**QUALITY OF DOSAGE FORM**

**Statistical methods of quality control:**

Statistical quality control (SQC) refers to the use of statistical methods in the monitoring and maintaining of the quality of products and services. Statistica1 quality control is the term used to describe the set of statistical tools used by quality professionals. Statistical quality control can be divided into three broad categories:

1. Descriptive Statistics
2. Statistical Process Control
3. Acceptance Sampling

**Descriptive statistics** are used to describe quality characteristics and relationships. This includes statistics such as the mean, standard deviation, the range, and a measure of the distribution of data.

**Statistical process control** (SPC) involves inspecting a random sample of the output from a process and deciding whether the process is producing products with characteristics that fall within a predetermined range. PC answers the question of whether the process is functioning properly or not.

**Acceptance sampling** is the process of randomly inspecting a sample of goods and deciding whether to accept the entire lot based on the results. Acceptance sampling determines whether a batch of goods should be accepted or rejected.

The tools in each of these categories provide different types of information for use in analyzing quality. Descriptive statistics are used to describe certain quality characteristics, such as the central tendency and variability of observed data. Although descriptions of certain characteristics are helpful, they are not enough to help us evaluate whether there is a problem with quality. Acceptance sampling can help us do this. Acceptance sampling helps us decide whether desirable quality has been achieved for a batch of products, and whether to accept or reject the items produced. Although this information is helpful in making the quality acceptance decision after the product has been produced, it does not help us identify and catch a quality problem during the production process. For this we need tools in the statistical process control (SPC) category.

All three of these statistical quality control categories are helpful in measuring and evaluating the quality of products or services. However, statistical process control (SPC) tools are used most frequently because they identify quality problems during the production process.

The quality control tools do not only measure the value of a quality characteristic, but they also help us identify a *change or variation* in some quality characteristic of the product or process.

Described first, are the **types of variation** observed when measuring quality followed by the **specific tools used for measuring this variation.**

**SOURCES OF VARIATION: COMMON AND ASSIGNABLE**

Variation in the production process leads to quality defects and lack of product consistency. Following are some causes of variation:

1. **Common, or random, causes of variation:** For example, bottles of a cough syrup in a chemist’s shop are not filled to exactly the same level. Some are filled slightly higher and some slightly lower. Similarly, no two tablets of the same strip weigh exactly the same. These types of differences are completely normal. No two products are exactly alike because of slight differences in materials, workers, machines, tools, and other factors. These are called common, or random, causes of variation.

Common causes of variation are based on random causes that we cannot identify. These types of variation are unavoidable and are due to slight differences in processing.

An important task in quality control is to find out the range of natural random variation in a process. For example, if the average bottle of a cough syrup contains 16 ounces of liquid, we may determine that the amount of natural variation is between 15. 8 to 16.2 ounce. If this were the case, we would monitor the production process to make sure that the amount stays within this range. If production goes out of this range—bottles are found to contain on average 15.6 ounce this would lead us to believe that there is a problem with the process because the variation is greater than the natural random variation.

1. **Assignable causes of variation:** The second type of variation that can be observed involves variations where the causes can be precisely identified and eliminated. These are called assignable causes of variation. Examples of this type of variation are poor quality in raw materials, an employee who needs more training, or a machine in need of repair. In each of these examples the problem can be identified and corrected. Also, if the problem is allowed to persist, it will continue to create a problem in the quality of the product.

In the example of the cough syrup bottling operation, bottles filled with 15.6 ounce of liquid would signal a problem. The machine may need to be readjusted. This would be an assignable cause of variation. We can assign the variation to a particular cause (machine needs to be readjusted) and we can correct the problem (readjust the machine).

**DESCRIPTIVE STATISTICS**

Descriptive statistics can be helpful in describing certain characteristics of a product and a process. The most important descriptive statistics are measures of central tendency such as the **mean**, measures of variability such as the **standard deviation** and **range**, and measures of the distribution of data.

**MEAN:** To compute the mean we simply sum all the observations and divide by the total number of observations. The equation for computing the mean is:



In the bottling example we also stated that the amount of natural variation in the bottling process is between 15.8 and 16.2 ounces. This information provides us with the amount of variability of the data. It tells us how spread out the data is around the mean. There are two measures that can be used to determine the amount of variation in the data. The first measure is the range, which is the difference between the largest and smallest observations. In our example, the range for natural variation is 0.4 ounces.

**STANDARD DEVIATION:** Another measure of variation is the standard deviation. The equation for computing the standard deviation is:



Small values of the range and standard deviation mean that the observations are closely clustered around the mean. Large values of the range and standard deviation mean that the observations are spread out around the mean. Figure 1 illustrates the differences between a small and a large standard deviation for our bottling operation. It is seen that the figure shows two distributions, both with a mean of 16 ounces. However, in the first distribution the standard deviation is large and the data are spread out far around the mean. In the second distribution the standard deviation is small and the data are clustered close to the mean of variation is the standard deviation.



