to meeting the in-house and legal or pharmacopoeial specifications of a product.

The main objective of the production pharmacist is only to see that the products manufactured by him gets approved/passed/accepted by the Q.C. department so that it will not have a failure in company as well as in the field during the product shelf life.

The entire management is concentrating on manufacturing operations.

They use only internal i.e. in-house quality measures.

The organization views quality only as a technical issue and all the quality related efforts are primarily coordinated by the quality head.

(b) External or customer focused view (Big-Q)

This is what Dr. Juran tried to advocate and propagate for the management of quality.

This view compares products with the best products of the competitors with a view to evaluate the gaps in our product with the other competitors.

The idea is that the customer should get satisfaction till the entire shelf life of the product.

The quality is considered as to satisfy the customer needs. For this reason the organization not only concentrate on manufacturing but covers all functions.

The specifications are modified to meet the internal as well as customer needs.

They consider quality as a business issue and not only a technical issue, because they know that if product quality is improved business will improve and naturally the profits.

In this view, top management themselves get involved in the quality movement and they do not leave it only to the quality head.

This brief introduction to ‘Quality’ will set the stage for our further study.