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Commentary

Methods for Pharmaceutical Quality Assurance and Quality Risk Management During Drug Production

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DESCRIPTION

The term Quality Assurance (QA) refers to any elements that could impact the standard of pharmaceutical products that are prescribed. Quality Assurance (QA) a broad notion that encompasses all elements that might affect the standard of care for prescribed pharmaceutical products. The goals of QA are to safeguard patients from mistakenly receiving an inaccurate dosage or contaminated drug, to ensure that prescribed medications correctly have the desired effect for the individual taking them, and to ensure medicines comply with the regulation. Functions of quality assurance is warehousing of incoming components, containers and closures, labels etc. Production record review, process monitoring and control, process checks, final approval or rejection of each batch of drug products before distribution and sale [1].

QA Professionals will evaluate the new medication for drug stability, which entails determining whether the medication or any of its constituent parts degrades under specific environmental circumstances. As a result, recommendations for safe and effective drug storage are established. Risk identification is the systematic utilization of data to pinpoint potential threats to the risk. Data from the past, theoretical analysis, and stakeholder concerns are all examples of information. To ensure that requirements and objectives for a product, service, or activity are met, a quality system must implement administrative and procedural operations. Error prevention is provided through systematic measurement, comparison with a standard, and monitoring of operations in a related feedback loop. In contrast to this, quality control is concerned with the results of the process [2].

Quality assurance includes two principles, right the first time and fit for purpose both refer to whether a thing is appropriate for its intended use (mistakes should be eliminated). Management of the quality of production related services, raw materials, assemblies, products, and components, as well as management, production, and inspection processes, is a component of Quality Assurance (QA). Statistical control, Analyses of both objective and subjective data form the foundation of statistical control. Many organizations prefer statistical process control as a tool for any effort to enhance quality [3].

In order to differentiate between common cause variation and special cause variation, product quality data is statistically charted.

Control can then be applied to the part, either through rework or scraping, or control can be applied to the manufacturing process, ideally removing the flaw before similar parts can be produced in the future. Total quality management, the quality of the contributing components affects the quality of the final goods. According to a study conducted by Forbes Insights in collaboration with the American Society for Quality, it is crucial to measure Quality Culture across the entire organization. A thorough, group-wide culture of quality, according to 75% of senior or C-suite titles, is present at their company. Among those with respectable work titles, however, support for that statement fell to fewer than half. In other words, the further away from the C-suite, the less favourably the culture of quality is perceived [4].

In addition to manufacturing, Quality Assurance (QA) can be used in a wide range of commercial and noncommercial activities, such as design, consulting, banking, insurance, computer software development, retailing, investment, transportation, education, and translation. It includes a generic quality improvement approach that can be used for any of these tasks and creates a quality culture that encourages the achievement of quality. The level of effort, formality, and documentation of the QRM process should be in line with the level of risk. Quality Risk Management (QRM) principles are successfully applied in a variety of corporate and governmental settings, including those that regulate these industries' respective areas of commerce, insurance, work-related safety, public health, and pharmacovigilance. Analyzing, identifying, and evaluating the risk should be done as part of the risk assessment process, and after the QRM plans have been implemented, they should be reviewed. Based on the most recent information available for determining the probability, severity, and occasionally detectability of the risk, the QRM implementation offers defined, understandable, and repeatable techniques to complete QRM process phases. Regulators and the pharmaceutical industry can evaluate, control, communicate, and review risks using QRM tools. Effective QRM implementation can encourage better and informed decisions, which can give regulators more confidence in a company's capacity to manage potential risks [5].

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