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Editorial

Pharmaceutical Quality by Design (QbD) in contrast to traditional regulatory system of quality by testing (QbT)

The concept of QbD was mentioned in the ICH Q8 guidance (3), which states that "quality cannot be tested into products, i.e., quality should be built in by design".

(QbT) regulatory framework quality is ensured by raw material testing, drug substance manufacturing, a fixed drug product manufacturing process, in-process material testing, and end product testing. The quality of raw materials including drug substance and excipients is monitored by testing. If they meet the manufacturer's proposed and FDA approved specifications or other standards such as USP for drug substance or excipients, they can be used for the manufacturing of the products. Under the traditional regulatory evaluation system, all products are treated equally without regard to the risk to the consumer. This has the effect of placing too much review time on low-risk products and more significantly, takes away needed resources from the review of high-risk products.

Product quality and performance are, in the traditional framework, achieved predominantly by restricting flexibility in the manufacturing process and by end product testing. The present regulatory review system places little or no emphasis on how the design of an effective and efficient manufacturing process can ensure product quality. As a result, the complexities of process scale-up, particularly for complex dosage forms are often not recognized. Product specifications often are derived using test data from one or more batches (often not at production scale), and mechanistic understanding does not play a significant role in this process. Finally, the burdensome regulatory requirement of supplements imposed on manufacturers for executing minor and incremental changes to manufacturing processes and controls inhibits continuous improvement and strategies for the implementation of continuous "real time" assurance of quality.

Pharmaceutical QbD is a systematic, scientific, risk-based, holistic and proactive approach to pharmaceutical development that begins with predefined objectives and emphases product and processes understanding and process control. It means designing and developing formulations and manufacturing processes to ensure predefined product quality objectives. QbD identifies characteristics that are critical to quality from the perspective of patients, translates them into the attributes that the drug product should possess, and establishes how the critical process parameters can be varied to consistently produce a drug product with the desired characteristics. In order to do this the relationships between formulation and manufacturing process variables (including drug substance and excipient attributes and process parameters) and product characteristics are established and sources of variability identified. This knowledge is then used to implement a flexible and robust manufacturing process that can adapt and produce a consistent product over time. Thus, some of the QbD elements may include:

- Define target product quality profile
- Design and develop product and manufacturing processes
- Identify critical quality attributes, process parameters, and sources of variability
- Control manufacturing processes to produce consistent quality over time.

In March 2011, the European Medicines Agency and the FDA announced a joint pilot programme for parallel assessment of QbD application – an important step towards QbD harmonisation in practice. Hence the concept of QbD is introduced in all Pharmaceutical companies to attain the product quality.

In contrast to the traditional regulatory system of quality by testing (QbT), pharmaceutical QbD is a systemic approach to pharmaceutical development that begins with predefined objectives and emphases product and processes understanding and process control. It means designing and developing formulations and manufacturing processes to ensure predefined product quality. Understanding and implementing QbD will enhance and modernize the regulation of pharmaceutical manufacturing and product quality. It will transform the Chemistry, Manufacturing, and Controls (CMC) regulatory review into a modern science-based pharmaceutical quality assessment.

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