Fig. 1 Normal distributions with varying standard deviations

**QUALITY MEASUREMENT: ATTRIBUTES Vs VARIABLES**

**Attributes:** Characteristics that are measured as either "acceptable" or "not acceptable", thus have only discrete, binary, or integer values.

**Variables:** Characteristics that are measured on a continuous scale.

**STATISTICAL PROCESS CONTROL (SPC)**

It includes the application of statistical techniques to determine whether a process is functioning as desired. Statistical process control monitors specified quality characteristics of a product or service so as:

* To detect whether the process has changed in a way that will affect product quality and
* To measure the current quality of products or services.

**SPC METHODS**

Control is maintained through the use of **control charts**. The charts have upper and lower control limits and the process is in control if sample measurements are between the limits.

**Control Charts for Attributes**

**P Charts** - measures proportion defective.

**C Charts** - measures the number of defects/unit.

**Control Charts for Variables**

X bar and R charts are used together - control a process by ensuring that the sample average and range remain within limits for both.

**Basic Procedure**

1. An upper control limit (UCL) and a lower control limit (LCL) are set for the process.

2. A random sample of the product or service is taken, and the specified quality characteristic is measured.

3. If the average of the sample of the quality characteristic is higher than the upper control limit or lower than the lower control limit, the process is considered to be "out of control".

**CONTROL CHARTS FOR ATTRIBUTES**

**P-Charts for Proportion Defective**

P-chart: a statistical control chart that plots movement in the sample proportion defective (p) over time

**Procedure:**

1. Take a random sample and inspect each item

2. Determine the sample proportion defective by dividing the number of defective items by the sample size

3. Plot the sample proportion defective on the control chart and compare with UCL and LCL to determine if process is out of control

The underlying statistical sampling distribution is the binomial distribution, but can be approximated by the normal distribution with:

Mean = u = np (Note - add the bars above the means used in all the equations in this section)

Standard deviation of p: sigma p = square root of (p(1 -p ) / n)

Where p = historical population proportion defective and n = sample size

**Control Limits:**

UCL = u + z sigma p

LCL = u - z sigma p

z is the number of standard deviations from the mean. It is set based how certain you wish to be that when a limit is exceeded it is due to a change in the process proportion defective rather than due to sample variability. For example:

If z = 1 if p has not changed you will still exceed the limits in 32% of the samples (68% confident that mean has changed if the limits are exceeded.

z = 2 - limits will be exceeded in 4.5 (95.5 % confidence that mean has changed)

z = 3 - limits will be exceeded in .03 (99.7% confidence)

**C-Charts for Number of Defects Per Unit**

**C-chart:** a statistical control chart that plots movement in the number of defects per unit.

**Procedure:**

1. Randomly select one item and count the number of defects in that item

2. Plot the number of defects on a control chart

3. Compare with UCL and LCL to determine if process is out of control

The underlying sampling distribution is the Poisson distribution, but can be approximated by the normal distribution with: mean = c

Standard deviation = square root of c

Where c is the historical average number of defects/unit

**Control Limits:**

UCL = c + z c

LCL = c - z c

**Control Charts for Variables**

Two charts are used together: R-chart ("range chart") and X bar chart ("average chart")

Both the process variability (measured by the R-chart) and the process average (measured by the X bar chart) must be in control before the process can be said to be in control.

Process variability must be in control before the X bar chart can be developed because a measure of process variability is required to determine the -chart control limits.

**R-Chart for Process Variability:**

UCLR = D4(R)

LCLR = D3(R)

where is the average of past R values, and D3 and D4 are constants based on the sample size

**X bar-Chart for Process Average:**

UCLR = X bar + A2(R)

LCL = X bar - A2(R)

where X bar is the average of several past values, and A2 is a constant based on the sample size

**Other Types of Attribute-Sampling Plans**

Double-Sampling Plan:

Specifies two sample sizes (n1 and n2) and two acceptance levels (c1 and c2)

1. If the first sample passes (actual defects c1), the lot is accepted

2. If the first sample fails and actual defects > c2, the lot is rejected

3. If first sample fails but c1 < actual defects c2, the second sample is taken and judged on the combined number of defectives found.

**Sequential-Sampling Plan:**

Each time an item is inspected, a decision is made whether to accept the lot, reject it, or continue sampling.

**ACCEPTANCE SAMPLING**

Goal: To accept or reject a batch of items. It is frequently used to test incoming materials from suppliers or other parts of the organization prior to entry into the production process.

Used to determine whether to accept or reject a batch of products and measures number of defects in a sample. Based on the number of defects in the sample the batch is either accepted or rejected. An acceptance level c is specified. If the number of defects in the sample is c the batch is accepted, otherwise it is rejected and subjected to 100% inspection.