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A Review: Quality Assurance and Quality Control

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Abstract: *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 intend 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”.*

Keywords: *Quality assurance, Quality control*

I. INTRODUCTION

A. Quality Management in Pharmaceutical Industry

A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives, Setting organization-wide direction, Engaging staff, Facilitating and identifying training opportunities, improving processes.

Each element of a quality management system serves a purpose toward the overall goals of meeting the customers' and organization's requirements. Ensuring each of the elements of a QMS is present ensures proper execution and function of the QMS-Improvement opportunities , Customer satisfaction from product quality , Internal processes , Data management ,Procedures, instructions, and records , Quality manual .



(Figure 1)

B. 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)

C. 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)

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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