Principles of TQM

We know that TQM is the enhancement of the traditional ways of doing businesses, is based on some set of principles that are six by numbers

(Continue to next slide….)

Principles of TQM (Continue…..)

1) Quality oriented managt
2) Focus on customer
3) Involving (entire) work force
4) Continuous improvement
5) Supplier Partnership
6) Measuring performance

1) Quality Oriented Managt

- The mission and vision should be such that balance the need of both company and customers.
- Managt (as a leader) should inspire and motivate the entire work force
- Managt must be as role model in ethical behavior, communication and in coaching.

  i-e role model in communication their should be open communication with both customer and employees

2) Focus on customer

- Customer consider as most important asset of an organization
- Consumer buy product and if they are satisfied will purchased more, in turn the organization will more profitable AND can compete over market
- Thus an organization must define all its process and function with customer point of view

3) Involving entire work force

- The work force should consider as internal customer and should be satisfy their basic needs whi

Safety, Job security, Communicating centers

- A satisfy employee will work his best for the attainment of organization goal.
- Another way to involve the employees is Employees empowerment
- Employee empowerment simply is the individual

Conti…

- Basic requirement for empowerment
- Knowledge about org Mission and vision
- Mutual trust between employee and org managt
- Employee must able (i.e. skillful) to take a task

4) Continuous improvement

- Continuous improvement means bringing perfection in all organization function and process
- Ways through which improvement can be made:
  - Dissatisfaction with current level of performance
  - Eliminating waste when it occurs through rework

Conti…

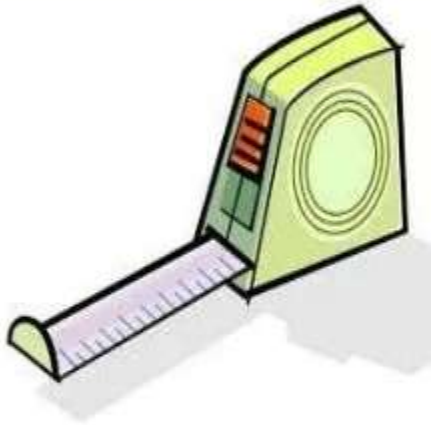
- Organization management Improvement can play a vital role such that break down the complex process into sub process and them improving them.

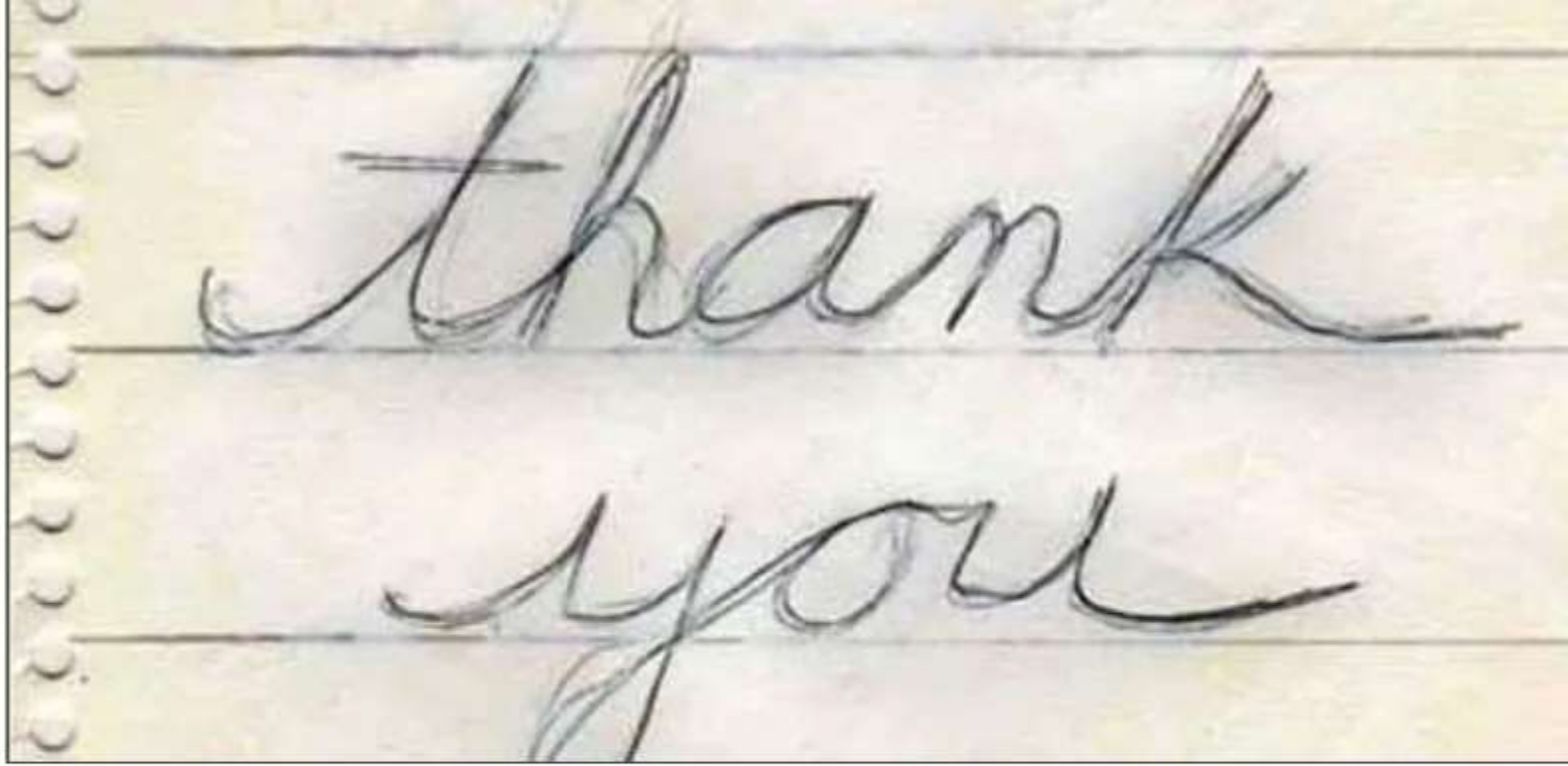
5) Supplier Partnership

- A supplier is considered as partner because:
- Need of trust supplier that supply the quality material
- J.I.T concept
- Principles of customer and supplier relation
- Mutual responsibility for quality material
- Both should independent from each other
- Contract on Quality, quantity, price of mateerial

6) Measuring performance

- Measuring performance means judging what have been planed either achieved or not
- Objective behind performance managt:
  - Indicate the process gain or loss
  - Compare the goal with what been achieved
  - Determine what process need to improve
  - Determine the over all performance of the organization





Question & Answering Session

Thanks to all

QUALITY SYSTEMS

aras

INNOVATION WITHOUT LIMITATION

Agenda

- Quality Systems – Product Overview
- Demo
- Open Forum Discussion

Aras Quality Management System

- Quality Management System (QMS) is a new application comprising:
  - Quality Planning (QP) - QMS 11R1 (Released: Dec 2015)
    - Replaces previous Aras application
  - Quality Systems (QS) - QMS 11R2
    - Derived from existing Community offering
    - Expected availability: Q3 2016
- **Focus for today is Quality Systems(QMS 11R2)**

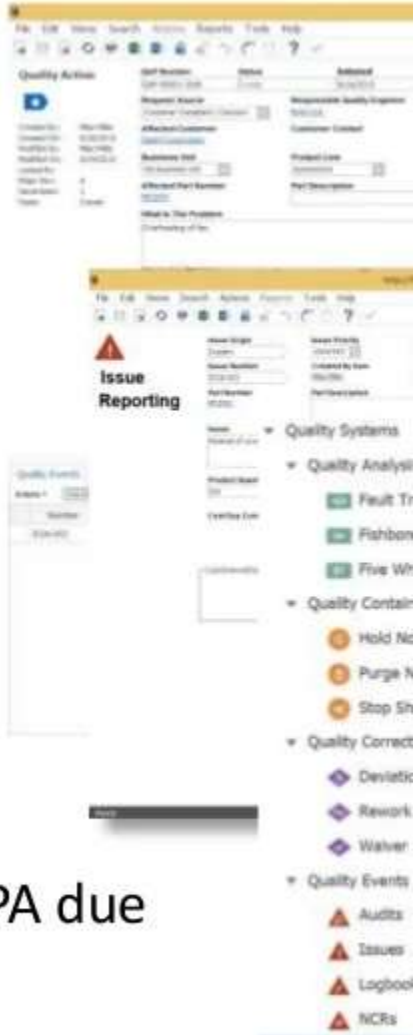
LORD Laird TECHNOLOGIES crucis TECHNOLOGY MAXION tellabs

