Review Article

Review on Implementing Quality Management Tools in Pharmaceutical Industry

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ABSTRACT

In modern days the pharmaceutical industries and processors have begun to implement the new tools in the quality processing tools which would nailing down the effluents and increases the better drugs in the process and new efficiencies. There are number of the quality tools which would help to meet the GMP certifications and ISO standards of ICH Q-7 & Q-10.The concept of the quality process tools which will aim on the prevention of the defects rather than identification of the defects in the process.

Keywords: GMP certifications, quality management tools, ICH Q-7 & Q-10.

INTRODUCTION[1]

In the world now a days all the pharmaceutical manufacturing Industries are under increasingly diverse and mounting pressures due to more sophisticated markets, changing customer choice and global competition. The pharmaceutical market for products is becoming increasingly national and international (Dangayachand Deshmukh, 2003). They must have to understand the new changes, innovative ideas, method and technologies in the competitive environment are unfolding. Industries should actively look for opportunities to exploit their strategic abilities, adapt and seek improvements in every area of the business, building on awareness and understanding of current strategies and successes (Papulova & Papulova, 2006).Accordingly, measures of modern quality management tools aiming for sustainable success do not only mean to avoid the delivery of defective products to the customer but seek to establish maximum efficiency in the performance of all processes of the company. With such optimized procedures, products of high quality can be provided with minimum effort of time and costs (Werner & Weckenmann, 2012). Quality management process have many names for these seven basic tools of quality, first emphasized by Kaoru Ishikawa, a professor of engineering at Tokyo University and the father of “quality circles.” To achieve a positive ranking and thus assure a high level of perceived quality, the company has to find a suitable position in the triangle of conflicting requirements on quality, costs and time (W. Geiger, 1994). No particular tool is mandatory; any one may be helpful, depending on circumstances. A number of software programs are available as aids to the application of some of these tools. Kaoru Ishikawa contends that 95% of a company's problems can be solved using these seven tools. The tools are designed for simplicity. Only one, control charts require any significant training. The Basic Seven Tools made statistical analysis less complicated for the average person• Good Visual Aids make statistical and quality control more comprehendible.

QUALITY MANAGEMENT TOOLS

A Quality management System (QMS) is defined as a set of interrelated or interacting elements such as policies, objectives, procedures, processes, and resources that are established individually or collectively to guide an organization.

The concept of quality management

It is applied in business of all sizes and all types. It is a relevant in manufacturing as it is in health care or food services. Of course, quality means different things for different industries, and takes

a different meaning depending on whether a product, a service, or a combination of both is offered. The core of quality management is being able to guide your business towards improved performance. There are three main components to quality management: quality assurance, quality control, and quality improvement. But it's not just about the condition of the products you sell or the caliber of services your business offers but the processes to achieve consistent quality. This guide highlights 10 tools that can help you to setup a management strategy to improve quality and documents you can use to track improvement. Many organizations use quality tools to help monitor and manage their quality initiatives. There are several types of tools that can be used. However, there are seven management tools for quality control that are the most common. Different tools are used for different problem solving opportunities and many of the tools can be used in different ways. The trick is to become familiar and comfortable with all of these quality tools so you can pull the appropriate one out of the toolbox when there is a problem solving need. otal quality management (QUALITY MANAGEMENT) tools help organizations to identify, analyze and assess qualitative and quantitative data that is relevant to their business. These tools can identify procedures, ideas, statistics, cause and effect concerns and other issues relevant to their organizations. Each of which can be examined and used to enhance the effectiveness, efficiency, standardization and overall quality of procedures, products or work environment, in accordance with ISO 9000 standards (SQ, 2004). According to Quality America, Inc. the number of QUALITY MANAGEMENT tools is close to 100 and come in various forms, such as brainstorming, focus groups, check lists, charts and graphs, diagrams and other analysis tools. In a different vein, manuals and standards are QUALITY MANAGEMENT tools as well, as they give direction and best practice guidelines to you and/or your staff. QUALITY MANAGEMENT tools illustrate and aid in the assimilation of complicated information such as:

