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Introduction of Quality Control and Quality Assurance

Savita Dattatreya Sonawne[1], Bais S. K.[2], Saurabh Bharatnavale[3]
Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India
saurabhnavale2001@gamil.com

Abstract: *This concise overview discusses many international methods for evaluating the concept of geotaxis. Pharmaceutical impurities, include residual solvents and different organic and inorganic impurities. Due to national and international requirements, it is now obligatory to provide information on a specific pharmaceutical product's impurity profile in addition to its purity profile. These characteristics, the importance of the quality, efficacy, and safety of medicines, as well as the origin, types, and regulation of impurities, are discussed. One of the requirements for the delivery of any nation's healthcare system has been highlighted as the availability of critical medicines of high quality, as subpar medications have the potential to hurt or even kill their users. a chemical environment that is undesirable in a specific medicine, Its safety and effectiveness may be affected, even in incredibly little levels. A pharmaceutical is a dynamic product that, unlike products from other industries, can alter between manufacture and final consumption in terms of colour, consistency, weight, and even chemical identification. Therefore, pharmaceutical product quality has been a worry for people all over the world, and regulatory agencies are now paying close attention to it. Pharmaceutical product impurities are a major source of concern due to their potential for detrimental effects on drug stability and shelf life as well as their intrinsic toxicity in some cases. Impurities in pharmaceutical and drug products are undesirable substances (organic, inorganic, and residual solvents) that arise or are added during formulation, or that remain with the active pharmaceutical ingredients (APIs) during storage. Even with sufficient precaution, organic impurities are the most prevalent contaminants discovered in every API and are not included during the multi-step manufacturing process.*

Keywords: Quality Control

I. INTRODUCTION

The term quality assurance (QA), which is used in both the services and manufacturing sectors, refers to the systematic steps taken to ensure that the product delivered to the customer needs to satisfy their collective expectations as well as other established performance, design, reliability, and maintainability assumptions. The main goal of quality assurance is to infection prevention and control and flaws in the design, development, and manufacturing of both primary commodities like cars and shoes, as well as given services like athletic shoe and car design. The "component of quality management focused on creating assurance that quality criteria will be satisfied" is what ISO 9000 identifies as ensuring quality and, as a result, preventing issues and delays while delivering products or services to customers. This element of fault prevention quality assurance differs from the unsure detection aspect of quality control and has been referred to as a shift left since it focuses on quality efforts earlier in product development and production (i.e., a shift to the left of a linear process diagram reading left to right) and on avoiding defects in the first place rather than correcting them after the fact.(16)

The terms "quality assurance" and "quality control" are often used interchangeably to refer to ways of ensuring the quality of a service or product.[3] For instance, the term "assurance" is often used in a context such as: Implementation of inspection and structured testing as a measure of quality assurance in a television set software project at Philips Semiconductors is described.[4] where "inspection and structured testing" are the measurement phase of a quality assurance strategy referred to as the DMAIC model (define, measure, analyze, improve, control). DMAIC is a data-driven quality strategy used to improve processes.[5] The term "control" is the fifth phase of this strategy.

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In the past, it has been more challenging to define what a suitable product or service's quality is. This has been done in a variety of ways, from the subjective user-based approach, which includes "the different weights that individuals typically attach to quality characteristics," to the value-based approach, which finds that consumers link quality and price and draw general conclusions about quality based on these associations. [10]

Quality control (QC) is a process by which entities review the quality of all factors involved in production. ISO 9000 defines quality control as "a part of quality management focused on fulfilling quality requirements".[11]
Elements such as controls, job management, defined and well managed processes,[13][14] performance and integrity criteria, and identification of records competence, such as knowledge, skills, experience, and qualifications
Soft elements, such as personnel, integrity, confidence, organizational culture, motivation, team spirit, and quality relationships. Inspection is a major component of quality control, where physical product is examined visually (or the end results of a service are analyzed). Product inspectors will be provided with lists and descriptions of unacceptable product defects such as cracks or surface blemishes for example.[12]

II. DEFINITION OF QA/QC

2.1 Quality Control

Quality Control (QC) is a system of routine technical activities, to measure and control the quality of the inventory as it is being developed. The QC system is designed to:

