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Process of Validation in Pharmaceutical Industry

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DESCRIPTION

Validation is an integral part of quality assurance it is a systematic analysis of facilities, systems, and processes to determine the perform their intended activities as effectively, adequately and consistently as specified. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. Although validation does not in and of itself improve processes, it does ensure that they have been properly developed and are under control.

Process Validation This sort of validation provides recorded evidence, which offers a higher level of assurance that the process will consistently create a product that satisfies all the predefined quality requirements and standards. Additionally, the process validation assures predictability and lowers the possibility of manufacturing issues, both of which improve output of a predefined quality.

The objective of the prospective validation is to prove or demonstrate that the process will work in accordance with the validation protocol prepared for the pilot production trials. Prior to the distribution and sale of the pharmaceutical product, prospective validation should normally be completed. Prospective validation, the validation protocol is executed before the process is put into commercial use. The criticality of these parameters should be assessed by a series of experiments. Concurrent validation it is a procedure where the processing parameters are observed using the current production batches. It provides information on the current batch under investigation and provides only a limited level of assurance regarding the consistency of quality from batch to batch. Concurrent validation means establishing documented evidence a process does what it is supposed to base on data generated during actual implementation of the process.

Retrospective validation conducted fir a product already being marked, and is based on extensive data accumulated over several lots and over time. Retrospective Validation may be used for older products which were not validated by the fabricator at the time that they were first marketed, and which is now to be validated to confirm to the requirements of division 2, Part C of the regulation to be food and drugs act. Retrospective validation is only acceptable for thoroughly documented, well-established processes an appropriate when there have been recent modifications to the operating methods, equipment, or facility. Revalidation in order to confirm initial validation for a periodic review, re-validation is typically done. The evidence from re-validation shows that introduced changes to a process and its environment do not adversely affect its characteristics or the quality of its product.

Validation is a dynamic, ongoing process. The validation process is a rigorous research of how the system and procedures function, ranging from the most basic to the most comprehensive theological aspects. The management of document revision control, training, and process and system upkeep are all included in its scope. Validation evidence has to be visible at the corporate level and appear in the management structure. Building and maintaining quality can be done through validation. A process cannot be controlled effectively without having a complete understanding of its capabilities therefore validation is an extension of the notions of quality assurance. Without validation and controlled processes, it is impossible to produce quality products consistently.

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