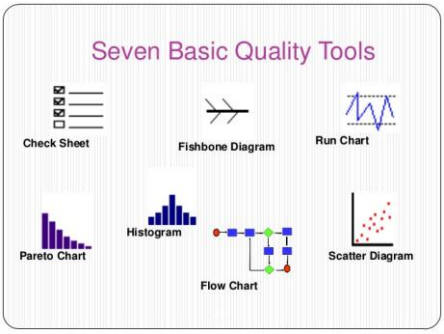

Fig. 1

1. Identification of your target audience
2. Assessment of customer needs
3. Competition analysis
4. Market analysis
5. Brainstorming ideas
6. Productivity changes
7. Various statistics
8. Staff duties and work flow analysis
9. Statement of purpose
10. Financial analysis
11. Model creation
12. Business structure
13. Logistic analysis

The list goes on, though essentially QUALITY MANAGEMENT tools can be used in any situation, for any number of reasons, and can be extremely effective if used properly.

Quality management Tools[2]

The following are some of the most common QUALITY MANAGEMENT tools in use today. Each is used for, and identifies, specific information in a specific manner. It should be noted that tools should be used in conjunction with other tools to understand the full scope of the issue being analyzed or illustrated. Simply using one tool may inhibit your understanding of the data provided, or may close you off to further possibilities.

Pie Charts and Bar Graphs

Used to identify and compare data units as they relate to one issue or the whole, such as budgets, vault space available, extent of funds, etc.

2) Histograms

To illustrate and examine various data element in order to make decisions regarding them Effective when comparing statistical, survey, or questionnaire results.

3) **Run Chart**
Follows a process over a specific period of time, such as accrual rates, to track high and low points in its run, and ultimately identify trends, shifts and patterns.

a) **Pareto Charts / Analysis** Rates issues according to importance and frequency by prioritizing specific problems or causes in a manner that facilitates problem solving. Identify groupings of qualitative data, such as most frequent complaint, most commonly purchased preservation aid, etc. in order to measure which have priority.· Can be scheduled over select periods of time to track changes. They can also be created in retrospect, as a before and after analysis of a process change.

4) **Force Field Analysis**
To identify driving and restraining forces occurring in a chosen process in order to understand why that particular process functions as it does. For example, identifying the driving and restraining forces of catering predominantly to genealogists. To identify restraining forces that need to be eradicated, or driving forces that need to be improved, in order to function at a higher level of efficiency.

5) **Focus Groups**
Useful for marketing or advertising organizations to test products on the general public. Consist of various people from the general public who use and discuss your product, providing impartial feedback to help you determine whether your product needs improvement or if it should be introduced onto the market.

6) **Brainstorming and Affinity Diagrams**
Teams using creative thinking to identify various aspects surrounding an issue. An affinity diagram, which can be created using anything from enabling software to post-it notes organized on a wall, is a tool to organize brainstorming ideas

7) Tree Diagram
To identify the various tasks involved in, and the full scope of, a project. To identify hierarchies, whether of personnel, business structure, or priorities. To identify inputs and outputs of a project, procedure, process, etc.

8) Flowcharts and Modeling Diagrams
Assist in the definition and analysis of each step in a process by illustrating it in a clear and comprehensive manner. Identify areas where workflow may be blocked, or diverted, and where workflow is fluid. Identify where steps need to be added or removed to improve efficiency and create standardized workflow.

9) Scatter Diagram
To illustrate and validate hunches· to discover cause and effect relationships, as well as bonds and correlations, between two variables to chart the positive and negative direction of relationships.

10) Relations Diagram
To understand the relationships between various factors, issues, events, etc. so as to understand their importance in the overall organizational view.

