WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 24, 246-258. Review Article ISSN 2277–7105

A REVIEW ON QUALITY CONTROL: MAINTAINING PRODUCT PURITY & PERFECTION

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Article Received on
25 October 2024,

Revised on 15 Nov. 2024,
Accepted on 05 Dec. 2024

DOI: 10.20959/wjpr202424-34889

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ABSTRACT

Nowadays one of the most important aspects in manufacturing is the minimization of defects and the perseverance of quality in the involved processes and products in introduction of the Industry. Quality control is a system of procedures and practices which result in the increase in precision and the decrease in bias. Quality control (QC) is a process through which a business seeks to ensure that product quality is maintained or improved. The seven basic tools of quality are a fixed set of visual exercises identified as being most helpful in troubleshooting issues related to quality. Quality control (QC) is a crucial aspect of production and service delivery. Here's a more detailed breakdown of its responsibilities. QC is responsible for analytical testing of incoming raw material and inspection of Packaging components including labeling. Six Sigma is a set of methodologies and tools used to improve business processes by reducing defects and errors, minimizing variation, and increasing quality and efficiency.

KEYWORDS: Quality control, Historical Context, Histogram, IPQC, FPQC etc.

INTRODUCTION

Nowadays one of the most important aspects in manufacturing is the minimization of defects and the perseverance of quality in the involved processes and products in introduction of the Industry. The process of inspection products to ensure that they meet the required quality standards. Quality control involves setting standards about how much variation is acceptable.

The aim is to insure that a product is manufactured, or a service is provided, to meet the specifications which ensure customer needs are meet. At its simplest quality control is achieved through inspection. The main objective of quality control is to ensure that the business is achieving the standards it sets for itself.[1,3]

Quality control is a system of procedures and practices which result in the increase in precision and the decrease in bias. The use of duplicate analysis, spiked samples, standard reference materials, and QC check samples are all mechanisms used to demonstrate the control of quality. Quality control is a sub-set of QA.[2]

Literature Survey & Objective[4]

A literature survey on quality control typically involves reviewing various studies, theories, and practices related to ensuring products and services meet certain standards. Here's a brief overview:

- Definition and Importance: Quality control (QC) refers to the processes and techniques used to ensure that products meet specified requirements and standards. It's crucial for maintaining customer satisfaction, reducing costs associated with defects, and complying with regulations.
- Historical context: The concept of quality control has evolved significantly over the years. Early methods focused on inspection and defect detection, while modern approaches emphasize prevention and continuous improvement. Pioneers like W. Edwards Deming and Joseph Juran introduced statistical methods and quality management principles that transformed QC practices.
- Key Techniques and Tools: Various tools are used in quality control, including Statistical Process Control (SPC), Six Sigma, and Total Quality Management (TQM). These methodologies focus on data analysis, process optimization, and fostering a culture of quality within organizations.
- Recent trends: Current research in quality control often explores the integration of technology, such as machine learning and automation, to enhance QC processes. There's also a growing emphasis on sustainable practices and the impact of quality on overall business performance.

Objective[5]

- Quality control (QC) is a process through which a business seeks to ensure that product quality is maintained or improved.

- Quality control involves testing units and determining if they are within the specifications for the final product.
- The quality control used in a business is highly dependent on the product or industry, and several techniques exist for measuring quality.
- The food industry uses quality control methods to ensure customers do not get sick from their products.
- Quality control creates safe measures that can be implemented to make sure deficient or damaged products do not end up with customers.

Basic requirement of quality control

All the batches of product should be analyzed approved According to the requirement of the relevant authorizations.

It should be ensure that the finished product contain APIs that Comply with the qualitative & quantitative composition of the marketing authorization are of the required purity & are enclosed in properly labeled container.[7]

Sample of starting material packaging material intermediates & Bulk finished product should be taken by personal & by method Approved by quality control department.