1. Offer regular, routine checks to guarantee the accuracy, completeness, and integrity of the data;
2. Spot mistakes and omissions and correct them;
3. Record all QC actions and document and archive inventory materials.

the use of authorised standardised processes for emission calculations, measurements, and uncertainty estimation, as well as general techniques like accuracy checks on data collecting and computations, information archiving, and reporting, are all examples of QC operations. Greater level QCactivities include technical reviews of source categories, activity and emission factor dataand
methods.[17

- ***Quality Assurance:-***

Quality Assurance (QA) activities include a planned system of review procedures conducted by preferable personnel not directly involved in the inventory compilation/development process. Reviews, preferably by independent third parties, should be performed upon a finalised inventory following the implementation of QC procedures. Reviews verify that data quality objectives were met, ensure that the inventory represents the best possible estimates of emissions and sinks given the current state of scientific knowledge and data available, and support the effectiveness of the QC programme.[17]

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2.2 QA and QC Role in Pharmaceutical Industry

Quality Assurance roles in Pharmaceutical Industry

Quality Assurance

In a pharmaceutical context, quality management plays a significant role in quality control. Quality assurance, on the other hand, is the process of ensuring that the quality requirements are fulfilled.

1. To assure that pharmaceutical goods are made to a reliable and safe level, the pharmaceutical industry relies on quality assurance (QA). Any factor that could have an impact on a drug's quality during its development, research, and manufacture is referred to as QA. The totality of the planned actions will guarantee that the created goods are of the calibre needed for their intended application. A drug that doesn't work as intended or that is defective in some way can present a threat to public health. Ensuring that pharmaceutical products are safe and effective is the primary goal of any pharmaceutical company's QA department.
2. A QA professional implements various measures at manufacturing facilities, such as calibrating equipment, maintaining documentation, and conducting quality tests, that are covered by GMP and that can help a facility pass its inspection .QA professionals maintain documentation to ensure regulatory compliance
3. The drug user seeks reassurances that the medications they use are safe and effective. The public may lose trust in a pharmaceutical manufacturer's ability to provide high-quality goods if they are discovered to be in violation of QA rules or if they produce a drug that is hazardous or does not function as intended.
4. A QA specialist plays a vital role in reassuring the public that a particular drug—and, by extension, that drug's manufacturer—can be trusted by making sure that safeguards are in place to ensure product quality. The maintenance of pharmaceutical businesses' public reputations, which is crucial for commercial success, is aided by this. [20]

Quality Control Roles in Pharmaceutical Industry

1. The primary role of quality control is to evaluate and confirm the product's conformance to established standards. Therefore, the most crucial component of the pharmaceutical sector is quality control.
2. Quality control is a symbol of the manufactured medications' dependability, efficacy, purity, and reliability.
3. In order to satisfy the established quality requirements, the quality control method and department are essential.
4. By using this approach, pharmaceutical companies may create high-quality medications and patients can prevent unfavourable side effects.
5. Pharma businesses cannot persuade customers to purchase their goods if the drugs lack authenticity certification.
6. All of the aforementioned assist the pharmaceutical company avoid fines, financial losses, and legal problems.
7. As a result, quality control procedures are crucial for pharmaceutical corporations as well as customers. Pharma corporations shouldn't at all costs avoid it. A pharmaceutical firm cannot expand or gain traction in the market without effective quality control procedures. [20]

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2.3 Types of Quality Control

The four types of quality control are QC is not a function of any single department or a person. It is the primary responsibility of any Supervisor to turn out work of acceptable quality. Quality control can be divided into three main Sub-areas, those are:

1. Off-line quality control,
2. Statistical process control
3. Acceptance sampling plans.

Off-Line Quality Control: Its approach deals with steps to determine and select Controllable product and process characteristics in a way that minimises the variation between the output of the Product or Process and the Standard. This work is largely completed through the design of the products and processes
Example: Taguchi method, principles of experimental design etc.

Statistical Process Control: SPC is comparing a process or service's output to a standard and taking corrective action when there is a gap between the two. Additionally, it entails figuring out whether a method can result in a product that fits the desired specifications or demands. When SPC is conducted online, data is obtained on the good, process, or service while it is in use. During that operational phase, the corrective action is taken. This is current basis.