11) PDCA
The Plan-Do-Check-Act style of management where each project or procedure is planned according to needs and outcome, it is then tested, examined for efficiency and effectiveness, and then acted upon if anything in the process needs to be altered.· This is a cyclical style to be iterated until the process is perfected. All of these QUALITY MANAGEMENT tools can be easily created and examined by using various types of computer software or by simply mapping them out on paper. They can also be easily integrated into team meetings, organizational newsletters, marketing reports, and for various other data analysis needs. Proper integration and use of these tools will ultimately assist in processing data such as identifying collecting policies, enhancing work flow such as mapping acquisition procedures, ensuring client satisfaction by surveying their needs and analyzing them accordingly, and creating an overall high level of quality in all areas of your organization.

The 7 Basic Quality Tools for Process Improvement[3]
“The Old Seven.”
“The First Seven.”
“The Basic Seven.”
Quality pros have many names for these seven basic tools of quality, first emphasized by Kaoru Ishikawa, a professor of engineering at Tokyo University and the father of “quality circles.”
Start your quality journey by mastering these tools, and you'll have a name for them too: "indispensable."

1. CAUSE AND EFFECT DIAGRAMS

Understanding the contributing factors or **causes** of a system failure can help develop actions that sustain the correction. A **cause and effect diagram**, often **called** a "**fishbone**" **diagram**, can help in brainstorming to identify possible **causes** of a problem and in sorting ideas into useful categories.

The cause & effect diagram is the brainchild of Kaoru Ishikawa, who pioneered quality management processes in the Kawasaki shipyards, and in the process became one of the founding fathers of modern management. The cause and effect diagram is used to explore all the potential or real causes (or inputs) that result in a single effect (or output). Causes are arranged according to their level of importance or detail, resulting in a depiction of relationships and hierarchy of events. This can help you search for root causes, identify areas where there may be problems, and compare the relative importance of different causes.

Causes in a cause & effect diagram are frequently arranged into four major categories. While these categories can be anything, you will often see:

- Manpower, methods, materials, and machinery (recommended for manufacturing)
- Equipment, policies, procedures, and people (recommended for administration and service).

These guidelines can be helpful but should not be used if they limit the diagram or are inappropriate. The categories you use should suit your needs. At SkyMark, we often create the branches of the cause and effect tree from the titles of the affinity sets in a preceding affinity diagram.

The C&E diagram is also known as the fishbone diagram because it was drawn to resemble the skeleton of a fish, with the main causal categories drawn as "bones" attached to the spine of the fish, as shown below.