Quality Planning (Proac
- Design
  - FMEA
- Process
  - PFMEA
  - Flow Diagrams
  - Control Plan

Quality Systems (Reacti
- Quality Events
  - Issues, Audits, NCRs..
- Quality Containment
  - Hold Notice, Pur Notice..
- Quality Analysis
  - 5-Whys, FTA, Fishbone
- CAPA

Quality Systems – Key Use Cases

- Manage CAPA data and processes in PLM
  - Single source – Design, Manufacturing and Quality data
  - Leverage core PLM capabilities – Workflow, Document Management, Search, Change, Reporting
- Track CAPA and affected Items
- Manage CAPA audit trail for regulatory compliance
- Report/Dashboard
  - Ability to track key CAPA metrics - % CAPA closed, % CAPA due



Quality Systems – Key Items

Discussion Topics

- QS Community solution?
- Core elements of your Quality Systems?
- Your CAPA process?
- How do you decide which issue kicks off a CAPA?
- Internal and External players in your CAPA process?
- How do you decide if a CAPA is effective?

STATISTICAL PROCESS CONTROL

STATISTICAL PROCESS CONTROL (SPC)

• Is the application of Statistical Methods to monitor and control a process to ensure that it operates at its full potential to produce conforming product.

OR

•Is an analytical decision making tool which allows you to see when a process is working correctly and when it is not.

• Variation is present in any process, deciding when the

HISTORY

•Was Pioneered By Walter .A. Shewhart In The Early 1920s.

•W. Edwards Deming Later Applied SPC Methods In The US During World war II, Successfully Improved Quality In Th Manufacture Of Munitions And Other Strategically Important Products.

•Deming introduced SPC Methods to Japanese Industry After Th War Had Ended.

•Concluded That While Every Process Displays Variation, Some Processes Display Controlled Variation That Is Natural To The Process (Common Causes Of Variation), While Others Display Uncontrolled Variation That Is Not Present In The Process Causal System At All Times (Special Causes Of Variation).

•In 1988, The Software Engineering Institute Introduced The Notion That SPC Can Be Usefully Applied To Non-manufacturing Processes

TRADITIONAL METHODS VS STATISTICAL PROCESS CONTROL

- The quality of the finished article was traditionally achieved through post-manufacturing inspection of the product; accepting or rejecting each article (or samples from a production lot) based on how well it met its design specifications

- SPC uses Statistical tools to observe the performance of the production process in order to predict significant deviations that may later result in rejected product.

TYPES OF VARIATION

Two kinds of variation occur in all manufacturing processes

1. Natural or Common Cause Variation
   consists of the variation inherent in the process as it is designed.
   may include variations in temperature, properties of raw materials, strength of an electrical current etc.

2. Special Cause Variation or Assignable-cause Variation

‘In Control’ and ‘Out Of Control’

❖**Process is said to be ‘in control’ and stable**

If common cause is the only type of variation that exists in the process

It is also predictable within set limits i.e. the probability o any future outcome falling within the limits can be stated approximately.

❖**Process is said to be ‘out of control’ and unstable**

Statistical process control -broadly broken down into 3 sets of activities

1. Understanding the process
2. Understanding the causes of variation
3. Elimination of the sources of special cause

Understanding the process

- Process is typically mapped out and the process is monitored using control charts.

Understanding the causes of variation

- Control charts are used to identify variation that may be due to special causes, and to free the user from concern over variatio due to common causes.

- It is a continuous, ongoing activity.

•When excessive variation is identified by the control chart detection rules, or the process capability is found lacking, additional effort is exerted to determine causes of that variance.

• The tools used include

- **Ishikawa diagrams**
- **Designed experiments**
- **Pareto charts**

•Designed experiments are critical -only means of objectively quantifying the relative importance of the many potential causes

Elimination of the sources of special cause variation

•Once the causes of variation have been quantified, effort is spent in eliminating those causes that are both statistically and practically significant.

•includes development of standard work, error-proofing and training.

•Additional process changes may be required to reduce variation or align the process with the desired target,

ADVANTAGES OF SPC

- Reduces waste

- Lead to a reduction in the time required to produce the product or service from end to end

due to a diminished likelihood that the final product will have to be reworked, identify bottlenecks, wait times, and other sources of delays within the process.

- A distinct advantage over other quality methods, such as inspection - its emphasis on early detection and prevention of problems

SPC CHARTS

- One method of identifying the type of variation present.

- Statistical Process Control (SPC) Charts are essentially:
  - ❖ Simple graphical tools that enable process performance monitoring.
  - ❖ Designed to identify which type of variation exists within the process.
  - ❖ Designed to highlight areas that may require further investigation.
  - ❖ Easy to construct and interpret.

•SPC charts can be applied to both dynamic processes and static processes.

Dynamic Processes

- A process that is observed across time is known as a dynamic process.
- An SPC chart for a dynamic process - 'time-series' or a 'longitudinal' SPC chart.

Static Processes

- A process that is observed at a particular point in time is known as a static process.

Control charts

- Show the variation in a measurement during the time period tha the process is observed.

- Monitor processes to show how the process is performing and how the process and capabilities are affected by changes to the process. This information is then used to make quality improvements.

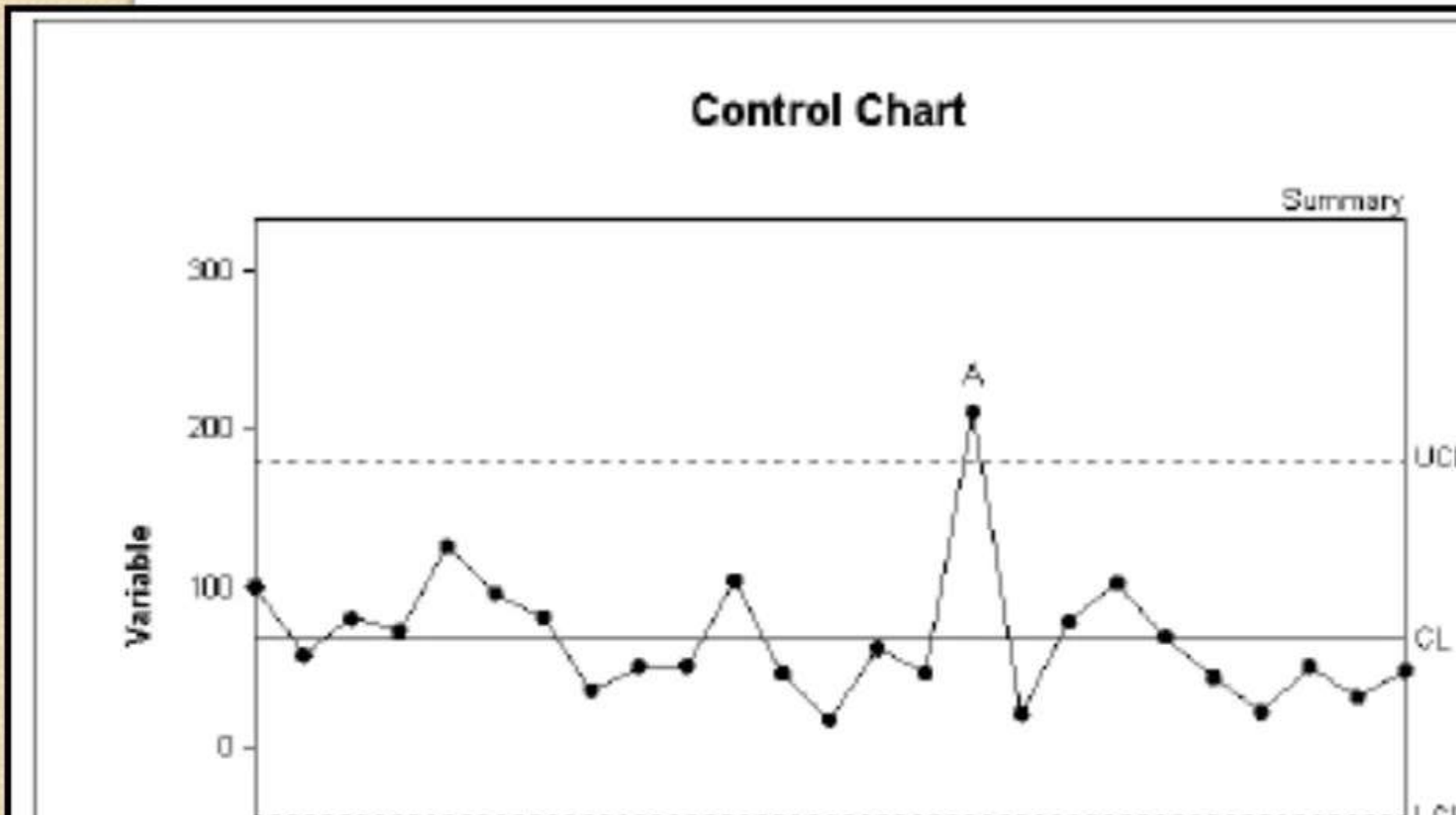
- A time ordered sequence of data, with a centre line calculated b the mean.