Sufficient facilities, trained person & approval procedure for Sampling inspection & testing of starting material, packaging Material, intermediates, bulk & finished product and the test Method should be validated.[8]

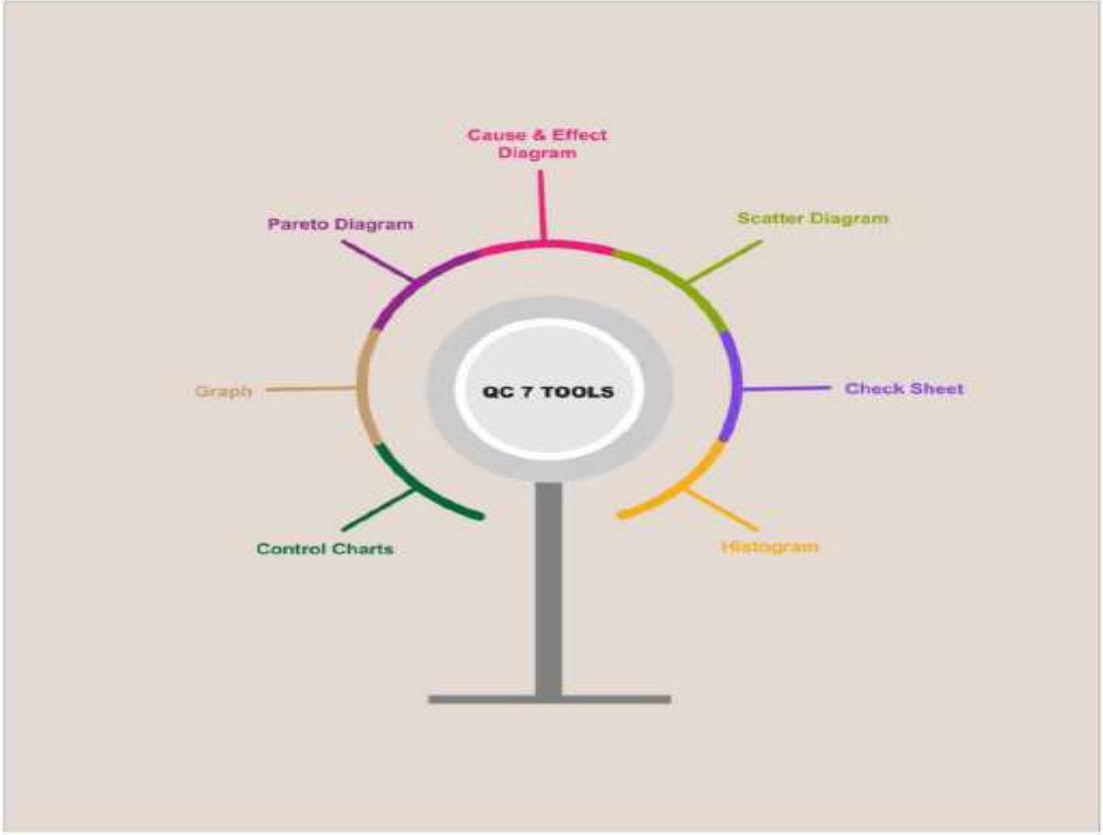
Record should be maintained either manually or by using Recording instrument to ensure that all the required sampling Inspection and testing procedure were conducted. If any Deviation is found it should also be recorded & further Evaluated.[9]

The result of inspection & testing of material, intermediates and Bulk & finished products should be recorded & formally Evaluated against standards products assuming should cover a Review & evaluation of relevant production documentation & an Assessment or deviation from specified procedures.[3,8]

Basic tools of quality control[10,11]

The seven basic tools of quality are a fixed set of visual exercises identified as being most helpful in troubleshooting issues related to quality. They are called *basic* because they are

suitable for people with little formal training in statistics and because they can be used to solve the vast majority of quality-related issues.



7 Basic tools	Quality improvement applicaton	Impact on customer satisfaction	Example
Histogram	Visualizes frequency distribution of data, helping identify patterns and variations.	Enables consistent product/service quality.	A shoe company finds that 70% of returns are due to size discrepancies. They adjust their sizing chart accordingly.
Pareto Chart	Highlights the most significant factors in a data set, allowing focus on critical issues.	Addresses the most common customer complaints, enhancing overall satisfaction.	A restaurant identifies that 80% of complaints are about slow service and cold food. They prioritize these issues for resolution.
Cause and Effect Diagram (Fishbone/Ishikawa)	Identifies potential root causes of problems, facilitating targeted solutions.	By addressing root causes, recurring issues are minimized, leading to happier customers.	A tech company finds that software crashes are often due to outdated drivers. They build an auto-update feature.
Flowchart	Maps out processes, helping identify bottlenecks or inefficiencies.	Streamlined processes lead to faster service or product delivery.	An e-commerce platform optimizes its checkout process, reducing the steps from 5 to 3, speeding up