2. Fishbone diagram

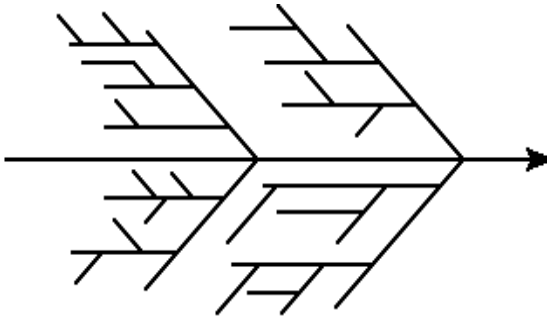

Fig. 2: Ishikawa or Fishbone diagram

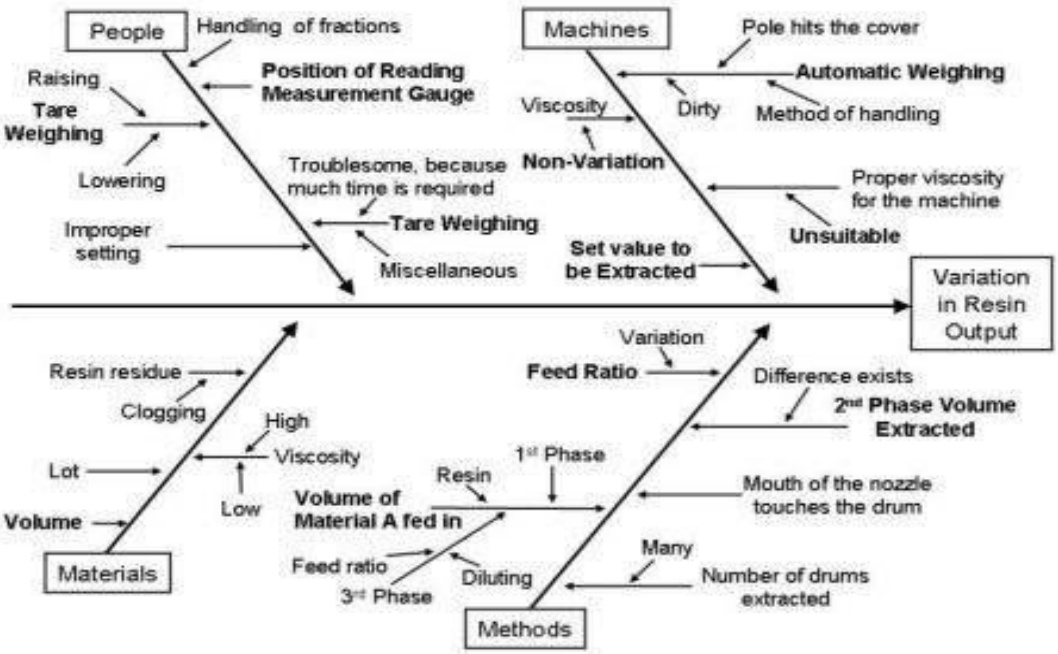

Fig. 3

Cause & effect diagrams can also be drawn as tree diagrams, resembling a tree turned on its side. From a single outcome or trunk, branches extend that represent major categories of inputs or causes that create that single outcome. These large branches then lead to smaller and smaller branches of causes all the way down to twigs at the ends. The tree structure has an advantage over the fishbone-style diagram. As a fishbone diagram becomes more and more complex, it becomes difficult to find and compare items that are the same distance from the effect because they are dispersed over the diagram. With the tree structure, all items on the same causal level are aligned vertically.

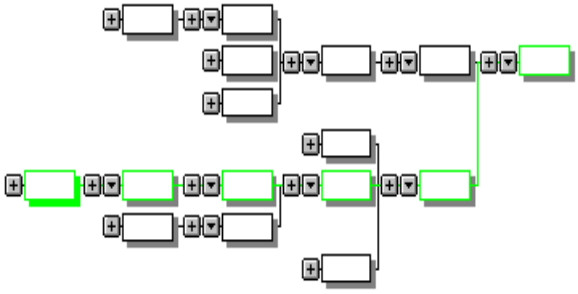

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Fig. 4: Tree structure of fishbone-style diagram

To successfully build a cause and effect diagram:

1. Be sure everyone agrees on the effect or problem statement before beginning.
2. Be succinct.
3. For each node, think what could be its causes. Add them to the tree.
4. Pursue each line of causality back to its root cause.
5. Consider grafting relatively empty branches onto others.
6. Consider splitting up overcrowded branches.
7. Consider which root causes are most likely to merit further investigation

Steps for Using the Tool

Following are the steps that can be followed to successfully draw a cause and effect diagram:

Step 1 - Properly identify the problem in hand

Start articulating the exact problem you are facing. Sometimes, identification of the problem may not be straightforward. In such instances, write down all the effects and observations in detail. A short brainstorming session may be able to point out t the actual problem.

When it comes to properly identifying the problem, there are four properties to consider; who are involved, what the problem is, when it occurs, and where it occurs. Write down the problem in a box, which is located at the left hand corner (refer the example cause and effect diagram). From the box, draw a line horizontally to the right hand side. The arrangement will now look like the head and the spine of a fish.

