Statistical Process Control (SPC)

Definition and Importance of SPC

- Statistical Process Control (SPC) is a quality control technique that uses statistical methods to monitor and control manufacturing processes.
- SPC helps determine whether a process is operating normally or whether unusual variations are present.
- The main goal of SPC is to prevent defects by controlling the manufacturing process rather than relying only on final product inspection.

Definition

- Statistical Process Control is the application of statistical techniques, especially control charts, to monitor process performance and maintain consistent product quality.

Objectives of SPC

- To monitor manufacturing processes continuously.
- To detect abnormal process variations.
- To prevent the production of defective products.
- To improve process stability.
- To reduce manufacturing costs by minimizing waste and rework.
- To ensure consistent product quality.

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Importance of SPC

A. Maintains Consistent Product Quality

- SPC helps ensure that every batch of pharmaceutical products meets the required quality standards.

B. Detects Problems Early

- SPC identifies process deviations before they result in defective products.

C. Reduces Manufacturing Costs

- Early detection of problems reduces waste, rework, and product rejection.

D. Improves Patient Safety

- Consistent manufacturing produces safe and effective medicines.

E. Supports Regulatory Compliance

- SPC helps pharmaceutical companies comply with Good Manufacturing Practices (GMP) and regulatory guidelines.

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F. Increases Manufacturing Efficiency

- Stable processes operate more efficiently and require fewer corrective actions.

Applications of SPC in Pharmaceuticals

- Monitoring tablet weight variation.
- Monitoring capsule fill weight.
- Monitoring dissolution performance.
- Monitoring sterile manufacturing processes.
- Monitoring packaging operations.

Quality Measurement in Manufacturing

Basic Idea

- Quality measurement in manufacturing is the process of evaluating products and manufacturing processes to determine whether they meet established quality standards.
- In pharmaceutical manufacturing, quality measurement ensures that medicines are safe, effective, pure, and consistent in every batch.

Objectives

- To evaluate product quality accurately.
- To identify process variations.
- To improve manufacturing performance.
- To ensure compliance with regulatory standards.
- To support continuous quality improvement.

Methods of Quality Measurement

A. Inspection

- Products are visually examined to identify defects.
- Inspection helps detect obvious manufacturing errors.

B. Laboratory Testing

- Samples are tested for identity, strength, purity, and quality.
- Testing confirms whether products meet approved specifications.

C. Process Monitoring

- Critical process parameters are monitored during manufacturing.
- Continuous monitoring helps maintain process consistency.

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D. Statistical Analysis

- Statistical tools are used to analyze manufacturing data.
- Trends and variations are identified through data analysis.

Common Quality Parameters

1. Weight Variation

- The weight of tablets or capsules is measured to ensure uniformity.

2. Content Uniformity

- Each dosage unit should contain the required amount of active pharmaceutical ingredient.

3. Dissolution

- Dissolution testing measures how quickly a medicine releases its active ingredient.

4. Hardness

- Tablet hardness is measured to ensure proper strength and handling.

5. Friability

- Friability testing evaluates the ability of tablets to resist breaking during handling.

Importance

- Quality measurement ensures consistent manufacturing.
- Product defects are detected before market release.
- Manufacturing efficiency improves.
- Patient safety is protected.

Statistical Control Charts – Concepts and General Aspects

- A statistical control chart is a graphical tool used to monitor process performance over time.
- It helps distinguish between normal process variation and abnormal variation that requires investigation.
- Control charts are one of the most important tools used in Statistical Process Control.

Concept of Control Charts

- Data collected from the manufacturing process are plotted on a graph.
- The graph helps determine whether the process remains under statistical control.
- Any unusual pattern or point outside the control limits indicates that the process requires investigation.

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Components of a Control Chart

A. Central Line (CL)

- The central line represents the average value of the process.
- It serves as the reference point for comparing process performance.