			purchases.
Scatter Diagram	Shows relationships between variables, helping understand how they correlate.	Improved understanding of variables ensures better product/service quality.	A car manufacturer finds that tire pressure affects fuel efficiency. They provide optimal tire pressure guidelines.
Control Chart	Monitors process performance over time, ensuring stability and predictability.	Consistent quality and delivery times lead to trust and loyalty among customers.	A bakery ensures that the baking time for bread remains consistent, ensuring the same taste and texture every time.
Check Sheet	Collects data in real-time, allowing for quick analysis and action.	Rapid response to issues enhances the customer experience.	A hotel uses a check sheet for room cleaning, ensuring all tasks are completed and maintaining room quality.

Methodology used in quality control [Six sigma techniques][12,13]

Six Sigma is a set of methodologies and tools used to improve business processes by reducing defects and errors, minimizing variation, and increasing quality and efficiency. The Six Sigma is a statistical methodology that is used to represent standard deviation and it is an indicator of the degree of variation in a set of measurements or a process. It is used to define problems systematically, provides tools to measure and influential factors and identifies the improvements that can be implemented easily. It is quality management tool.

Six Sigma consists of 2 primary improvement methodologies depending on the use case: Six Sigma DMAIC and Six Sigma DMADV. The term's name is derived from the significant steps in the process, and the last two steps vary depending on which method is used. Each term's name is derived from the important steps in each process, but each is used for a different purpose.

- **Dmaic** (Define, Measure, Analyze, Improve, Control) is used to correct/improve an existing process, product, or service.
- **Dmadv** (Define, Measure, Analyze, Design, Validate) is used to design a new process, product, or service.[14]

Define

A team of people, led by a Six Sigma expert, chooses a process to focus on and defines the problem it wishes to solve.

Measure

The team measures the initial performance of the process, creating a benchmark, and pinpoints a list of inputs that may be hindering performance.

Analyze

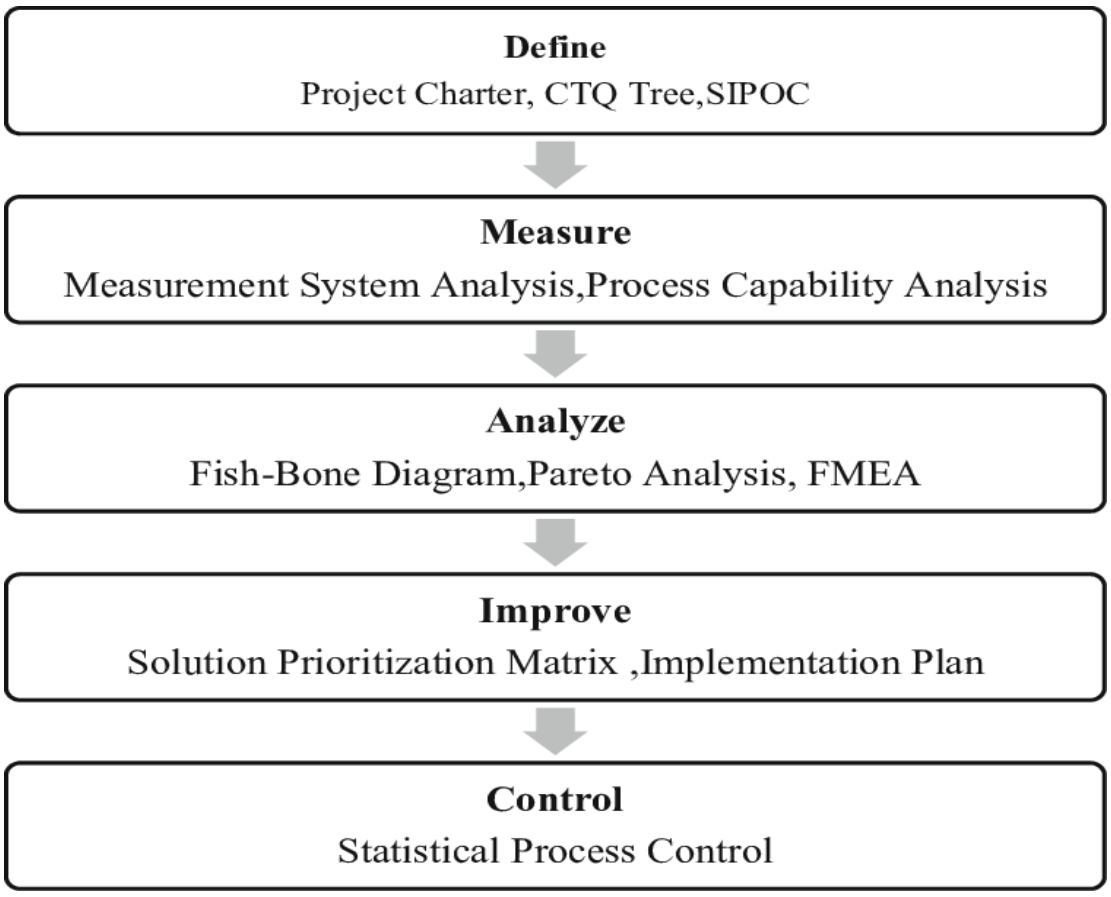
Next the team analyzes the process by isolating each input, or potential reason for any failures, and testing it as the possible root of the problem.