Step 2 - Add the major factors that contribute to the problem

In this step, the main factors of the problem are identified. For each factor, draw off a line from the fish's spine and properly label it. These factors can be various things such as people, material, machinery or external influences. Think more and add as many as factors into the cause and effect diagram. Brainstorming becomes quite useful in this phase, as people can look at the problem in different angles and identify different contributing factors. The factors you added now become the bones of the fish.

Step 3 - Identify the causes

Take one factor at a time when identifying possible causes. Brainstorm and try to identify all causes that apply to each factor. Add these causes horizontally off from the fish bones and label them. If the cause is large in size or complex in nature, you can further breakdown and add them as sub causes to the main cause. These sub causes should come off from the relevant cause lines.

Spend more time in this step; the collection of causes should be comprehensive.Step 4 - Diagram analysis

When this step starts, you have a diagram that indicates the problem, the contributing factors, and all possible causes for the problem.

Depending on the brainstorming ideas and nature of the problem, you can now prioritize the causes and look for the most likely cause.

This analysis may lead to further activities such as investigations, interviews and surveys. Refer the following sample cause and effect diagram:

Use of cause and effect diagrams

When it comes to the use of cause and effect diagrams, brainstorming is a critical step. Without proper brainstorming, a fruitful cause and effect diagram cannot be derived.

Therefore, following considerations should be addressed in the process of deriving a cause and effect diagram:

- There should be a problem statement that describes the problem accurately. Everyone in the brainstorming session should agree on the problem statement.
- Need to be succinct in the process.
- For each node, think all the possible causes and add them into the tree.
- Connect each casualty line back to its root cause.
- Connect relatively empty branches to others.
- If a branch is too bulky, consider splitting it in two.

3. CHECK SHEET

Check sheets are special types of forms for data collection. They make it easier to collect data, they tend to make the data collection effort more accurate, and they automatically produce some sort of data summarization which is often very effective for a quick analysis. The form of the check sheet is individualized for each situation. The differences between the actual and the intended process are often surprising and provide many ideas for improvements. Figure 3 shows the flow chart for a hypothetical technical report review process. Measurements could be taken at each step to find the most significant causes of delays, these may then be flagged for improvement.

A flowchart can also be used to define a process or project to be implemented. Such a diagram is useful because:

- it spells out clearly the steps that have to be implemented
- it provides the basis for identifying potential problems
- responsibilities for different parts of the process can be clearly defined.