B. Upper Control Limit (UCL)

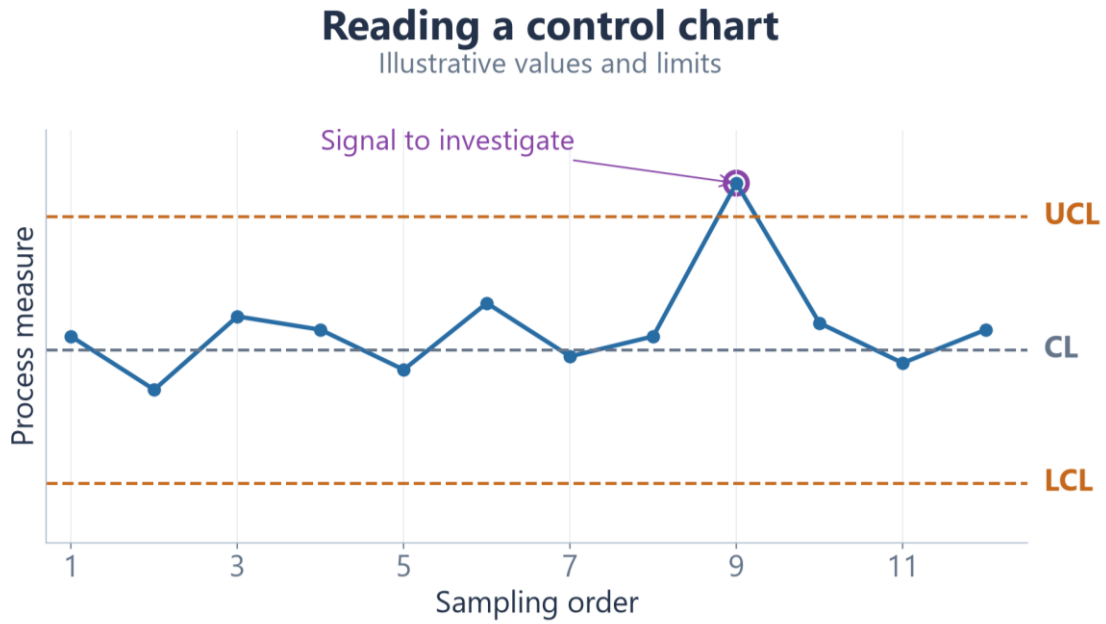
- The Upper Control Limit represents the highest acceptable process value.
- Values above the UCL indicate that the process may be out of control.

C. Lower Control Limit (LCL)

- The Lower Control Limit represents the lowest acceptable process value.
- Values below the LCL suggest abnormal process variation.

D. Data Points

- Individual measurements are plotted on the control chart.
- The pattern of data points helps evaluate process performance.



This illustrative chart uses process-based control limits to flag a signal for investigation; these are not specification limits

Types of Process Variation

1. Common Cause Variation

Basic Idea

- Common cause variation is the normal variation that naturally occurs in every manufacturing process.

Characteristics

- It is predictable.

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- It occurs continuously.
- It cannot be completely eliminated.

Examples

- Minor environmental changes.
- Small equipment variations.
- Normal raw material variation.

2. Special Cause Variation

Basic Idea

- Special cause variation results from unexpected or abnormal events that affect the process.

Characteristics

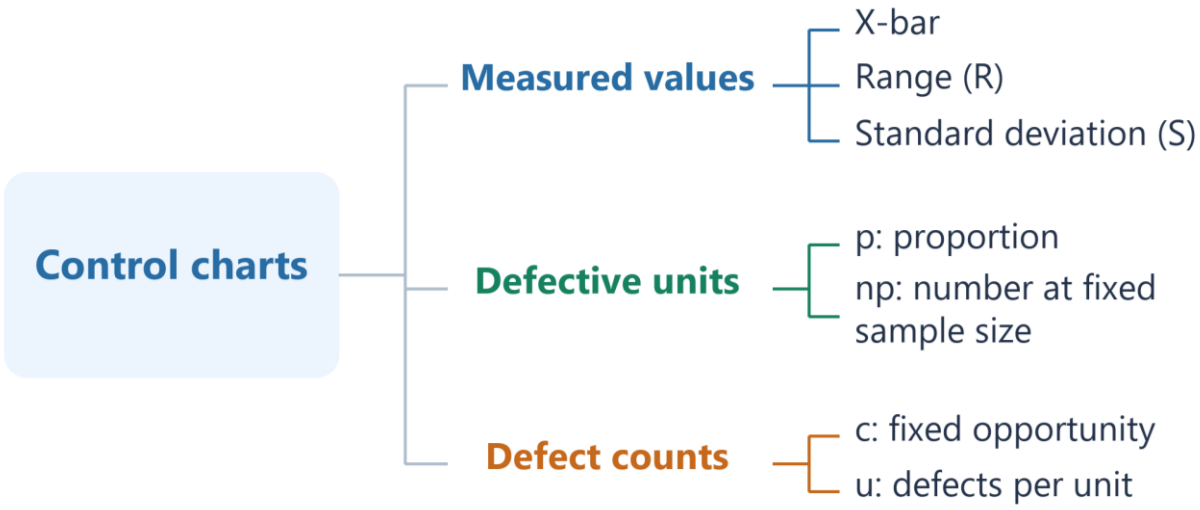
- It is unpredictable.
- It indicates that the process is not under control.
- It requires immediate investigation.

Examples

- Equipment failure.
- Operator error.
- Incorrect machine settings.
- Defective raw materials.

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Common Types of Control Charts



The chart family depends on whether the data describe measured values, defective units or defect counts

1. $\bar{X}$ (X-Bar) Chart

- It monitors changes in the process average.
- It is commonly used for continuous data.

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