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INTRODUCTION TO QUALITY ASSURANCE AND QUALITY CONTROL

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ABSTRACT

The purpose of quality assurance in the pharmaceutical supply chain is to guarantee that every medication that is given to a patient is safe, efficient, and of a suitable calibre. Although thorough program of quality assurance consists both administrative and technical tasks. One crucial function of the pharmaceutical sector is quality control. It might also carry out a statistical analysis of the test findings to demonstrate the reproducibility of the procedure. In order to determine how successful its test program has been in keeping rejectable products off the market, it examines the product complaints. Due to national and international requirements, it is now required to disclose not just the purity profile, in addition to the profile of an impurity of specific pharmaceutical drug product. These elements are explored together with the importance of the efficacy, safety, and quality of drug, as well as the types, sources, and controls of impurities as well as regulatory issues. Among the requirements regarding the implementation of the any nation's medical system is the availability of the necessary medications of high quality, since subpar medications have the potential to cause harm or even death to patients. Even in minute amounts, the presence of undesirable compounds in a specific medication may have an impact on its effectiveness & safety. A pharmaceutical is a dynamic product, unlike those in other sectors, whose changes can occur in colour, consistency, weight, and even chemical identity between the moment of creation and the moment of final consumption.

KEYWORDS: Quality Assurance, Quality Control, Difference between QA & QC.

INTRODUCTION

The quality of products offered by pharmaceutical manufacturers is determined by how well a standard of quality assurance, quality control, and good manufacturing practises (GMP) has been applied in the production, distribution, and marketing of products throughout their entire shelf life. This review's primary goal is to highlight the fundamental distinctions between good manufacturing practices, quality assurance, and control while also highlighting how important they are for pharmaceutical products.

The QA/QC good practice guidelines that are presented here take into account experience, acceptability, cost-effectiveness, practicality, and potential global application. The goals of good practice guidelines, which include enhancing national inventories of emissions estimates' confidence and their transparency, consistency, comparability, and completeness, are furthered by QA/QC programs. The results of the QA/QC procedure might force a revision of the inventory or source category uncertainty estimates. For instance, the uncertainty estimates can be reassessed if it turns out that the data quality is worse than initially believed and that this circumstance cannot be resolved within this parameters of the stock that is on hand.[1]

Definitions of QA and QC as per WHO

QA –Quality Assurance is the board term that encompasses all factors that either separately or jointly affect a product's quality. It is the culmination of all planned actions taken to guarantee that pharmaceutical products meet the standards of quality necessary for the purposes for which they are intended.

QC – Quality control, which addresses organisation, documentation, release procedures, testing, specifications, and sampling, is an essential part of good manufacturing practise (GMP). These procedures ensure that relevant and required testing is carried out and that products and materials are not made available for use or sale until their quality has been acceptable.[2]

'QUALITY ASSURANCE'

Quality assurance encompasses GLP (good laboratory practises), GMP (good manufacturing practises), and original product design and development.

• GMP + QC + Product Development & Design + Quality Objective Activities = QA.

1. Functions of QA

- Creating the pharmaceutical product in accordance with GMP requirements as well as other related codes like GLP (Good Laboratory Practice) and GCP (Good Clinical Practice.)
- Adopting the GMP (Good Manufacturing Practice) requirements along with clearly defining production & control operations in writing.
- Clearly stating in job descriptions the managerial and key personnel responsibilities.
- Making the necessary preparations to ensure that the right starting and packing materials are manufactured, supplied, and used.
- Carrying out the necessary in-process controls, validations, and calibrations on the starting materials, intermediate, and bulb products.

✓ **Eight Pillars of Pharmaceutical Quality System**

i. Auditing
ii. QMS consultancy and design
iii. GMP compliance
iv. Training
v. SOP development
vi. QA provision
vii. Inspection, preparation and support
viii. Quality Risk Management (QRM)[3]

2. Quality by design (QbD)

In order to ensure the consistent provision of superior products, a tactical methodology recognised as Quality by Design (QbD) is used in a number of industries, including manufacturing, product development, and pharmaceuticals. Quality considerations are integrated into the entire product lifecycle, from conception to production, through a methodical and proactive process. In order to enhance the general quality, safety, and efficacy of the medications, Quality by Design in the pharmaceutical industry focuses on optimising the development, production, and quality control processes.[4]

3. Quality Risk Management (QRM)

Quality risk management is a process whereby risks to the quality of a drug (medical) product are assessed, controlled, communicated, and reviewed throughout the product lifecycle. Decisions can be made at any point in the process.