Acceptance Sampling Plans: An acceptance sampling plan is a strategy that establishes the quantity of samples to be taken and the lot's acceptance standards based on the fulfilment of predetermined requirements (such as the possibility of accepting or rejecting a good lot). [21]

2.4 Steps in Quality Control

Following are the steps in quality control process:

1. Formulate quality policy.
2. Set the standards or specifications on the basis of customer’s preference, cost and profit.
3. Select inspection plan and set up procedure for checking.
4. Detect deviations from set standards of specifications.
5. Take corrective actions or necessary changes to achieve standards.
6. Decide on salvage method i.e., to decide how the defective parts are disposed of, entirrScrap or rework.
7. Coordination of quality problems.
8. Developing quality consciousness both within and outside the organization.
9. Developing procedures for good vendor-vendee relations.[21]

2.5 Objectives of Quality Control

Following are the objectives of quality control:

1. To improve the companies income by making the production more acceptable to the
2. Customers, i.e., by providing long life, greater usefulness, maintainability etc.
3. To reduce companies cost through reduction of losses due to defects.
4. To achieve interchangeability of manufacture in large scale production.
5. To produce optimal quality at reduced price.
6. To ensure satisfaction of customers with productions or services or high quality level, toBuild customer goodwill, confidence and reputation of manufacturer.
7. To make inspection prompt to ensure quality control.
8. To check the variation during manufacturing.[21]
9. The broad areas of application of quality control are incoming material control, processControl and product control.

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2.6 Benefits of Quality Control

- Improving the quality of products and services.
- Increasing the productivity of manufacturing processes, commercial businesscorporations.
- Reducing manufacturing and corporate costs.
- Determining and improving the marketability of products and services.
- Reducing consumer prices of products and services. Improving and/or assuring on timedeliveries and availability.
- Assisting in the management of an enterprise. [21]

1. Process control,
2. Control charts,
3. Acceptance sampling, and
4. Product quality control

Control Charts

To examine how processes change over time, use a graph or chart. The production and commercial processes are examined statistically to determine whether they are "under control."

Process Control

Processes are evaluated and modified as needed to maintain and enhance performance. In order to attain consistency, this is often a technical procedure employing feedback loops, controls at the industrial level, and chemical processes

Acceptance Sampling

A statistical measure is used to determine if a batch or sample of products meets the overall manufacturing standard.

Product Quality Control

A company's efforts to maintain or raise product quality are achieved through the quality control (QC) process. Testing units to see if they meet the requirements for the finished product is known as quality control.

Term used in Quality Assurance

1. Development,
2. Quality control,
3. Production,
4. Distribution, and
5. Inspections.

Developmental

Quality Assurance is described as a combination of quality assurance and research and development that assures the invention complies with established quality standards set by regulatory norms and that the methodology, procedure, and process will reliably satisfy the quality standards time and time again.

Quality Control

Quality control (QC) of Manufacturing procedures undoubtedly play a crucial role in a product's dependability. An overall reliability programme can be thought of as having QC as a vital component. In general, reliability is concerned with breakdowns that occur over time of a product.

Production

Production quality, also known as manufacturing quality, is a measurement that describes how well the manufacturing process develops products to fit their initial design specifications. When producing goods, manufacturers create a plan for how they want the items to look and function.

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Distribution

A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary. Distribution records must be constructed and procedures established to facilitate recall of defective product.

Inspection

Quality assurance inspections confirm that products and processes meet expected levels of quality.

Analysis is Important for Quality Control (QC)

Testing and Analysis

- Testing and inspecting goods, services, or procedures to assess their performance or quality
- The samples taken must be sent to analysis, and the results must be communicated to the heads of production and storage. Rejected material must be removed and placed in a separate area with access restricted to authorised individuals. Containers must be properly labelled with "Approved" or "Rejected" labels, depending on the situation.

Analysis is Important for quality Assurance

A technique called quality assurance is used to determine whether your product or service is up to par and whether you are providing clients with the kind of good or service that will keep them coming back. The goal is to continually provide a high-quality product or service. In a proactive approach, flaws are found before a good or service is made available to the general public. The success of the business depends on this. Your business is significantly better off when its clients are satisfied well.