Improve

The team works from there to implement changes that will improve system performance.

Control

The group adds controls to the process to ensure it does not regress and become ineffective once again.



Responsibility of quality control[15,16]

Quality control (QC) is a crucial aspect of production and service delivery. Here's a more detailed breakdown of its responsibilities:

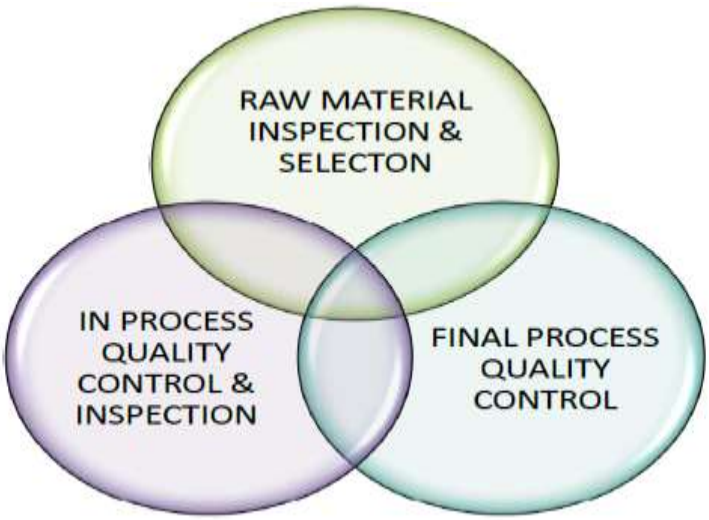
- **Inspection and Testing:** QC involves inspecting and testing products at various stages of production. This can include checking raw materials, in-process items, and finished goods to ensure they meet specified standards.
- **Standards development:** Quality control teams help develop quality standards and guidelines that products or services must meet. These standards can be based on industry regulations, customer expectations, and company policies.
- **Data Collection and Analysis:** QC professionals collect data on product performance and defects. They analyze this data to identify trends, pinpoint areas for improvement, and make informed decisions.
- **Process improvement:** Based on their findings, QC teams work to improve manufacturing or service processes. This might involve recommending changes to equipment, procedures, or training programs to enhance quality.
- **Compliance monitoring:** QC ensures that products comply with relevant regulations and standards, such as safety, environmental, and industry-specific guidelines. This is

essential for avoiding legal issues and maintaining a good reputation.

- **Training and Development:** Quality control personnel often train staff on quality standards and best practices. This helps create a culture of quality within the organization.
- **Documentation:** Maintaining accurate records of inspections, tests, and compliance is essential. This documentation can be critical for audits and quality certifications.
- **Customer feedback:** QC teams often gather and analyze customer feedback to identify quality issues and areas for improvement. This helps ensure that the final product meets customer expectations.

In summary, the responsibility of quality control is to ensure that products and services are of high quality, meet customer expectations, and comply with regulations. It's a vital part of any business that aims to deliver reliable and safe products.[15]

QC is responsible for analytical testing of incoming raw material and inspection of Packaging components including labeling.



