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A Review - Quality Assurance & Quality Control

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Abstract: ***Quality Assurance (QA) and Quality Control (QC) are complementary systems ensuring product quality, with QA being process-focused and preventative (building quality in through standards and procedures) and QC being product-focused and reactive (inspecting and testing to find defects in finished goods). Together, QA sets the framework and QC verifies the outcome, both vital for meeting customer needs, adhering to regulations, and delivering safe, effective products in fields from software to pharmaceuticals.***
Keywords: Quality assurance, Quality control.

I. INTRODUCTION

Quality assurance is part of quality management that ensured the pharmaceutical products are of required quality. It includes GMP, GLP, GCP, product design and development. The finished product is tested & checked according to their procedure. The confidence delivered by quality assurance is twice intrinsically to management and extrinsically to clients, government agencies, regulators, certifiers, and third parties Quality control is a procedure which contemplates on performing the quality demand. Quality control intends to distinguish (and dead-on) imperfection in the finished product. Quality control, in consequence, is a reactive procedure. Quality control can be delineated as "section of quality management emphasized on furnishing quality must-have".

A. Quality Assurance

Quality assurance can be delineated as "section of quality management concentrated on delivering confidence that quality must-have will be performed." Functions of QA in Pharmaceutical industry To Ensure: Raw materials used in the manufacturing are approved and procured from approved vendor. All data's are recorded as per c GMP and is reviewed for accuracy and traceability. Procedures are in place for performing the activities, operating and calibrating the equipment [3, 4].

Pharmaceutical Quality Systems (PQS) consist of eight pillars, which are designed to provide high quality finished pharmaceutical products, with QA and PQS working together in synergy (Figure 2). Pharmaceutical companies strive to provide high quality products to enable them to enhance their reputation, maximize profit and to provide high quality drugs to humans and animals. To meet these targets, they rely on well-designed PQS, which involve the coordination of quality through processes, with the aim of producing finished products of the highest quality.[4]

(Figure 2)

B. Quality Control

Quality control is the traditional way of managing quality .Quality control is concerned with checking and reviewing work that has been done. For example, this would include lots of inspection, testing and sampling. Quality control is mainly about "detecting" defective output - rather than preventing it. Quality control can also be a very expensive process. Hence, in recent years, businesses have focused on quality management and quality assurance. Quality control means the" recognition and removal of identifiable causes and defects, and variables from the set standards". When raw materials are received prior to entering production whilst products are going through the production process. When products are finished - inspection or testing takes place before products are dispatched to customers. Then evaluating the product quality through customer compliance.[5]

(Figure 3)

Steps for quality control (QC) and quality assurance (QA) involve defining standards, implementing processes, testing and monitoring, taking corrective action, and continuous improvement. QA focuses on the processes and systems to prevent defects, while QC focuses on identifying defects in the finished product or service.

C. Quality Assurance (QA) steps

1) Plan: Define quality objectives, standards, and requirements for the process.
2) Design and Develop: Create and implement processes, procedures, and guidelines to meet the quality objectives during the design and development phases.
3) Implement: Put the planned processes and procedures into action to ensure consistent quality in the production or delivery of products and services.
4) Train: Ensure the team is trained on the established processes and quality standards.
5) Document and Report: Maintain detailed records of all QA activities, such as audits and process reviews, and report findings to stakeholders.
6) Continuous Improvement: Use feedback and data to identify areas for improvement and implement preventive actions.

D. Quality Control (QC) steps

1) Define Quality Standards: Set clear and specific quality standards for the product or service.
2) Implement Inspection and Testing: Conduct inspections, tests, and other evaluations to check if products or services meet the defined standards.
3) Monitor Quality: Continuously monitor the quality of the products or services being produced.
4) Compare and Identify Deviations: Compare the actual performance against the set standards to identify any deviations or defects.
5) Take Corrective Action: Address the root cause of any deviations to correct the problem and prevent its reoccurrence.
6) Improve Continuously: Use the findings from quality control to make ongoing improvements to the overall process.

Quality assurance (QA) and quality control (QC) have complementary applications: QA is a proactive, process-oriented approach that prevents defects by designing and implementing standards, while QC is a reactive, product-oriented approach that identifies and fixes defects through testing and inspection of the final product. The primary application of QA is to build quality into a process to prevent future errors, while the primary application of QC is to verify that the end product meets requirements before it is released.

E. Quality Assurance (QA) applications

1) Process prevention: QA ensures that the right processes and standards are defined and followed from the start to prevent defects from occurring in the first place.
2) Process improvement: Through activities like process audits, risk assessment, and training, QA aims to systematically improve the processes used by the entire organization.
3) Standardization: QA is used to create and standardize procedures, methodologies, and quality policies for the entire organization, such as by implementing standards like ISO 9001.
4) Confidence building: QA provides confidence that quality requirements will be met by establishing a robust framework for how a product is built.