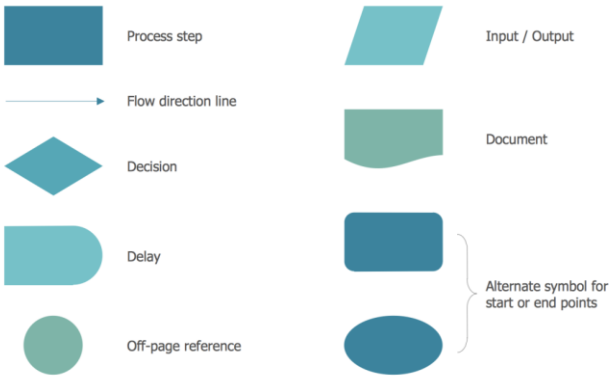

Fig. 5: Pictograms of flow chart

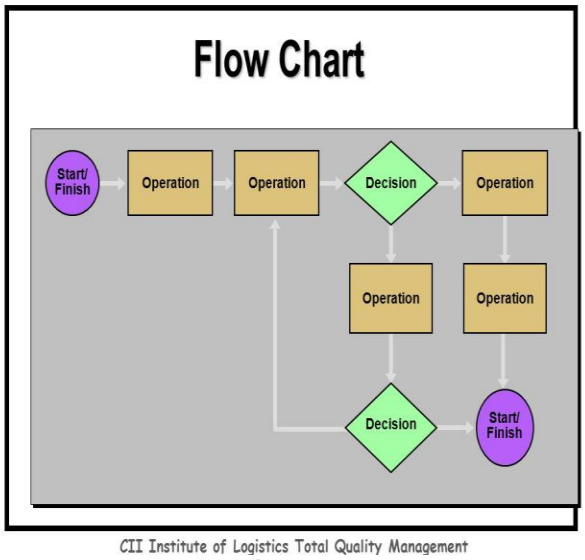

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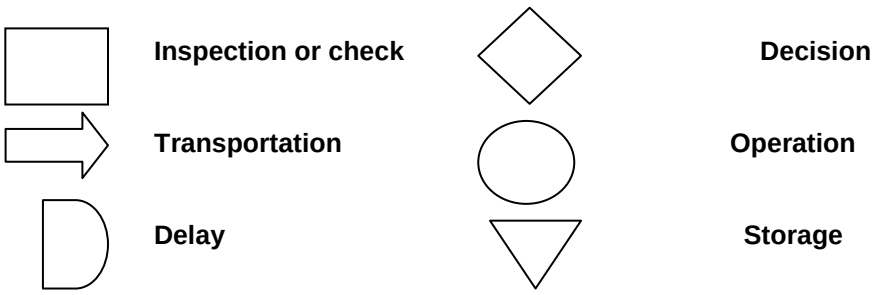
Fig. 6

ANOTHER SET OF FLOW CARTING SYMBOLS



The check sheet is a simple document that is used for collecting data in real-time and at the location where the data is generated. The document is typically a blank form that is designed for the quick, easy, and efficient recording of the desired information, which can be either quantitative or qualitative. When the information is quantitative, the check sheet is sometimes called a tally sheet.

A defining characteristic of a check sheet is that data is recorded by making marks ("checks") on it. A typical check sheet is divided into regions, and marks made in different regions have different significance. Data is read by observing the location and number of marks on the sheet.

5 Basic types of Check Sheets:

- Classification: A trait such as a defect or failure mode must be classified into a category.
- Location: The physical location of a trait is indicated on a picture of a part or item being evaluated.
- Frequency: The presence or absence of a trait or combination of traits is indicated. Also number of occurrences of a trait on a part can be indicated.
- Measurement Scale: A measurement scale is divided into intervals, and measurements are indicated by checking an appropriate interval.
- Check List: The items to be performed for a task are listed so that, as each is accomplished, it can be indicated as having been completed.

4. PARETO CHART

The **Pareto chart** is one of the seven basic **tools** of **quality control**. The independent variables on the **chart** are shown on the horizontal axis and the dependent variables are portrayed as the heights of bars. A point-to-point **graph**, which shows the cumulative relative frequency, may be superimposed on the bar **graph.**

A Pareto chart, also called a Pareto distribution diagram, is a vertical bar graph in which values are plotted in decreasing order of relative frequency from left to right. Pareto charts are extremely useful for analyzing what problems need attention first because the taller bars on the chart, which represent frequency, clearly illustrate which variables have the greatest cumulative effect on a given system.

When to Use a Pareto Chart

- 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.
- When communicating with others about your data.

There are two types of the charts available

1. Weighted Pareto chart,
2. Comparative Pareto charts

The Pareto chart provides a graphic depiction of the Pareto principle, a theory maintaining that 80% of the output in a given situation or system is produced by 20% of the input. The Pareto chart is one of the seven basic tools of quality control. The independent variables on the chart are shown on the horizontal axis and the dependent variables are portrayed as the heights of bars. A point-to-point graph, which shows the cumulative relative frequency, may be superimposed on the bar graph. Because the values of the statistical variables are placed in order of relative frequency, the graph clearly reveals which factors have the greatest impact and where attention is likely to yield the greatest benefit.