Control charts have four key features:

1) **Data Points:**
   Either averages of subgroup measurements or individual measurements plotted on the x/y axis and joined by a line. Tim is always on the x-axis.

2) **The Average or Center Line**
   The average or mean of the data points and is drawn across the middle section of the graph, usually as a heavy or solid line

3) **The Upper Control Limit (UCL)**
   Drawn above the centerline and annotated as "UCL". This is often called the "+ 3 sigma" line.


Control Chart
Summary
300
200
100
0
Variable
A
UCL
CL
LCL

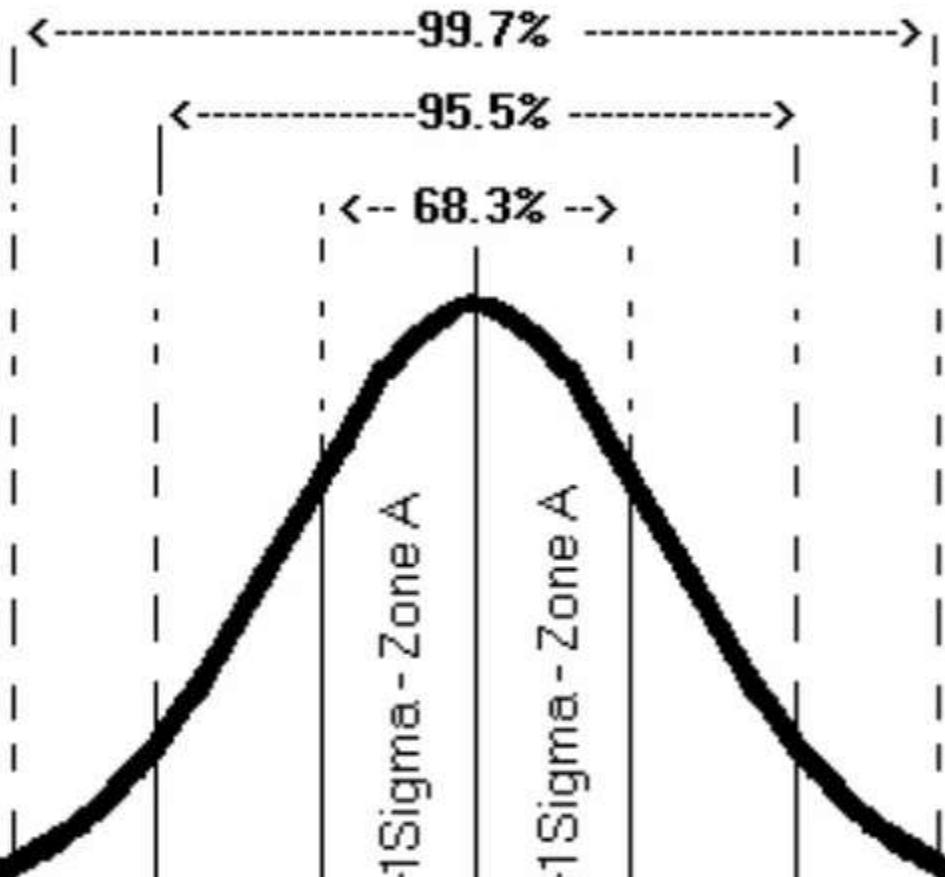
- Control limits define the zone where the observed data for a stable and consistent process occurs virtually all of the time (99.7%).

- Any fluctuations within these limits come from common causes inherent to the system, such as choice of equipment, scheduled maintenance or the precision of the operation that results from the design.

- An outcome beyond the control limits results from a *special cause.*

•The area between each control limit and the centerline is divided into thirds.

1) Zone A - "1-sigma zone“
2) Zone B - "2-sigma zone"
3) Zone C - " 3-sigma zone “

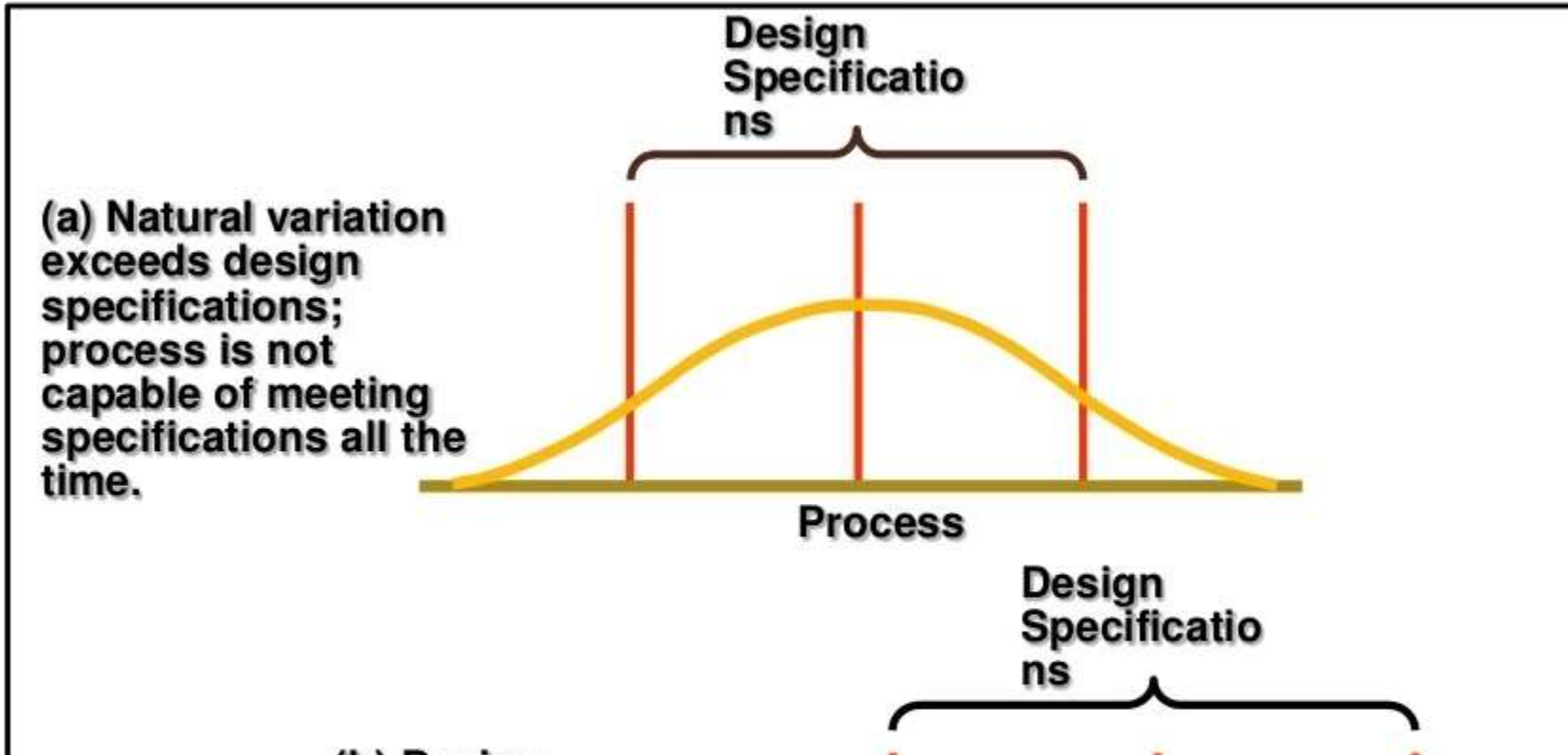

99.7%
95.5%
68.3%
+1Sigma - Zone A
-1Sigma - Zone A

PROCESS CAPABILITY ANALYSIS

- Examines
  - whether the process is capable of producing products which conform to specifications
  - range of natural variability in a process what we measure with contro charts

