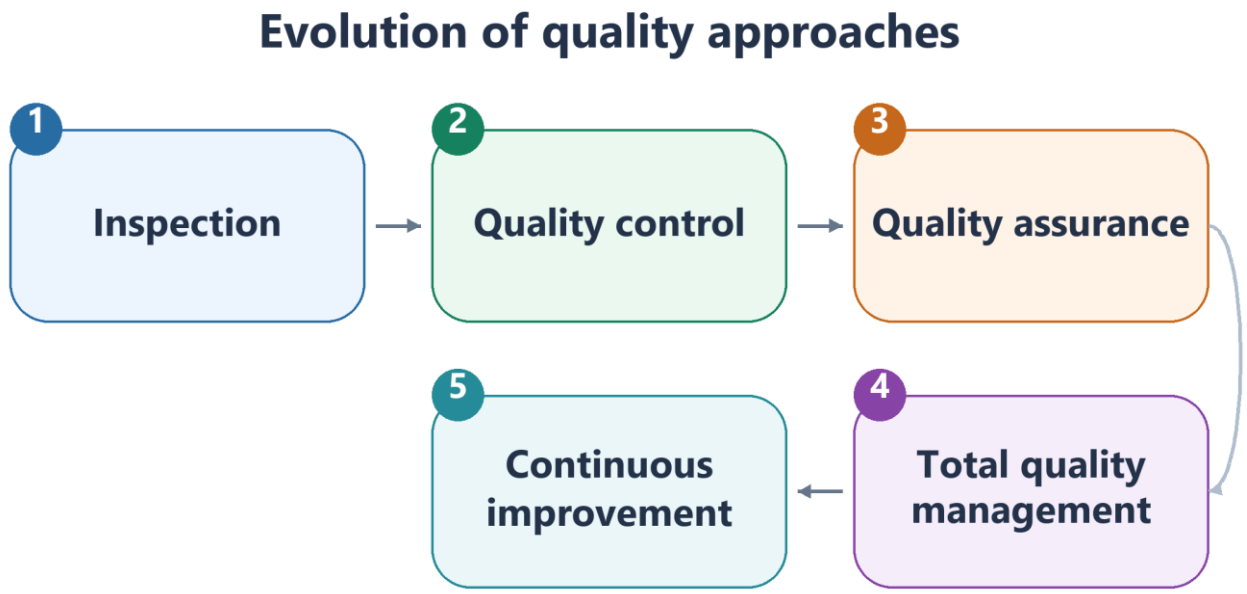
Introduction to Quality

Evolution of Quality

Basic Idea

- The concept of quality has changed over time as industries, healthcare systems, and customer expectations have developed.
- In the past, quality mainly meant checking products after they were made.
- Today, quality means preventing errors, continuously improving processes, and satisfying customers or patients.

Stages of Evolution



Quality approaches have expanded from finding defects to prevention and continual improvement

A. Inspection Stage

- Quality was ensured by inspecting products after they were manufactured.
- Defective products were identified and removed before reaching customers.
- This method focused on detecting errors instead of preventing them.

B. Quality Control (QC)

- Quality Control introduced systematic testing and inspection during manufacturing.
- Products were checked against predefined quality standards.
- Defective products were identified before distribution.
- The main goal was to ensure that only acceptable products reached customers.

C. Quality Assurance (QA)

- Quality Assurance focused on preventing defects rather than only detecting them.

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- Standard operating procedures (SOPs) and documented processes were introduced.
- Every step of production was monitored to maintain quality.
- Employees were trained to follow quality standards consistently.

D. Total Quality Management (TQM)

- Total Quality Management involved every employee in improving quality.
- Customer satisfaction became the primary goal.
- Continuous improvement became an important part of every activity.
- Teamwork, leadership, and employee participation were emphasized.

E. Continuous Quality Improvement (CQI)

- Continuous Quality Improvement focuses on making small and regular improvements.
- Data are collected and analyzed to identify problems.
- Corrective actions are implemented to improve processes.
- Quality improvement becomes an ongoing activity rather than a one-time effort.

