

Quality control and assurance in the Asian pharmaceutical industry.

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Received date: March 21, 2023, Manuscript No. AJPTI-23-98695; **Editor assigned date:** March 23, 2023, Pre QC No. AJPTI-23-98695 (PQ); **Reviewed date:** April 14, 2023, QC No. AJPTI-23-98695; **Revised date:** April 21, 2023, Manuscript No. AJPTI-23-98695 (R); **Published date:** April 28, 2023.

Accepted on 25th April, 2023

Description

The Asian pharmaceutical industry plays a vital role in ensuring the production and distribution of safe and effective medications. Quality control and assurance are vital aspects of this industry, ensuring that pharmaceutical products meet regulatory standards and fulfill their intended purpose. This will discuss the concepts of quality control and assurance in the Asian pharmaceutical industry, highlighting their importance, key components, and regulatory frameworks.

Quality Control (QC) is a systematic process implemented to ensure that pharmaceutical products consistently meet specific quality standards. It involves monitoring and testing various aspects of the manufacturing process, from raw material procurement to the final product's release. The key objective of quality control is to detect and correct any deviations or defects that may compromise the safety, efficacy, or quality of the medications.

Raw Material Testing (RMT) QC starts with thorough testing of incoming raw materials to ensure their quality, purity, and compliance with established specifications. This includes assessing the identity, strength, and quality of Active Pharmaceutical Ingredients (APIs) and excipients.

In-Process Testing throughout the manufacturing process, regular sampling and testing are conducted to verify important parameters such as temperature, pressure, pH levels, and formulation characteristics. This helps identify and rectify any potential deviations that might affect the final product's quality.

Finished Product Testing the final pharmaceutical products undergo comprehensive testing to evaluate their quality, potency, stability, dissolution rate, and microbial contamination. These tests ensure that the medications meet the required standards and are safe for patient use.

Proper calibration of manufacturing equipment is essential for maintaining accuracy and precision during production. Regular calibration and validation activities are conducted to ensure the reliability of equipment used in the manufacturing process.

Quality control laboratories play a pivotal role in the Asian pharmaceutical industry. Equipped with state-of-the-art analytical instruments and staffed by highly skilled professionals, these laboratories perform a wide range of tests to assess the quality and integrity of pharmaceutical products. They adhere to strict protocols

and guidelines, including Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), to ensure accurate and reliable results.

Quality Assurance (QA) encompasses all activities and processes designed to ensure that pharmaceutical products consistently meet the required quality standards throughout their lifecycle. It involves establishing robust systems, processes, and procedures to prevent quality issues and detect them early if they occur. Quality assurance aims to instill confidence in the reliability, safety, and efficacy of pharmaceutical products.

Quality Management Systems (QMS) Quality assurance relies on the implementation of effective QMS that govern all aspects of pharmaceutical manufacturing. These systems define standard operating procedures, document control, change control, deviation management, and risk assessment processes, among others.

Regulatory Compliance QA ensures compliance with relevant regulatory requirements and guidelines. In Asia, pharmaceutical companies must adhere to national regulations as well as international standards such as those issued by the World Health Organization (WHO) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Training and Personnel Competence (TPC) QA emphasizes the importance of competent personnel through continuous training and development programs. Well-trained staff are essential for maintaining quality standards and ensuring compliance with regulatory expectations.

Documentation and Record Keeping Comprehensive documentation is a fundamental aspect of quality assurance. This includes maintaining accurate records of manufacturing processes, test results, quality control activities, and any deviations or corrective actions taken. Documentation provides a traceable history of product quality and aids in investigations and audits.

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Citation: Pruksakorn R. *Quality control and assurance in the asian pharmaceutical industry AJPTI 2023;11(S41):1.*