A Simple Example

A Pareto chart can be used to quickly identify what business issues need attention. By using hard data instead of intuition, there can be no question about what problems are influencing the outcome most. In the example below, XYZ Clothing Store was seeing a steady decline in business. Before the manager did a customer survey, he assumed the decline was due to customer dissatisfaction with the clothing line he was selling and he blamed his supply chain for his problems. After charting the frequency of the answers in his customer survey, however, it was very clear that the real reasons for the decline of his business had nothing to do with his supply chain. By collecting data and displaying it in a Pareto chart, the manager could see which variables were having the most influence. In this example, parking difficulties, rude sales people and poor lighting were hurting his business most. Following the Pareto Principle, those are the areas where he should focus his attention to build his business back up.

Fig. 7: Pareto chart

5. Histogram

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.

When to Use a Histogram

- 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.
- When determining whether the outputs of two or more processes are different.
- When you wish to communicate the distribution of data quickly and easily to others.

6. Scatter Diagram

Also called: scatter plot, X–Y graph

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

When to Use a Scatter Diagram

- 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.
- When determining whether two effects that appear to be related both occur with the same cause.
- When testing for autocorrelation before constructing a control chart.

Benefits:

- Helps identify and test probable causes.
- By knowing which elements of your process are related and how they are related, you will know what to control or what to vary to affect a quality characteristic.

7. CONTROL CHARTS

Check Sheets and Check Lists are the final major QUALITY MANAGEMENT tools. Check Sheets are forms that gather data and allow users to easily analyze and interpret that data. The Check Sheet, however, is only meant to gather one type of data at a time so these are really only good for data that's going to repeat often.

Check Lists, on the other hand, are meant to deal with a specific problem. These allow managers to check and see if all necessary steps have been done. While Check Lists are similar to Check Sheets, they are used to assist with the process operations and not the gathering of data.

Control charts are used to routinely monitor quality. Depending on the number of process characteristics to be monitored, there are two basic types of control charts. The first, referred to as a univariate control chart, is a graphical display (chart) of one quality characteristic. The second, referred to as a multivariate control chart, is a graphical display of a statistic that summarizes or represents more than one quality characteristic.

In general, the chart contains a center line that represents the mean value for the in-control process. Two other horizontal lines, called the

upper control limit (*UCL*) and the lower control limit (*LCL*), are also shown on the chart. These control limits are chosen so that almost all of the data points will fall within these limits as long as the process remains in-control.

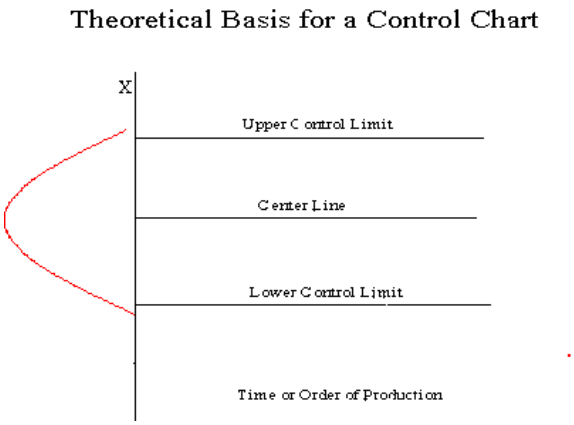


Fig. 8: CONTROL CHART

Types of control charts
• Control Charts for Attributes
– P-chart (fraction defective chart)
– np-chart (number of defectives chart)
– stabilized p-chart
– C-chart (chart for number of defects)
– U-chart (chart for number of defects per unit).

CONCLUSION

The responsibilities of the pharmaceutical manufacturers and industries to attain the quality management and implement the quality management tools to ensure the quality are tremendous. The standard professional bodies like GMP, ISO AND ICH will organized, adequately staffed accurately performed process and dosage form control before, during and after production that adequate quality assurance of the product can be achieved. To impart the product quality and safety they must be implement the quality tools in the pharmaceutical industries not only quality and but also for the safety is the major responsibility for the pharmaceutical products.

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