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Quality Management and Assurance

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Abstract

The goal of quality management is to maintain a high standard of quality in all areas that directly or indirectly affect customer satisfaction. The establishment of guidelines by QM provides the framework for a low rejection rate and high customer satisfaction. It is crucial to record and examine each step of the process, from creation through delivery. Afterward, these are improved (if possible). The product should surpass the needs of the customer. Thus, QM focuses on the goal of enhancing product quality through organisational tasks. But QM requires on-going adaptation because it is constantly changing. In this context, the ISO 9000 series of standards is the most significant. For instance, DIN EN ISO 9000 deals with the fundamentals and terminology of quality management systems, and DIN EN ISO 9001 specifies the requirements for such a system, in accordance with which businesses can receive certification. Only effects that could be detrimental to the final product's quality are examined in quality assurance, and they are ideally removed.

Keywords: Management • QM • System

Introduction

Quality control, also known as QA, is the process of preventing flaws or irregularities in the products or processing services of a firm to prevent unhappy consumers. A considerably broader concept than quality assurance, the quality management system, or QMS, includes more elements of an organisation. It is a collection of particular procedures or methods used throughout the entire organisation with the goal of meeting consumers' reasonable expectations for goods or services [1].

This makes sure that the quality management guidelines are followed and properly put into practise. There, all business operations are examined to determine whether they adhere to the self-imposed quality criteria. The quality control, in contrast, is concerned with the product's quality. Products that don't conform to the standard are either discarded or reworked until they do. A high quality standard is what quality assurance seeks to establish and uphold [2].

Description

The fundamental components of consistent manufacturing are quality assurance (QA), quality control, and the overarching quality management system. They serve as the foundational tools used by manufacturers to uphold regulatory compliance and make on-going improvements. However, because the life sciences sector is filled with terminology that has a similar ring to it, it is simple to misread their definitions and misunderstand their specific functions. The definitions that follow remove any ambiguity from the duties, differences, and effects of each quality function [3].

There isn't necessarily an adversarial relationship between quality assurance and quality control, despite the fact that the terminology may lead some people to believe such. Instead, they work in tandem to support a manufacturer's overall quality approach. Both functions in life sciences organisations depend on a rigorous quality management system (QMS). A company may use a contemporary QMS software solution that unifies all quality data and processes within a comprehensive platform, depending on where it falls on the digital maturity spectrum, or it may continue to use an ineffective and disjointed collection of spread sheets and file cabinets full of paper documents [4,5].

Conclusion

Tools for quality control are employed proactively and are designed to stop the production of nonconforming goods. Through the development, refinement, and application of well-defined processes that guarantee the quality of a product when adhered to exactly, they are intended to eliminate process variance. This means that the QA department must be separate from operations and manufacturing. QA groups are in charge of conducting on-going audits of the quality system's implementation to stop the production of goods that don't adhere to specified quality standards. To do this, they frequently use quality control tools. According to the U.S. Food and Drug Administration's (FDA) Quality Systems Approach to Pharmaceutical CGMP Regulations guidance, QA activities in life sciences manufacturing are those that principally entail the following:

- Review and approval of all procedures related to production and maintenance.
- Review of associated records.
- Auditing and performing and/or evaluating trend analyses.

Independent authority is what makes QA effective, in accordance with guidelines published by the FDA and International Organization for Standardization (ISO). QA leaders in life sciences companies typically report to a chief operations officer (COO) or other senior director, depending on the size of the organisation and its quality management system, even though the independence of the QA function mandates that it not be subordinate to any other organisational unit. QA leaders must always maintain a certain level of independence from manufacturing processes, regardless of who they report to. QA need not be a separate entity, but there cannot be any conflicts of interest if the integrity of product quality is to be maintained by the overall quality management system.

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