Uses of Quality Assurance

1. Quality control enables a business to satisfy the needs and expectations of its customers.
2. High quality fosters client trust, which increases your ability to compete in the market.
3. By avoiding problems from occurring in the first place, it helps to establish and maintain quality standards by saving money and fixing problems before they worsen.
4. In many companies nowadays, spending money on quality assurance is essential. It works best when it is implemented from the beginning.
5. When quality assurance is carried out properly, it gives consumers trust, tests the product, and allows businesses to advertise their goods with little concern.

Uses of Quality Control

Quality control enables the manufacture of high-quality goods, which is very beneficial in drawing in more customers and boosting sales.

1. It significantly contributes to both sustaining and generating demand for the product.
2. It has been correctly noted that quality control is a potent tool that may be used to increase domestic and international markets.

If you're unsure whether you actually need to improve your quality control, look at theseimportant

III. DOCUMENTATION, ARCHIVING AND REPORTING

3.1 Internal Documentation and Archiving

It is best practise to record and archive all the data needed to create the national emissions inventory estimates as part of routine QC procedures. This entails:

- Presumptions and standards for choosing activity data and emission factors;
- References to published References or other documentation for emission factors used in higher tier approaches, including references to the IPCC publication for default factors;
- Activity data or information that allows activity data to be linked back to the source being cited

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- Information on the uncertainty associated with activity data and emission factors;

Methods employed, including those to estimate uncertainty; justifications for method selection; modifications to previous years' data inputs or methodologies;

The names and credentials of those who provide expert opinion for uncertainty estimations.
QA/QC plans and the results of QA/QC procedures. Details of electronic databases or software used in the production of the inventory, including versions, operating manuals, hardware requirements, and any other information needed to enable their later use. Worksheets and interim calculations for source category estimates and aggregated estimates, as well as any recalculations of previous estimates.
It is good practice for inventory agencies to maintain this documentation for every annual inventory produced And to provide it for review. It is good practice to maintain and archive this documentation in such a way that Every inventory estimate can be fully documented and reproduced if necessary. Inventory agencies should ensure That records are unambiguous; for example, a reference to 'IPCC default factor' is not sufficient. A full reference the particular document (e.g. Revised 1996 IPCC Guidelines for National Greenhouse Gas Inventories) is
Because there may have been multiple revisions to the default factors when new information became available, it is essential to pinpoint the emission factor's source. For the purpose of enabling ongoing development of inventory estimates, records of QA/QC procedures are crucial information. Records of QA/QC activities should include the checks, audits, and reviews that were carried out, the dates and people who carried them out, as well as any adjustments and alterations to the inventory that were made as a result of the QA/QC activity.

3.2 Reporting

It is recommended to supplement each nation's national inventory with a summary of the implemented QA/QC activities and key findings. However, reporting every piece of internal documentation that the inventory agency keeps is not practical nor essential. According to the QA/QC plan, the report should specify which internal actions and external evaluations were carried out for each source category and on the complete inventory. The important findings should highlight significant flaws with input data quality, processing techniques, or archiving, and demonstrate how they have been or will be resolved. [22]

3.3 Validation

The terminological situation may be clarified if the term validation is limited to the demonstration of a method's suitability for its intended purpose and the term verification is limited to the demonstration of a method's suitability for use under specific experimental conditions that may or may not be appropriate given the conditions present during the validation.
These actual circumstances include particular components or goods, as well as certain lab workers, tools, and reagents. However, there are some passages in the literature when this distinction is lost. Take into account the validation definition from the dictionary that was just provided, which also lists verification as a synonym for validation. It further complicates matters when terms like "system suitability tests" are used. The phrase is also found in Chapter 61, "Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests," Chapter 62, "Microbiological Examination of Nonstories Products: Tests for Specified Microorganisms," and Chapter 71, "Sterility Tests," in the sections titled "Validation Test" and "Suitability of the Test Method" (23). In any situation, the goal is to make sure that the validated method will work under the specific conditions the analyst plans to use.
If after incubation there is clearly apparent microbe growth that is comparable to that in the control vessel without the product, either the product exhibits antimicrobial action under the conditions of the test, or such activity has been detected. successfully eliminated The sterility test can then be performed without further alterations.
The content in Chapter 71 might be altered to "Suitability of the Test Method," if not "Verification of the Test Method," to be more beneficial and consistent. Given that what is being evaluated is the verification that the actual test conditions relative to those defined during the validation permits the proper functioning of the method, the latter adjustment may also be suitable for Chapters 61 and 62. Given that these three chapters have been harmonised, any adjustments would probably take longer to become effective..(23)

