IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
Volume 3, Issue 2, March 2023
Impact Factor: 7.301

Quality Control and Quality Assurance in Pharmaceutical Industry

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Abstract: *Quality assurance can be defined as "the part of quality management aimed at ensuring confidence that quality must be performed". The trust provided by quality assurance is dual internal to management and external to clients, government agencies, regulators, certification bodies and third parties. An alternative definition is "the complete performance of targeted and organized activities within the framework of a quality method that can be documented to provide assurance that the commodity or service will meet the required quality. Quality assurance is comprehensive and does not have to do with the specific necessity of the product being developed. Quality Assurance (QA), Quality Control (QC), and Good Manufacturing Practice (GMP) are major considerations in the manufacturing, distribution, and marketing of pharmaceutical products to ensure their identification, potency, purity, pharmacological safety, and efficacy and effectiveness. (8) The terms Quality Assurance, Quality Control and Good Manufacturing Practices are defined in most international regulatory documents including WHO, USFDA, MHRA,TGA, MCC, etc. The quality of a pharmaceutical manufacturer's products depends on the fact that up to what satisfactory level of QA, QC and GMP system has been adopted in the process of production, distribution and marketing of products during their total shelf life. The main objective of this article is to demonstrate the fundamental difference between quality assurance, quality control and good manufacturing practice (GMP) and to emphasize their necessity for a pharmaceutical product. (8) This overview describes quality by design and identifies some of its elements. Process parameters and quality attributes are identified for every unit operation. The advantages, opportunities and steps involved in Quality by Design for pharmaceutical products are described. It is based on ICH guidelines Q8 for pharmaceutical development, Q9 for quality risk management and Q10 for pharmaceutical quality systems. It also provides the application of Quality by Design in pharmaceutical drug development and manufacturing.*

Keywords: Quality assurance

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