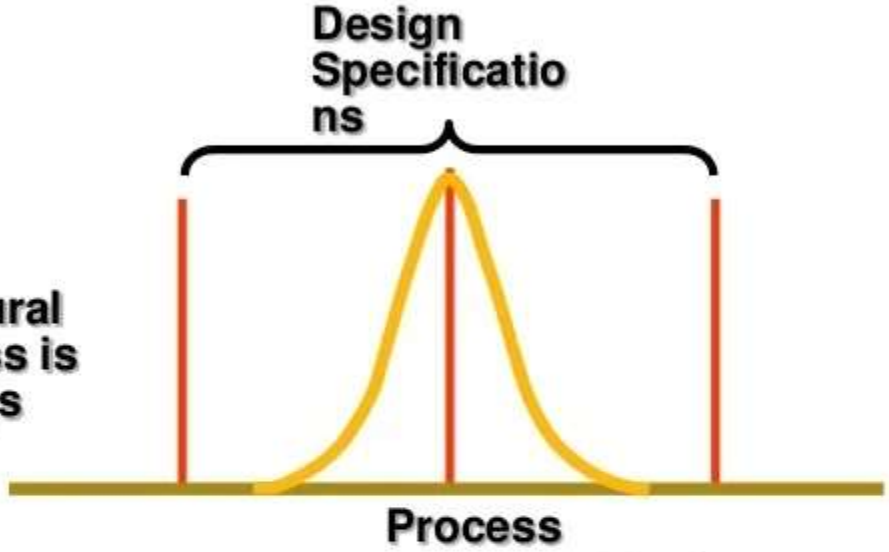
- Process capability studies distinguish between conformance to **control limits** and conformance to **specification limits** (also called **tolerance limits**)

Process Capability analysis cont.



Process Capability (cont.)

(c) Design specifications greater than natural variation; process is capable of always conforming to specifications.



THANK

TOTAL QUALITY MANAGEMENT

Contents

- Introduction.
- Concepts of tqm.
- Benefits of tqm.
- Characteristics of tqm.
- Key elements of tqm.
- Tqm in pharma industry.
- Advantages.
- Disadvantages

Introduction

Total - made up of the whole

Quality - degree of excellence a product or service provides

Management - act, art or manner of planning, controlling, directing,....

Therefore, TQM is the art of managing the whole to achieve excellence.

The concept of TQM

- Produce quality work the first time.
- Focus on the customer.
- Have a strategic approach to improvement.
- Improve continuously.

Various Definitions

- Total quality management (TQM) has been defined as a integrated organizational effort designed to improve quality a every level.

- The process to produce a perfect product by a series of measure require an organized effort by the entire company to prevent d eliminate errors at every stage in production is called tota quality management.

- According to international organization for standards define tqm as, "TQM is a management approach for an organizatio

Characteristics of TQM

- Committed management.
- Adopting and communicating about total quality management.
- Closer customer relations.
- Closer provider relations.
- Benchmarking.
- Increased training.
- Open organization
- Employee empowerment.

Traditional approach and TQM

Quality element	Previous state	TQM
Definition	Product-oriented	Customer-oriented
Priorities	Second to service and cost	First among equals of service and cost
Decisions	Short-term	Long-term
Emphasis	Detection	Prevention
Errors	Operations	System
Responsibility	Quality Control	Everyone
Problem solving	Managers	Teams

The three aspects of TQM

Counting	*Tools, techniques, and training in their use for analyzing, understanding, and solving quality problems*
Customers	*Quality for the customer as a driving force and central concern.*
Culture	*Shared values and beliefs,*

Principles of tqm

1. Produce quality work the first time and every time.

2. Focus on the customer.

3. Have a strategic approach to improvement.

4. Improve continuously.

5. Encourage mutual respect and teamwork

The key elements of the TQM

- Focus on the customer.
- Employee involvement
- Continuous improvement

Focus on the customer

- It is important to identify the organization's customers.
- External customers consume the organization's product or service.
- Internal customers are employees who receive the output of other employees.

Employee Involvement

- Since the quality is considered the job of all employee employees should be involved in quality initiatives.

- Front line employees are likely to have the closest contact wit external customers and thus can make the most valuabl contribution to quality.

- Therefore, employees must have the authority to innovate an

Continuous improvement

Continuous improvement

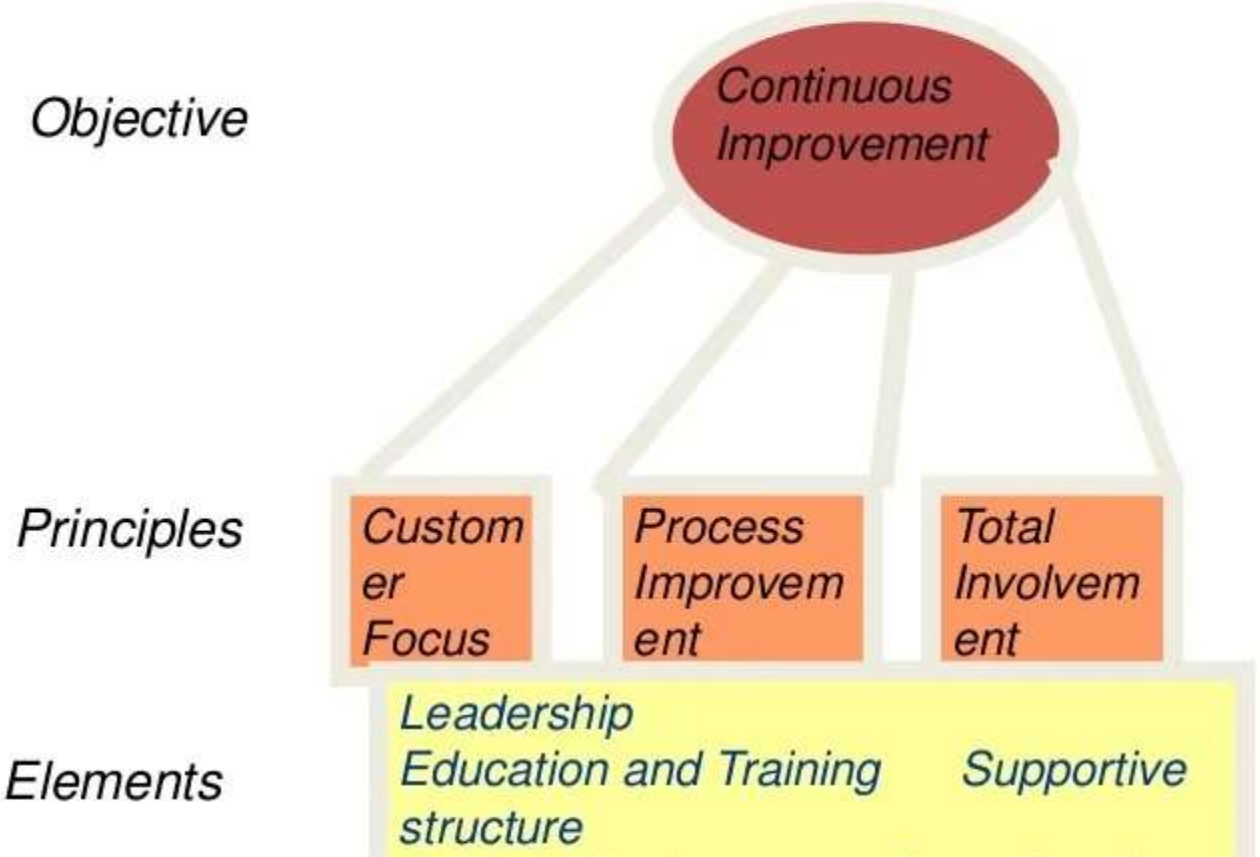
CONTINUOUS IMPROVEMENT

- The quest for quality is a never-ending process in which peop are continuously working to improve the performance, speed a number of features of the product or service.
- Continuous improvement means that small, incremen improvement that occurs on a regular basis will eventually add to vast improvement in quality.
- TQM is the management process used to make continuo improvements to all functions.
- TQM represents an ongoing, continuous commitment improvement.
- The foundation of total quality is a management philosophy th

Continuous Process Improvement.