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The FDA also released the updated version of the guidance document "Analytical Procedures and Methods Validation of Drugs and Biologics" in July 2015. The final document is a more condensed version of the earlier version, which was an adaption of the ICH Q2 standards. Much of the content from the ICH has been omitted, and its place has been taken by references to the ICH. Based on the ICH recommendations, the FDA advice suggests that when choosing the analytical instruments and methodology, the intended purpose and breadth of the analytical method be taken into account. The validation report now includes an analytical method development section that explains how method parameters were chosen in accordance with the desired objective and analytical process. 4 Additionally, this final directive also provides the us FDA production regulations authority

3.3 Difference between Quality Control and Assurance[15]

	Quality Assurance	Quality Control
Definition	QA is a set of activites for ensuring quality in the processes by which products are developed	Qc is set of activites for ensuring quality in product, focused on identifying defects in the products produced.
Focus	QA is a proactive quality process which aims to prevent defects in the process used to make the product	QC is reactive process to identify and correct defects in the finished product
Goal	To improve development and test processes to reduce defects when the product is being developed.	To identify defects in a developed product before its released
How	QA establishes good quality management system and the assessment of its adequacy and conformance audits of the system	QC find and eliminates sources through tools and equipment so that customers requirement and continually meet
What	Prevention of quality of quality problem through planned and systematic activites including documentation	The activities used to achieve and maintain the product quality, process and services
Responsibility	Everyone on the team involved in developing the product is responsible for QA	It is usually the responsiblites of a specific team that testes the product for defect
Example	Verification	Validation/ software testing
Technique	Statistical tools and techniques can be applied in both QA & QC. When they are applied to process , they are called statistical process control (SPC) and it becomes the part of QA	When statistical tools and techniques are applied to finished products, they are called as statistical quality control(SQC) and comes under QC
As a tool	QA is a managerial tool	QC is a corrective tool
Orientation	QA is process oriented	QC is process oriented

QA	QC	COMMON
Proactive	Reactive	Release high- quality products
Training	Product oriented	Improve processes and procedure
Active process monitoring	Look for defects or errors in product	Gains customer trust and loyalty
Root cause analysis	Write and maintain testing and inspection reports	Find issues before they become major problem
Documentation	Verification	Optimize use of existing resources
Collect and evaluate feedback from customers	Lab testing	Increases proficiency
Process improvement	Evaluate customer feedback	Reduce costs

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Audit	Inspection	
Creation	Automatic testing	
Process comply with industry standards	Product sampling	

	QA	QC
Definition	QA is set of activites for ensuring quality in the process by which products are developed	QC is set of activites for ensuring quality of products, focused on identifying defects in the production produced
Goal	It is proactive quality process which aims to prevent defects in the process used to make the product	It is reactive process to identify defects in the finished product
How	It establish good quality management system and the assessment of its adequacy and conformance audits of the system	It finds & eliminates sources of quality problems through tools & equipment so that customers requirement are continually me
What	Prevention of quality problems through planned and systematic	The activities used to achieve and maintain the product quality, process and services
Responsibility	Everyone on the team involved in developing the product is responsible for quality assurance	QC is usually the reponsiblity of a specific team that tests the product for defect
Example	Verification	Validation/ software technique
Techniques	Statistical tools and technique can be applied in both QA & QC.	When statistical tools and technique are applied to finished product , they are called Statistical Qualtiy Control(SQC)
As a tool	It is managerial tool	It is corrective tool
orientation	QA is process oriented	QC is process oriented

IV. QUALITY ASSURANCE REVIEW PROCESS

The QAR process ensures that a comprehensive review is carried out in accordance with International standards. Generally, it involves the standard four phases i.e. planning, Conducting, reporting, and follow-up.

