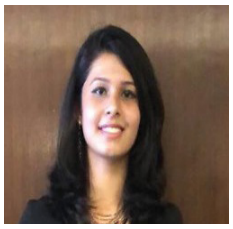
United Journal of Quality and Validation

KEY ASPECTS OF QUALITY AND VALIDATION IN PHARMACEUTICALS

Simrita Chawla*

Clinical research coordinator in CMC Ludhiana, India



Author Biography

Simrita Chawla

Simrita Chawla has completed her M.sc clinical research recently. She is currently working as a clinical research coordinator in CMC Ludhiana. Simrita Chawla did her bachelor's in biotechnology (hons.) from Punjab University with throughout distinction.

Simrita Chawla has a an experience of one month internship at Jaypee University solan and three month experience of clinical pharmacology at Max Hospital Dehradun

*Corresponding Aurthor: Simrita Chawla

Clinical research coordinator in CMC Ludhiana, India.

Article Information

Article Type: Editorial

Article Received: 06-18-2021

Article Accepted: 06-20-2020

Article Published: 06-29-2021

Vol:2, Issue:1

OPEN ACCESS

EDITORIAL

Every pharmaceutical product requires this procedure of quality and validation .In specific if we talk about research products we bring in the GMP practices while manufacturing the product. Most investigational products need to comply with ISO 9001 i.e. the International Standard that specifies requirements for Quality Management System. Thus ensuring good Quality management for a product/ device is the aim. Validating the product so as to confirm the product/device has met the requirements for a specific intend use or application gives the company its baseline standard and the heights to gain people's trust. The state to which the companies can hold up the reputation is mainly through these standard procedures. The purpose of these procedures is to check for chemical and microbiological contamination. Quality check is a continuous process. It is not an end step process. Various process are are employed for this method. Ensuring best Quality practices would encourage employees to create high quality goods which will lead to better marketing. The added advantage is that resources can be used in a cost effective way and inspection cost will be reduced. Validation is a documented evidence which can be performed effectively and reproducibility to produce a medicinal product. It is a process to provide information and evidence that the transformation of inputs produced the expected and right result. Good manufacturing Practices (GMPs) for finished pharmaceuticals (21 CFR211) and of GMP regulations for medical devices (21CFR820) and thereof applies to the manufacture of both drug products and medical devices. Quality and Validation can really be a stepping stone for a company's success. A properly designed system will provide a high degree of assurance that every step process and change can be implemented properly and ethically . and that very batch is able to meet its specified requirements. Not implementing the Quality and Validation procedures not only affects the company's stake it's a overall loss for the employees. The economic loss market loss everything a company might not desire in their lifetime. These procedures deepen the understanding of processes; decrease the risk of preventing problems defect costs, regulatory non compliance. The regulations set out an expectation that the different part of the production processes are well defined and controlled, such that the results of that production will not substantially change over time. The goal is to make sure that standard is maintained at every step. These procedures are basically performed in a step wise manner with strict vigilance. Inspections from the regulators take place in between. There compliance to these procedures is of utmost importance. For a company to hold the place in the market this quality management and validation is necessary.

Citetion: Simrita Chawla / United Journal of Quality and Validation 1(2021): 1-1