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Opinion Article

Process of Validation and Qualification in Pharmaceutical Industry

Hasen Kwenty*

Department of Pharmaceutical Technology, University of Basel, Basel, Switzerland

DESCRIPTION

In essence, validation and qualification are parts of the same notion. Equipment, utilities, and systems are often qualified, and procedures are typically validated. In this regard, validation includes qualifying.

A crucial component of Good Manufacturing Practises (GMP) is validation. Therefore, it is a component of the quality assurance programme for that specific product or process. The creation of products that are appropriate for their intended purpose is the main objective of assurance of quality. There are two fundamental methods for validating a claim: prospective and concurrent validation, which is focused on testing to gather evidence, and retrospective validation, which is based on the examination of accumulated (historical) data. The ideal method of validation is prospective wherever possible. Retrospective validation is no longer recommended and, in any event, is not relevant to the production of sterile products.

The right system, with the right organisational structure, the right infrastructure for documentation, the right amount of staff, and the right amount of money, should be in place to carry out validation tasks on schedule. There should be participation from management and those in charge of quality assurance.

Validation should be carried out by someone with the necessary training and experience. Depending on the validation work to be done, they ought to symbolise various departments. When necessary, periodic review of information and statistics can be used to determine whether periodic verification or renewals is necessary instead of periodic verification or requalification. Validation should be carried out in compliance with documented protocols. The results of the validation should be documented in writing. To show uniformity, validation should be carried out over a period of time, such as at least three consecutive batches. The worst-case scenarios should be taken into account. In-process controls and validation ought to be distinct from one another. Each batch is manufactured while in-process tests are carried out in accordance with the requirements and procedures developed during the development stage.

The suitability of a new manufacturing formula or procedure for routine processing should be demonstrated before adoption. It should be demonstrated that the specified materials and equipment, when used in accordance with the stated process, produce products of the appropriate calibre on a regular basis. Manufacturers need to determine what validation work is required to demonstrate that crucial activities are properly regulated. It is important to validate significant process and equipment changes that could have an impact on the final product's quality. To identify the type and amount of validation needed, a risk assessment approach should be employed.

It ought to be finished before process validation is carried out. The qualification process should be rational and systematic, and it should begin with the design phase of the facilities, furnishings, amenities, and equipment. According to the equipment, utility, or system's function and mode of operation, only Installation Qualification (IQ) and Operational Qualification (OQ) may be necessary. This is because the equipment, utility, or system's proper operation may be regarded as a sufficient indicator of its performance and Performance Qualification (PQ). Then, in accordance with a regular timetable, the system, utilities, and equipment ought to be maintained, watched over, and validated.

Machinery, devices, and additional instruments used in production and quality control need to be calibrated and verified on a regular basis, as appropriate. The right credentials and training should be provided to those who perform calibration and preventative maintenance. A calibration programme should be accessible and give details such as calibration standards and limitations, responsible parties, calibration intervals, records, and measures to be done when errors are found. Standards employed in the calibration should be traceable.

Correspondence to: Hasen Kwenty, Department of Pharmaceutical Technology, University of Basel, Basel, Switzerland, E-mail: kwentyhasenHK@gmail.com

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