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Editorial

Role of Quality Assurance in Drug Formulation

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EDITORIAL

Quality is the heart of any drug formulation as it is the main key role for a drug to exhibit its action based on the quality of all the aspects during drug formulation. The quality is mainly dependent on the form and norms given by the regulatory board. The quality is determined by performing certain tests, reports and even documentation of the work process starting from the raw material information to the product reaching out to the pharmacy shops. The main aim of the quality is assuring whether the products are of the required quality or not. Quality assurance plays major role in the drug development or the drug discovery or drug development. The quality assurance includes the quality control as well as the GMP. The quality assurance has the control over the raw material quality, ancillary material quality, operational quality, equipment and instrumental quality, manufacturing and testing quality.

The quality of the formulation is based on with the overall manufacturing process of the product. The fine quality input only can give a fine quality output. The quality of a product includes ISO as well as GMP initially. ISO stands for the International Organization for Standardization, which works for the favor of customer and focuses on the product quality. GMP stands for the Good Manufacturing Practice, which works in favor of the manufacturer and focuses on the manufacturing. According to the Quality Assurance, the products designed and developed in a way that takes an account on requirements of GMP and other codes such as GLP and GCP. All necessary control is made on the starting materials with the intermediate products and bulk products and other in-process controls and calibrations, validations as well. The completed or finished products are checked according to the defined procedures.

This quality assurance involves in the evaluation and analysis of the deviations, specifications, change control during the manufacturing is made, as well as the complaint handling, registration of the documents etc. There are certain factors that influence the quality of the drug formulation. This is basically of three forms such as; pre-analytical, analytical and post analytical qualities. The pre-analytical factors include the right specimen, right collection, right labeling etc. The analytical factors include the laboratory, professionals those who are handling, the reagents, equipment etc. The post analytical parameters include the recording, interpretation of the data obtained during analysis.

The quality assurance activities include the technology transfer, validation, documentation, assurance of the quality of the product, planning for the quality improvements etc. The technology transfer is from the receipt from the research center to the data that is error. The preparation of the master plans is also an important role in the quality of the product. Proper planning is very important. There is a simple difference between the quality assurance and the quality control. The quality assurance is the sum of the objectives with an aim to ensure the quality of the product and that is required by the intended use. Whereas, the quality control is concerned with the sampling and specifications which plays a key role that is interlinked with the quality assurance.

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