✓ Principles of QRM

- The evaluation of the risk to quality must be based on knowledge from science and ultimately have to do with patient safety.
- QRM needs to be flexible, dynamic, and change-responsive.
- The level of formality, effort, and documentation required by the QRM process should correspond to the level of risk.
- The ability to continuously enhance and improve should be ingrained in the QRM procedure

✓ QRM process

Establishing a Quality Risk Management Process Good risk management should include systematic processes designed to organise, facilitate, and improve risk-related science-based decision making.[5]

A quality risk management process could be initiated and organised by completing the following steps:

I. Risk Assessment

a) Identification of Risk

b) Analysis of Risk

c) Evaluation of Risk

II. Risk Control

a) Reduction of Risk

b) Acceptance of Risk

III. Risk Communication

IV. Risk review

V. Risk Management Methods

4. Total Quality Management (TQM)

Total quality management (TQM) is not a method; rather, it is a concept. It is a philosophy that emphasizes an all-encompassing, integrated, and systematic viewpoint that would include every member of the organization. It is commonly known that Total Quality Management (TQM) enhances not only an organization's competitive edge but also its productivity, profit, and market share.

✓ Elements of TQM

To successful implementation of TQM organisation must concentrate on following 8 important keys:

i. Trust
ii. Ethics
iii. Integrity
iv. Teamwork
v. Leadership
vi. Recognition
vii. Communication
viii. Training

✓ Principle of TQM

In the field of business operations management, TQM is recognised as a customer-centric process with an ongoing improvement objective. It attempts to ensure that all associated workers are striving for the same goals of improving the production processes and raising the standard of the goods or services. TQM is characterised by several guiding concepts.

i. The management's dedication
ii. Workers' Empowerment
iii. Continuous improvement
iv. Emphasis on the Customer
v. Process related
vi. Making Decisions Only Based on Facts, Not Opinions

✓ Benefits of TQM

a) This will raise awareness of the organization's quality culture.
b) There will be a focus on teamwork in particular.
c) Continuous improvement will become a commitment as a result of TQM.

d) The owner's or customer's satisfaction serves as the benchmark for quality.[6]

5. Quality Assurance Review Process

A thorough review that complies with international standards is guaranteed by the QAR process. The usual four stages are involved, which are planning, carrying out, reporting, and follow-up.

a) Phase of Planning.

b) Phase of Conducting.

c) Phase of Reporting.

d) Check out.[7]

6. Quality Assurance in Regulatory Affairs of Pharmaceutical Industry

As stated in the headline, this is a regulatory affair. When we see the word regulatory, we immediately think of laws and regulations. This section will address the relationship between quality assurance and the regulatory affairs department and how they collaborate to improve the pharmaceutical industry and increase industry profits. Regulatory affairs specifically handle the regulatory side of the pharmaceutical and medicine industries; as such, they also handle the regulation side of QA documentation to secure clearance on any associated regulatory issues. The general scope of work in regulatory affairs includes close collaboration with authorities to guarantee that the product is registered in compliance with regulatory guidelines.[8]

'QUALITY CONTROL'

- To achieve the quality objectives, quality control must be applied throughout the entire process, not just in laboratory operations. Decisions regarding product quality must be made at every level.

Q.C. = Assessment + Testing.

1. Objectives of Quality Control

The objectives of quality control are as follows:

- To increase the company's revenue by improving customer acceptance of the production—that is, by offering features like longer lifespan, increased utility, and maintainability.
- To lower costs for business by minimizing losses from flaws.
- To achieve interchangeability in large-scale production manufacturing.
- To achieve the best possible quality at a lower cost.[9]

2. Benefits and Significance of a Quality Control System

Customers and manufacturers benefit from the quality control program. A high-quality product will, on the one hand, satisfy customer needs, thereby increasing demand and facilitating mass production. Conversely, as a producer of superior products, the business's standing increases.