F. Quality Control (QC) applications

1) Defect detection: QC focuses on identifying and correcting defects after they have occurred through activities like testing, inspections, and reviews.
2) Product verification: QC confirms that a product meets its specified requirements and standards before it is delivered to customers, using techniques like functional testing, unit testing, and system testing.
3) Fixing issues: When defects are found, QC logs them and returns them to the development team for correction, creating an iterative process until the product meets all quality standards.
4) Final product evaluation: QC is the operational part of quality management that applies techniques to verify the quality of the final product.

II. CONCLUSION

Quality assurance can be delineated as “section of quality management emphasized on furnishing confidence that quality must-have will be performed.” The confidence furnished by quality assurance is twofold intrinsically to management and extrinsically to clients, government agencies, regulators, certifiers, and third parties. An alternate delineation is “entire the planned and systematic activities performed within the quality system that can be substantiated to furnish confidence that a commodity or service will perform must-have for quality.”Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer. Quality control is a product-oriented process. Quality control makes sure the end product meets the quality requirements Quality control can be noted as a reactive process.

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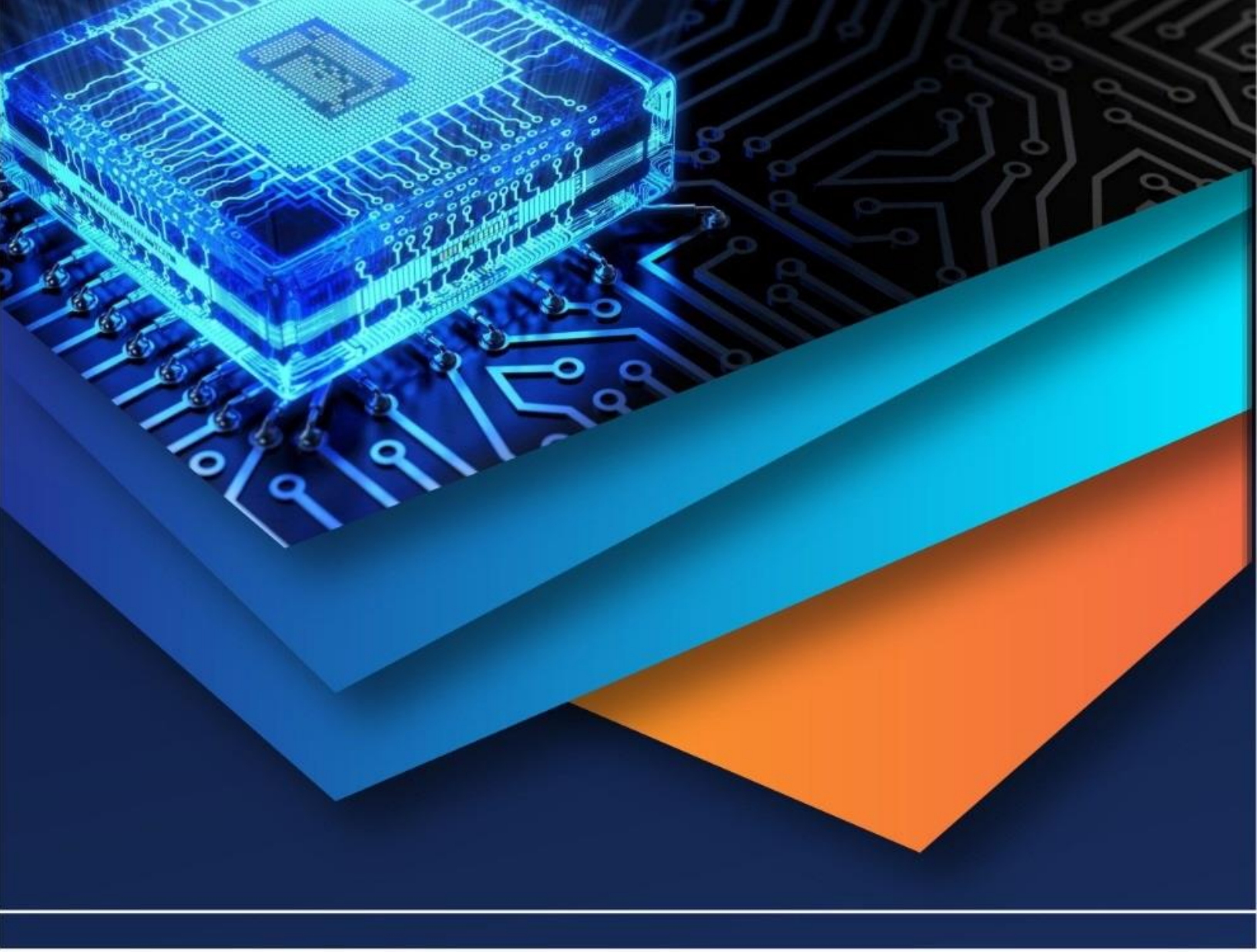

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