- View all work as process – production and business.
- Process – purchasing, design, invoicing, etc.
- Inputs – process – outputs.
- Process improvement – increased customer satisfaction.
- Improvement – 5 ways:
- reduce resources, reduce errors, meet expectations of

THE TQM SYSTEM



BENEFITS OF TQM:

- Improved quality.
- Employee participation.
- Team work.
- Working relationships.
- Customer satisfaction.
- Employee satisfaction.
- Productivity.
- Communication.

Importance of TQM in pharma industry

Handling:

- Containers should be opened carefully and subsequently resealed in an approved manner.
- Highly sensitising material such as penicillins and cephalosporins should be handled in separate production areas.
- Highly active or toxic API (e.g. certain steroids, cytostatic substances) should be manufactured in a dedicated area and using dedicated equipment.
- Pure and final API should be handled in an environment

Storage:

- Secure storage facilities should be designated for use to prevent damage or deterioration of materials.
- These should be kept clean and tidy and subject to appropriate pest control measures.
- Environmental conditions should be recorded.
- The condition of stored material should be assessed at appropriate intervals.

Packaging:

- Labelling and packaging processes should be defined and controlled to ensure that correct packaging materials are used correctly and other specified requirements are met.
- Printed labels should be securely stored to avoid mix-ups arising.
- Marking and labelling should be legible and durable, provide sufficient information, for accurate identification and indicate, if appropriate, required storage conditions, retest and/or expiry date.

Facilities and equipment:

- The location, design, and construction of buildings should be suitable for the type and stage of manufacture involved, protecting the product from contamination (including cross-contamination) and protecting operators and the environment from the product.

- Equipment surfaces in contact with materials used in api manufacture should be non-reactive.

Sterile area

- Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should avoid activities which could compromise the quality of API.

- Smoking, eating, drinking, chewing and storage of food should be restricted to designated areas separated from production or control areas.

Labelling

- Each container should be identified by an appropriate label, showing at least the product identification and the assigned batch code, or any other easily understandable combination of both.

- . Containers for external distribution may require additional labels.

Computerised systems

- . Computer systems should be designed and operated to prevent unauthorised entries or changes to the programme.

- In the case of manual entry of quality critical data there should be a second independent check to verify accuracy of the initial entry.

- A back-up system should be provided of all quality critical data.

Advantages of tqm

- Improves reputation- faults and problems are spotted and sorted quicker.
- Higher employee morale- workers motivated by extra responsibility ,team work and involvement indecisions of tqm.
- Lower cost.

Disadvantages of tqm

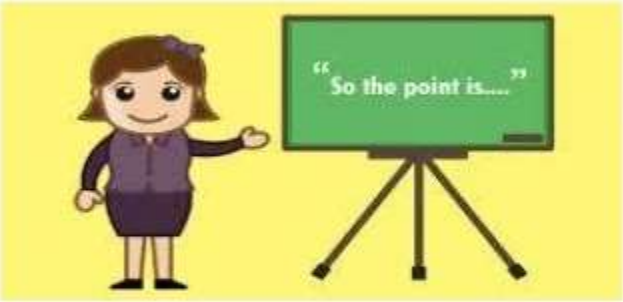
- Initial introduction cost.
- Benefits may not be seen for several years.
- Workers may be resistant to change.

A model for organization management.

Models of tqm

BENEFITS OF TOTAL QUALITY MANAGEMENT

- Financial benefits include lower costs, higher returns on sales a investment, and the ability to charge higher rather th competitive prices.
- Improved access to global markets, higher customer retenti levels, less
- Time required to develop new innovations, and a reputation a quality firm.
- Total quality management (tqm) is one such approach that see to improve quality and



CONCLUSION:

- TQM encourages participation amongst employees, managers ar organization as whole.
- Using Quality management reduces rework nearly to zero in an achievab goal .The responsibilities either its professional, social, legal one that rest wit the pharmaceutical manufacturer for the assurance of quality of product a tremendous and it can only be achieved by well organised.
- Work culture and complete engagement of the employees at the work place. should be realised that national & international regulations must b implemented systematically and process.
- Control should be practiced rigorously.
- Thus quality is critically important ingredient to organisational success toda

Reference:

- Text book of Total Quality Management by L.Suganthi and Anand A.Samuel,2nd edition,2005,page no.49-61.
- Total Quality Management by R.S Nagarajan, A.A.Arivalangar,new age international publishers,1st edition,2009,page no.21.
- www.slideshare.com/tqm in pharma industry.


Thank You

TQM TOOLS

INTRODUCTION

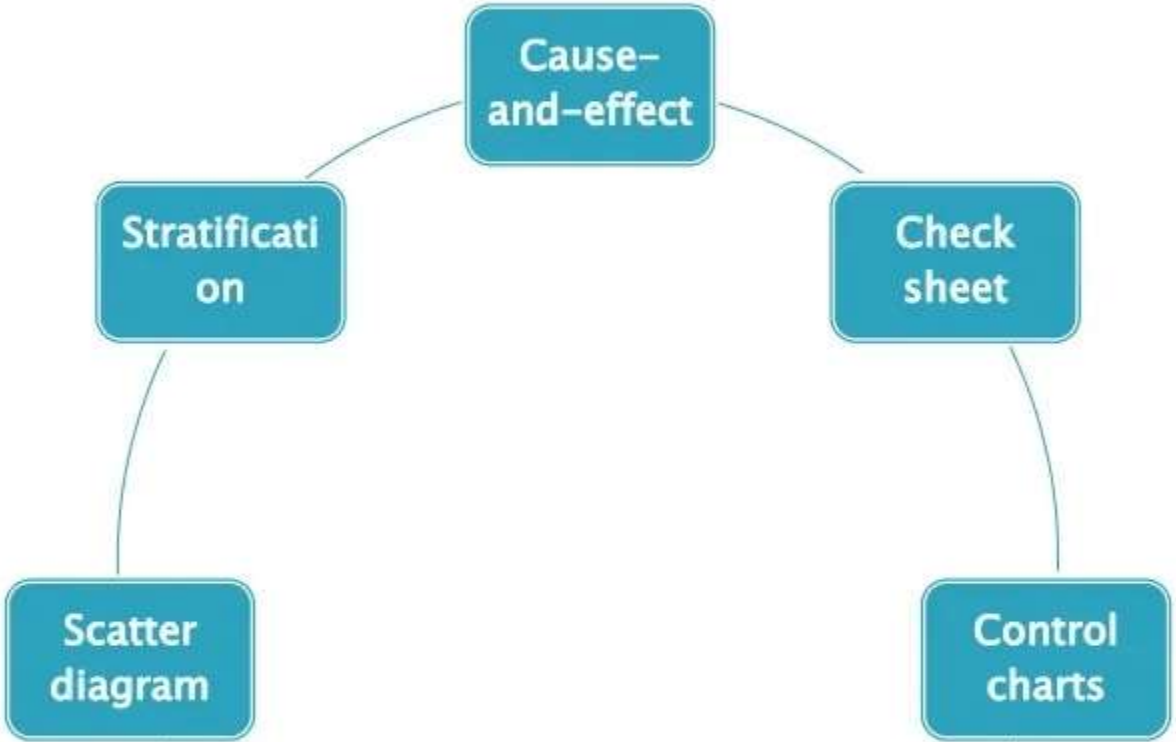
- Quality tool are more specific, tools which can be applied to solving problem in improving quality in organizations,manufacturing or even in individual processes.

- these seven basic tools of quality, first emphasized by "KAORU ISHIKAWA" a

WHY USE THE TOOLS

- Effective problem-solving is data driven. Data are impersonal; opinions are not.
- Experience is gained quickest by collecting and analyzing data.
- The tools provide common methods of analysis to help problem solving teams operate effectively.
- Operations problems – usually may be solved by these tools
  - **Note:** product – process design problems often require more advanced tools such as design of experiments.