Importance of the Evolution of Quality

- It has shifted the focus from finding defects to preventing defects.
- It has improved product safety and reliability.
- It has increased customer satisfaction.
- It has reduced manufacturing errors and costs.
- It has improved healthcare and pharmaceutical services.

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Definition of Quality

- Quality is the degree to which a product or service consistently satisfies the stated and expected needs of the customer.
- In the pharmaceutical industry, quality means that every medicine is safe, effective, pure, and manufactured according to established standards.

Common Definitions of Quality

A. General Definition

- Quality is the ability of a product or service to satisfy customer needs and expectations.

B. ISO Definition

- According to the International Organization for Standardization (ISO), quality is the degree to which a set of inherent characteristics fulfills specified requirements.

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C. Pharmaceutical Definition

- In pharmaceutical manufacturing, quality means that a medicine consistently meets all required standards for identity, strength, purity, safety, efficacy, and stability.

Characteristics of Quality

- Quality must be consistent from batch to batch.
- Quality must be measurable using predefined standards.
- Quality should meet regulatory requirements.
- Quality should satisfy both healthcare professionals and patients.
- Quality should be maintained throughout the product life cycle.

Factors Affecting Quality

1. Raw Materials

- High-quality raw materials are essential for producing high-quality medicines.
- Poor-quality raw materials can result in defective products.

2. Manufacturing Process

- Proper manufacturing procedures ensure consistent product quality.
- Validated processes reduce variability and errors.

3. Equipment

- Well-maintained and calibrated equipment improves manufacturing accuracy.
- Faulty equipment can produce defective products.

4. Personnel

- Properly trained employees perform manufacturing activities correctly.
- Human errors can affect product quality.

5. Storage Conditions

- Medicines should be stored under recommended temperature and humidity conditions.
- Improper storage can reduce product stability and effectiveness.

Importance of Quality in Pharmacy

- Quality ensures patient safety.
- Quality improves therapeutic effectiveness.
- Quality reduces product recalls and manufacturing failures.
- Quality helps pharmaceutical companies comply with regulatory standards.
- Quality increases public trust in pharmaceutical products.

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Dimensions of Quality

Basic Idea

- Dimensions of quality are the different characteristics used to evaluate the overall quality of a product or service.
- These dimensions help organizations understand what customers value and where improvements are needed.

Main Dimensions of Quality

1. Performance

- Performance refers to how well a product or service performs its intended function.
- A product should work efficiently and meet the user's expectations.

2. Reliability

- Reliability refers to the ability of a product or service to perform consistently over time.
- A reliable product functions properly without frequent failures.

3. Durability

- Durability refers to how long a product remains useful before it needs replacement.
- Durable products have a longer service life.

4. Conformance

- Conformance means that a product or service meets established specifications and standards.
- Products should be manufactured according to approved requirements.

5. Features

- Features are additional characteristics that increase the usefulness or attractiveness of a product.
- Extra functions may improve customer satisfaction.

6. Serviceability

- Serviceability refers to the ease and speed of repairing or maintaining a product.
- Good service support helps solve problems quickly.

7. Aesthetics

- Aesthetics refers to the appearance, design, and overall attractiveness of a product.
- Customers often consider appearance when evaluating quality.

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8. Perceived Quality

- Perceived quality refers to the customer's opinion about the quality of a product or service.
- Brand reputation, previous experience, and recommendations often influence perception.

Dimensions of Quality in Healthcare

A. Safety

- Healthcare services should prevent harm to patients.
- Medical errors should be minimized.

B. Effectiveness

- Treatments should be based on scientific evidence.
- Patients should receive appropriate care that improves health outcomes.

C. Patient-Centeredness

- Healthcare providers should respect the needs, preferences, and values of patients.
- Patients should participate in decisions about their care.

D. Timeliness

- Healthcare services should be provided without unnecessary delays.
- Early treatment often leads to better outcomes.

E. Efficiency

- Resources should be used wisely without unnecessary waste.
- High-quality care should be delivered at a reasonable cost.

F. Equity

- All patients should receive fair and equal healthcare regardless of age, gender, income, religion, or background.

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