The following elements demonstrate the importance of quality control facts:

a) Reduction in Costs.
b) Improvement in workers' morale.
c) Maximum Utilization of Resources.
d) Growth in Sales.
e) Customers' Satisfaction.
f) Reduce the Variations.[10]

3. Key Components of QC

a) Inspection: The practise of routinely inspecting products, materials, or services to look for defects, infractions, or deviations from standards of quality.

b) Testing: Performing different measurements and tests to evaluate a product or service's features, functionality, or performance.

c) Documentation and Records: Test, inspection, and remedial action records must be kept in-depth in order to guarantee accountability and traceability.

d) Corrective Action: Putting the right policies in place to deal with any quality problems that have been found and stop them from happening again.

e) Training and Education: Giving employees the tools they need to successfully maintain quality standards.

f) Continuous Improvement: Examining data and feedback frequently in order to identify areas for improvement and enhance the quality management system overall.[11]

4. Quality Control Types

There are four categories of quality control: QC is not the responsibility of a single division or individual. Any supervisor's main duty is to produce work that is of a reasonable caliber. There are three primary sub-areas into which quality control can be separated:

A. Quality control offline.
B. Control of statistical processes.
C. Plans for acceptance sampling.

5. Steps involved in Quality Control

The following are the steps in the quality control procedure**:**

- Create a policy for quality.
- Decide on the standards or specifications based on profit, cost, and customer preference.
- Decide on an inspection schedule and organize the verification process.
- Identify alterations from predetermined criteria or standards.
- To meet standards, make the required adjustments or take corrective action.
- Choose a salvage strategy, meaning how to dispose of the faulty parts—as scrap or to rework them entirely.
- Coordination of issues related to quality.
- Cultivating quality awareness both inside and outside the company.
- Establishing protocols for positive vendor-vendee interactions.[12]

6. Quality Control's Functions and Duties in the Pharmaceutical Sector

It's critical to understand that quality control involves many different roles and duties. Furthermore, it is not the same as quality assurance. While quality assurance looks at the processes used to prevent defects, quality control is particularly concerned with the measurement and analysis processes involved in determining the quality of the product. Quality control uses specialized research instruments to complete fact-finding procedures and conduct analyses. A quality control specialist is in charge of analyzing these measurements in light of industry associations, business regulations, regulatory bodies, and standards established by the quality management department. Quality control will use the information gathered to recommend changes.[13]

‘Quality Assurance Vs. Quality Control'

Although the terms quality assurance and control are occasionally used interchangeably, they have some significant differences. The main focus of quality control is on quality standards, such as ensuring that a product satisfies requirements. Quality assurance is the finalisation of all processes and actions necessary to demonstrate that the requirements for quality are fulfilled.

This distinction could lead quality specialists to transition from quality assurance to quality control as their careers advance. In order to satisfy government inspectors, consumers, and upper management, quality assurance departments and programmes make sure that products adhere to all safety and quality standards. Good control is a component of good assurance.[14]

CONCLUSION

Taking the whole conversation together, it is evident that quality assurance is connected to every department within the pharmaceutical industry and that it is critical to improving each department's operations. As stated in the title, quality assurance is considered the foundation of the pharmaceutical industry and plays a critical role in it. When it comes to quality assurance, they place a strong emphasis on client satisfaction and follow the rules that the government has established. The long-ago thalidomide incident demonstrates blatant shortcomings in clinical trial phase and quality assurance that resulted in such catastrophic events that caused teratogenicity (Phocomelia).

Regarding our focus, we recognize that quality control is a process that is focused on the product. Quality assurance is a procedure-oriented field of work. While quality assurance ensures that the manufacturing process follows standards, quality control ensures that the final product satisfies quality requirements. Consequently, it is possible to identify quality assurance as a proactive process and quality control as a reactive one.[15]

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