7 BASIC QUALITY TOOLS



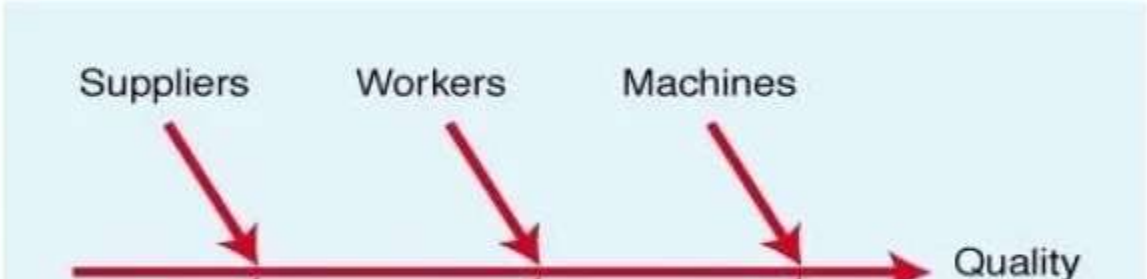
1.CAUSE AND EFFECT DIAGRAM

- It is also called Ishikawa or fishbone chart.
- Identifies many possible causes for an effector problem and sorts ideas into useful categories.
- A cause and effect diagram is “a fish-bone diagram that presents a systematic

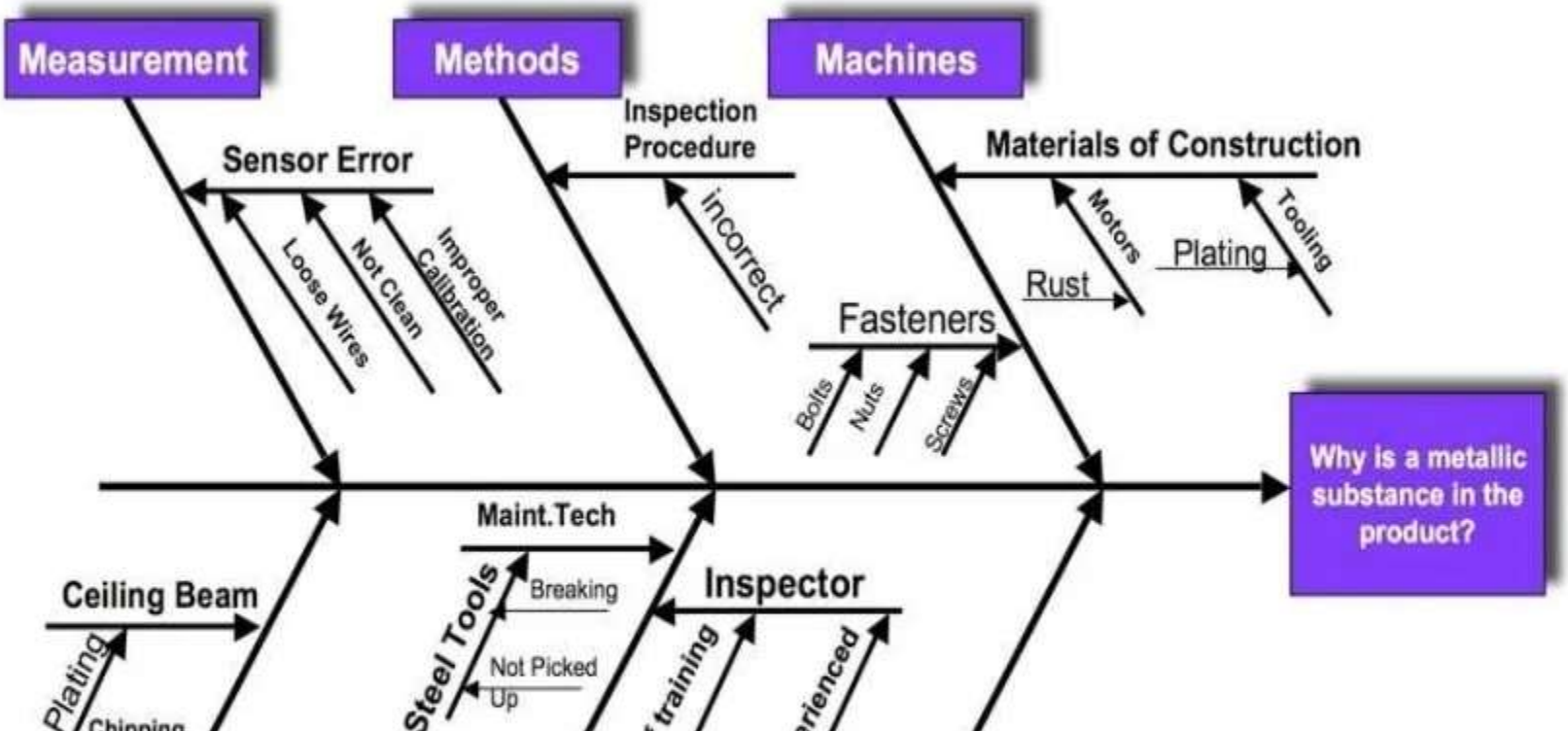
CAUSE AND EFFECT DIAGRAM

When To use

- When identifying possible causes for a problem.
- Especially when a team's thinking tends to fall into ruts.



CAUSE AND EFFECT DIAGRAM



2.CHECK SHEET

- A structured, prepared form for collecting and analyzing da a generic tool that can be adapted for a wide variety of purposes.
- A check sheet is “a sheet designed in advance to allow easy collection and aggregation of data.” By just entering check marks on a check sheet, data can be collected to extract necessary information, or a thorough inspection can be

CHECK SHEET

When To use

- When data can be observed and collected repeatedly by the same person or at the same location.
- When collecting data on the frequency or patterns of events, problems, defects, defect location, defect causes,

CHECK SHEET

- **A check sheet used to identify defects**

	／1	／2	／3	／4	／5	／8	／9	
	正	丅	正	丅	正	丅	丅	4 5
	下	一	下		丅	下	丅	2 4
		下		下	下	一	下	3 2

3.CONTROL CHARTS

- Graphs used to study how a process changes over time.
- A control chart is used to examine a process to see if it is stable or to maintain the stability of a process.
- There are two types of control charts: one used for managerial purposes and the other