4.1 Planning Phase

Planning

- Understand the OAGN or Audit environment
- Define QAR
- Objective & scope
- Identify key areas for QAR
- Select appropriate audits for QAR Decide
- Methodology
- Define roles and responsibilities
- Estimate resources including time
- Prepare QAR plan

4.2 Conducting Phase

In the second phase, the review team conducts the review using the QAR plan to Guide the gathering of evidence.

Conducting of QAR

- Conduct entry meeting
- Gather information

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- Record and analyse information
- Discuss QAR findings with audit team

4.3 Reporting Phase

The third phase is where the review team uses the outputs (preliminary findings And recommendations) of the conducting phase as inputs to prepare a draft QAR Report.

Reporting of QAR

- Prepare draft QAR Report
- Conduct exit meeting with
- Finalise QAR Report

4.4 Follow-up

The final phase is where the review team uses the action plan prepared by the Audit line functions as inputs, and assesses the extent of implementation of the QAR recommendations and reasons for non-implementation, if any.

Follow up QAR

- Management
- implements Action Assess
- implementation of action plan [16]

4.5 Importance and Advantages of Quality Control System

Both manufacturers and consumers profit from the quality control programme. On the one hand, a high-quality product will meet the needs of the clients, which will increase demand and lead to mass manufacturing. On the other hand, as a manufacturer of high-quality goods, the company's reputation grows. The following factors highlight how crucial quality control is facts.

A. Reduction in Costs

Because less raw materials, semi-finished products, and final items are wasted when a quality control system is effective, a standard-quality product is produced on a large scale, and The price of reworking the defective goods is minimum.

B. Improvement in the Morale of Employees

The staff learn to value quality through the quality control programme. They are well aware of the requirements for the product and work hard to raise them in order to manufacture great products. Consequently, it raises the staff's morale. employees

C. Maximum Utilization of Resources

By implementing a quality control system, the organization is able to exert the necessary control over its machinery, tools, personnel, materials, and other resources. The system will also regulate the improper use of resources, waste of all kinds, and subpar output. Consequently, the organization makes the most of its resources use.

D. Increase in Sales

The primary goal of the quality control system is to increase product sales. A quality product is made available to consumers and that too at lesser prices thanks to the introduction of quality control programmers in the manufacturing process. It thus raises business demand product.

E. Consumers' Satisfaction

Consumers always get quality products of standard specifications to their utmost satisfaction.

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F. Minimize Variations

It is a well-known reality that despite thorough planning, there will inevitably be some variances in the nature of manufacturing. The production process, including the machinery, materials, activities, etc., determines how large the differences will be. The methods of quality control aid in the analysis of these variances in product quality and operate as a helpful tool for addressing a variety of production issues that cannot be adequately resolved by other ways. Therefore, quality control is a crucial tool in the management's toolbox for preserving product quality. [17]

4.6 Importance of Validation

Quality assurance and cost reduction are the most convincing justifications for optimising and validating pharmaceutical products and supporting procedures. The creation of goods that are suitable for their intended use is the aim of the fundamental principles of quality assurance. (24) These guiding principles Each step of the manufacturing process must be regulated to increase the likelihood that the finished product will fulfil all quality and design requirements. Quality, safety, and effectiveness must be engineered into the product; quality cannot be checked or tested in finished items. Despite the fact that the relationship between quality assurance and process validation goes much beyond the purview of any quality assurance responsibilities, it is accurate to argue that process validation is a quality assurance tool because it is establishes a quality standard for the specific process.

As a component of GMP, quality control is concerned with testing, organisation documentation, sampling specifications, and release protocols. (25) In contrast, assurance of quality results from paying close attention to a number of factors, such as the choice of high-quality materials, tools, an adequate product, process design, the choice of authorised vendors, proper GMP inspections, employee training, technical audit, critical analysis of market complaints, in-process control of processes, and the final product testing.[26)]

Process validation should lead to less troubleshooting and product recalls. Less process assistance is needed, there is less downtime, there are fewer batch failures, and the process may function more effectively and produce more when it is consistently under control. Additionally, timely and appropriate validation enhances quality assurance, boosts cost reduction through process optimization, enables more effective and quick troubleshooting, reduces lead time leading to low inventories, empowers all employees to take charge of their processes and make them better, enhances system control, and maintains and improves a high degree of assurance that a particular process will consistently produce a product that meets its predetermined specifications and quality.[28)]

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