Raw Material Inspection & Selection[17]

Raw material inspection and testing refer to the comprehensive examination of the incoming materials before they are utilized in the production process. It involves assessing the physical, chemical, and mechanical properties of the materials, as well as verifying their compliance with industry standards and specifications. Raw material inspection quality control is typically carried out by dedicated quality control teams using specialized equipment and testing methods**.**

❖ **Ensuring product quality**

By inspecting raw materials, companies can identify any deviations or discrepancies that might affect the quality of the final product. This allows them to take corrective actions early on and prevent defective or substandard goods from reaching the market.

❖ **Cost reduction**

Catching defects or inconsistencies in raw materials at an early stage can save companies significant costs. By identifying and rejecting subpar materials, businesses can avoid costly rework, production delays, and customer complaints.

In Process Quality Control & Inspection[18]

IPQC is concerned with providing accurate, specific and definite description of the procedures to be employed from the receipt of raw materials to the release of the finished dosage form .

Physical and chemical test

- **Identity test**- These tests are qualitative chemical method used to confirm the actual

presence of compound. E.g. color formation, precipitation.

- **Quality test–** These tests are physical method used to measure accurate the characteristics properties of drug. e.g.- absorbance, refractive index.
- **Purity test-** It is deigns to estimate the level of all known and significant impurities and contamination in the drug substances. E.g. test for clarity of solution, acidity/alkalinity.
- **Potency test-** these tests always estimate the quality of an active ingredient in drug.

Final process quality control

Final Process Quality Control is the act of comprehensively inspecting and testing the quality of the product after all the processes are completed to before the product is put into storage. It is also the final quality control work before the product is packaged or boxed. The quality control at this stage mainly focuses on appearance inspection and performance inspection. For example, color, gloss, roughness, burrs, whether there are scratches; physical or chemical properties of materials, electrical properties, mechanical properties, operation control, etc. The purpose of the inspection at this stage is to ensure that the product meets the shipping specifications and even meets the customer's requirements (Fitness for Requirement). Therefore, product defects of different degrees (serious, major, and minor levels) must be detected at this stage.[19]

Authorities Regulating QC In India[20,21]

Here are some regulatory bodies that regulate quality control in the pharmaceutical industry:

Main bodies

- **Central Drugs Standard Control Organization (CDSCO)**

The Primary Regulatory body in India for the Pharmaceutical Industry. CDSCO regulates the import, Sale, and Manufacture of medical devices and drugs. They also establish standards for drugs, Cosmetics, diagnostics, and devices. Headquartered in New Delhi, the CDSCO is India's main regulatory body for pharmaceuticals and medical devices and Within the CDSCO, the Drug Controller General of India (DCGI) is responsible for the regulation of pharmaceuticals and medical devices.

- **United States Food and Drug Administration (FDA)**

A regulatory body that establishes and enforces legal standards and regulations for the pharmaceutical industry. The FDA's Office of Pharmaceutical Quality (OPQ) ensures that drug quality is uniform across all manufacturing sites.

- **European Medicines Agency (EMA)**

A regulatory body that establishes and enforces legal standards and regulations for the pharmaceutical industry. EMA Provides independent, science-based recommendations on the quality, safety and efficacy of medicines. Applies efficient and transparent evaluation procedures to help bring new medicines to the market. Implements measures for continuously supervising the quality, safety and efficacy of authorized medicines.

- **World Health Organization (WHO)**

A regulatory body that establishes and enforces legal standards and regulations for the pharmaceutical industry.

- **National Institute of Health and Family Welfare (NIHFW)**

NIHFW is an Apex Technical Institute, funded by Ministry of Health and Family Welfare, for promotion of health and family welfare programmers in the country through education, training, research, evaluation, consultancy and specialized services. The NIHFW was established on March 9, 1977 by a merger of the National Institute of Health Administration and Education (NIHAE) with the National Institute of Family Planning (NIFP).

CONCLUSION

Quality control is a system of procedures and practices which result in the increase in precision and the decrease in bias. Quality control (QC) is a process through which a business seeks to ensure that product quality is maintained or improved. The seven basic tools of quality are a fixed set of visual exercises identified as being most helpful in

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