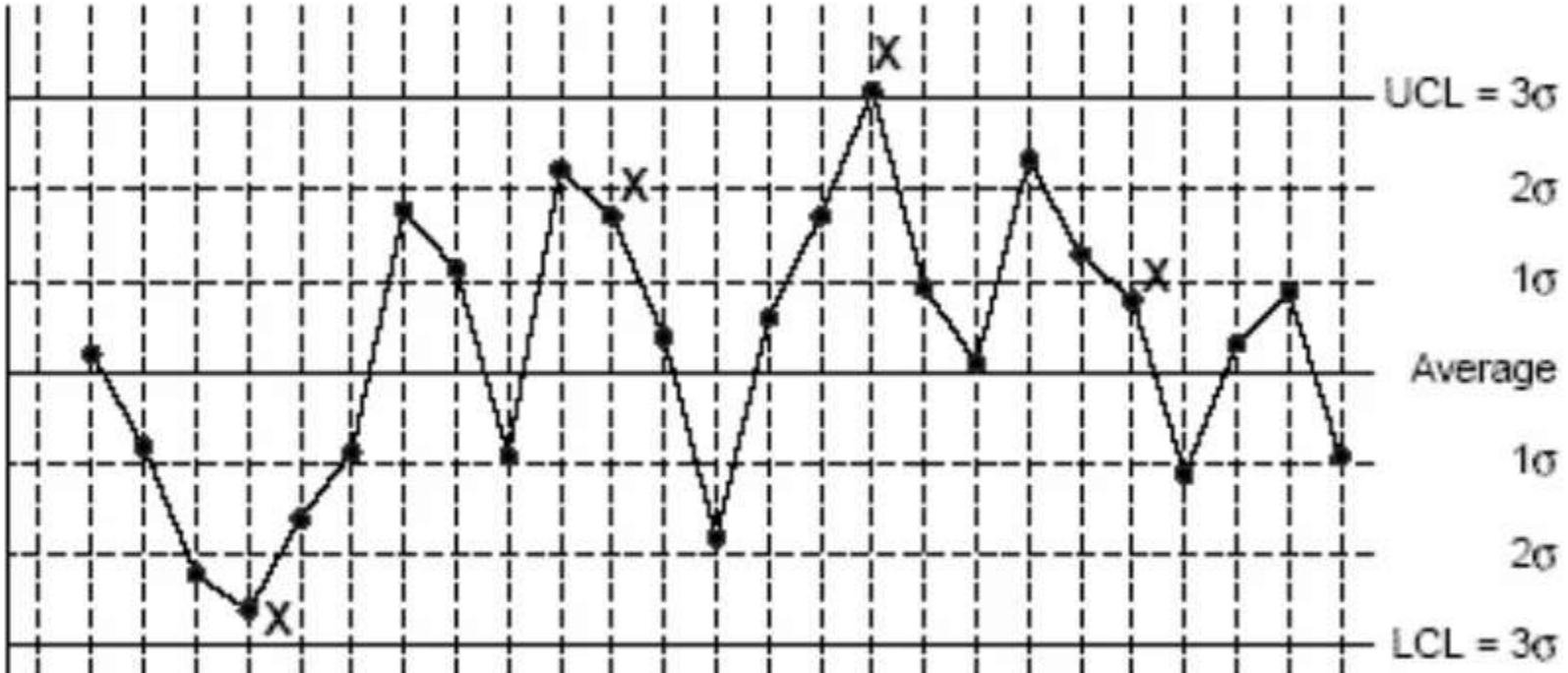
CONTROL CHARTS

- **Process variations can be one of two types:**
  - **Random variations** which are created by many minor factors.
  - **Assignable variations** whose main source can be identified and corrected.
- **There are four types of control charts:**
  - Control Charts for Variables. Variables are measured such as length of time a certain item is out of stock. Control charts can be:
    - **Mean Control Charts** (central tendency of process)
    - **Range Control Charts** (variability of process)
- Control Charts for Attributes. Attributes are counted such as number of service calls and number of returns on an item

CONTROL CHARTS

- **When To use**
  - When controlling ongoing processes by finding and correcting problems as they occur.
  - When predicting the expected range of outcomes from a process.
  - When determining whether a process is stable (in statistical control).
  - When analyzing patterns of process variation from special causes (non-routine events)
    or common causes (built into the process).

CONTROL CHARTS



4.HISTOGRAM

Description

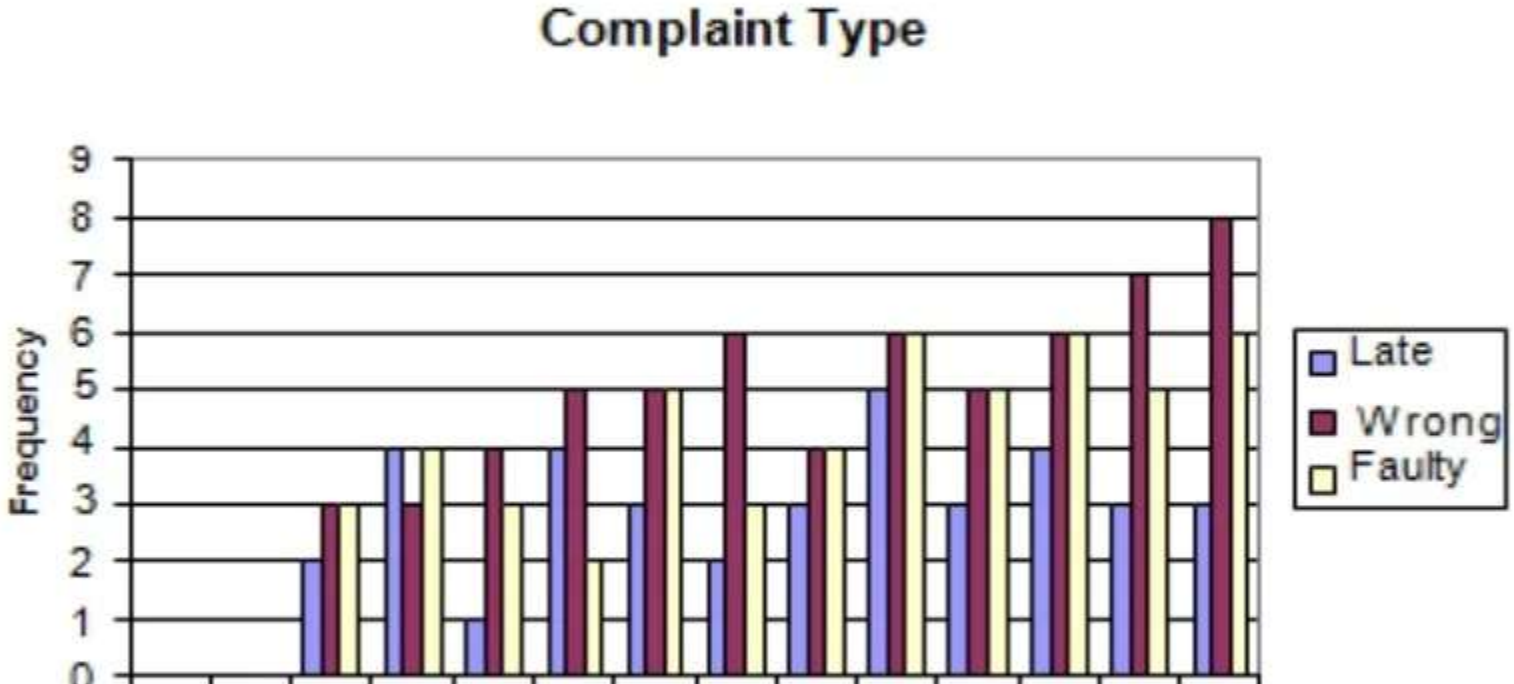
- A frequency distribution shows how often each different value in a set of data occurs. A histogram is the most commonly used graph to show frequency distributions. It looks very much like a bar chart, but there are important differences between them.

HISTOGRAM

When to Use

- When the data are numerical.
- When you want to see the shape of the data's distribution, especially when determining whether the output of a process is distributed approximately normally.
- When analyzing whether a process can meet the customer's requirements.
- When analyzing what the output from a supplier's process looks like.
- When seeing whether a process change has occurred from one time period to another.

HISTOGRAM



5.PARETO CHART

Description

- A Pareto chart is a bar graph. The lengths of the bars represent frequency or cost (time or money), and are arranged with longest bars on the left and the shortest to the right. In this way the chart visually depicts which situations are more significant.

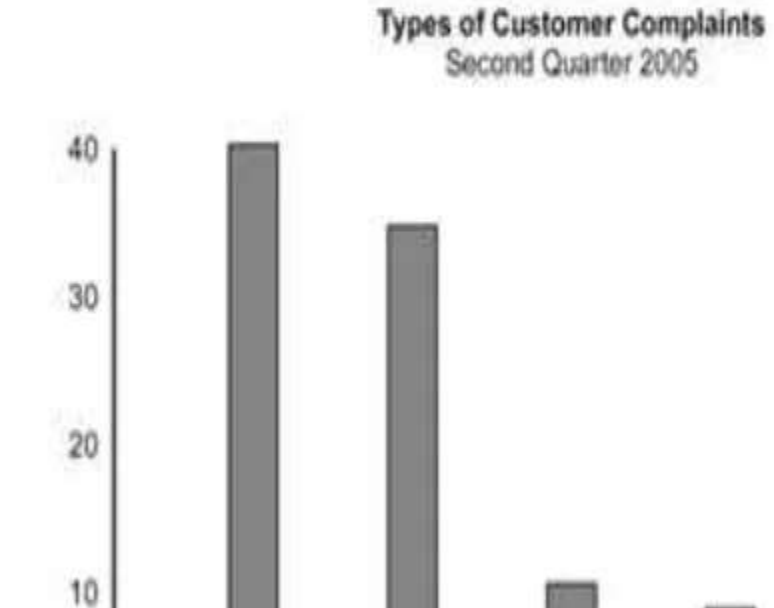
Often called the 80-20 Rule

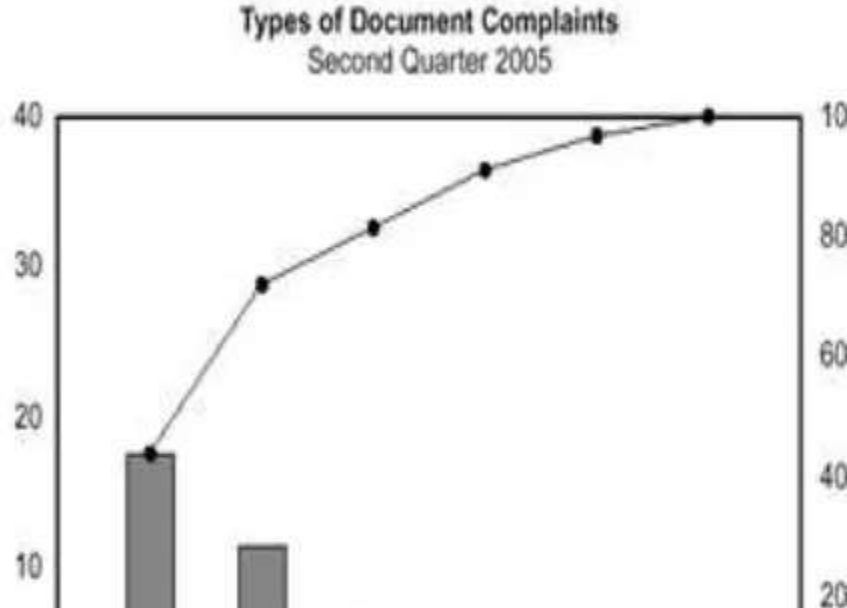
- Principle is that quality problems are the result of only a few problems e.g. 80% of the problems caused by 20% of causes

PARETO CHART

- **When to Use**
  - When analyzing data about the frequency of problems or causes in a process.
  - When there are many problems or causes and you want to focus on the most significant.
  - When analyzing broad causes by looking at their specific components.

PARETO CHART





6.SCATTER DIAGRAM

Description

- The scatter diagram graphs pairs of numerical data, with on variable on each axis, to look for a relationship between them If the variables are correlated, the points will fall along a line c curve. The better the correlation, the tighter the points will hu the line.

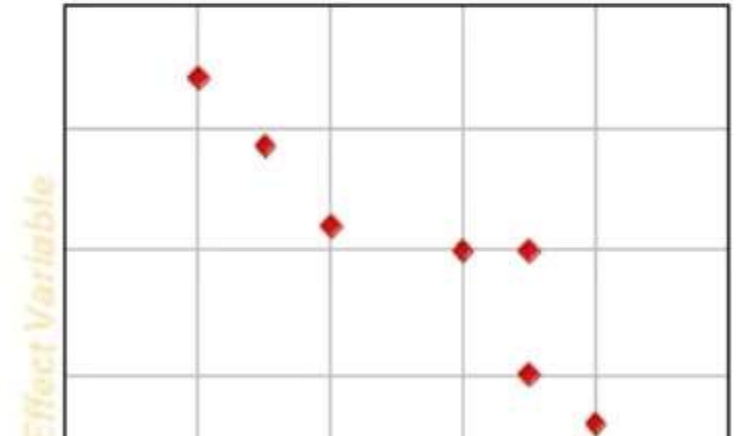
SCATTER DIAGRAM

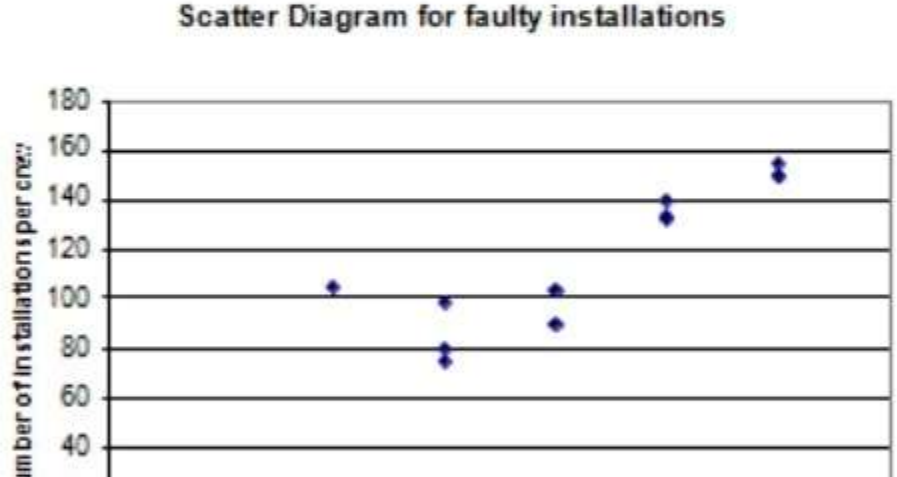
When to Use

- When you have paired numerical data.
- When your dependent variable may have multiple values for each value of your independent variable.
- When trying to determine whether the two variables are related, such as…
  - When trying to identify potential root causes of problems.
  - After brainstorming causes and effects using a fishbone diagram, to determine objectively whether a particular cause and effect are related.

SCATTER DIAGRAM

- A graphical tool to check if two relationships exist between two variables.

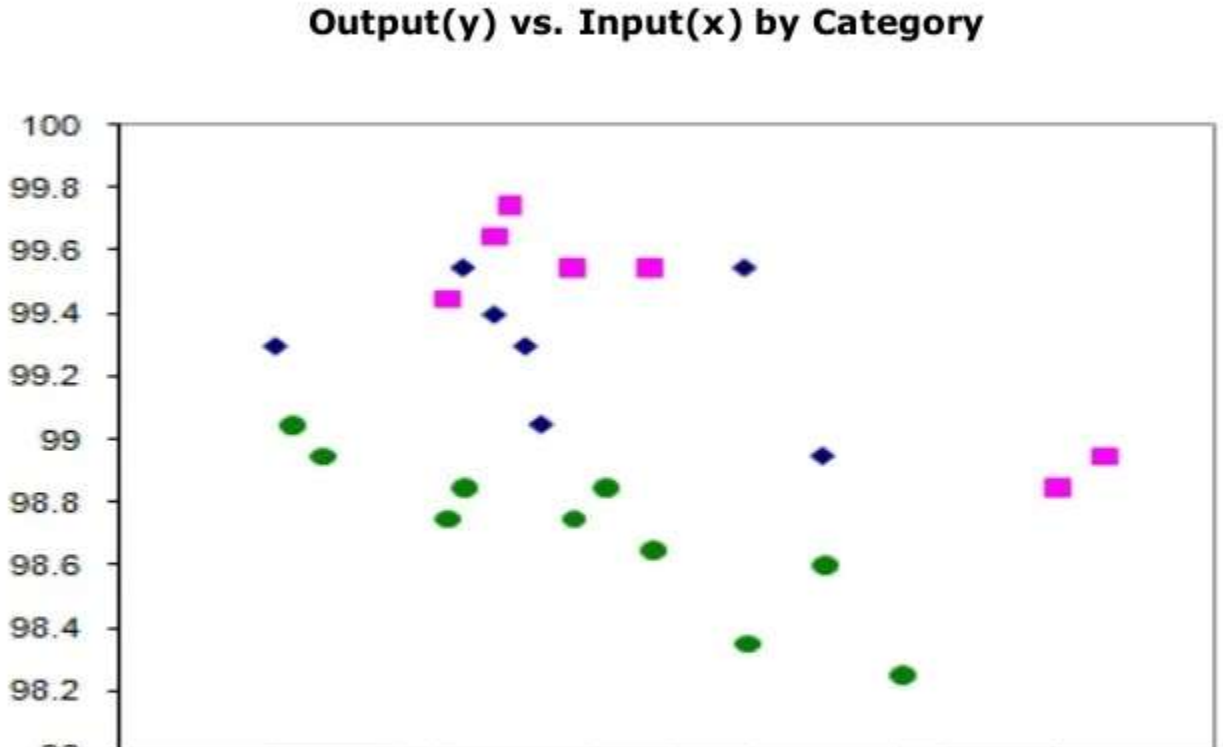




7.STRATIFICATION

- **Description**
  - Stratification is a technique used in combination with other data analysis tools. When data from a variety of sources or categories have been lumped together, the meaning of the data can be impossible to see. This technique separates the data so that patterns can be seen.
- **When to Use**
  - Before collecting data.
  - When data come from several sources or conditions, such as shifts, days of the week, suppliers or population

STRATIFICATION



Thank you