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Short Communication

Are We Doing Justice to the 'Quality by Design'?

Dhawal Chobisa[1,2]*

[1]*IPDO Innovation Plaza, Dr. Reddy's Laboratories, Hyderabad, India*

[2]*Department of Industrial and Physical Pharmacy, College of Pharmacy, Purdue University, West Lafayette, USA*

***Corresponding Author:** Dhawal Chobisa, IPDO Innovation Plaza, Dr. Reddy's Laboratories, Hyderabad, India and Department of Industrial and Physical Pharmacy, College of Pharmacy, Purdue University, West Lafayette, USA.

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Abstract

'Building quality into pharmaceutical drug products' instead of 'end product testing' was focus of implementation of quality by design (QbD). Quality pharmaceutical drug products should be able produce desired pharmacological effects for intended time. Sustained manufacturing processes lead to decreased variability and reliable drug products quality. Quality by design and six sigma framework offers various tools and techniques to achieve the goals. A few techniques such as design of experiments, have been explored widely by researchers. However, various techniques are yet to be used for effective drug product development. This paper briefly describes about a few tools viz. quality function deployment (QFD), failure mode and effects analysis (FMEA), and process capability analysis, that can be used at various stages of drug products development.

Keywords: Quality by Design (QbD); Pharmaceutical Drug Product Development; Design of Experiments (DoE)

'Quality by Design' or 'QbD' is commonly used amongst researchers in pharmaceutical sector from more than a decade. It has been used as a 'term' rather than a 'concept'. The intension of implementing QbD in pharmaceutical drug product development is to build the quality into the product. QbD based development is not restricted to apply QbD concepts at specific stages of drug product development, rather it goes hand in hand with all stages right from the beginning to the end. It should start with selection of product design and end with achieving the desired outcomes. There are multiple tools available to help implement QbD concepts effectively at each step of drug product development. A few examples might be identification of patient's needs, to describe the cost to benefit matrices, to develop the right process and process controls that lead to quality products, risk identification and mitigation approaches, and continuous improvement [1-4].

According to Janet Woodcock, the director of the Center for Drug Evaluation and Research (CDER), a high-quality product should be free from contamination and able to deliver the therapeutic benefits reliably [5]. This includes three major considerations- thorough risk assessment to prevent future failures, robust process development to minimize the batch to batch variability and continual improvement for sustained quality for long term. Figure 1 shows the QbD framework with a few examples of tools that can be used at each step. QbD framework with integration of six sigma tools might offer strong foundation of robust drug product development [1,5].

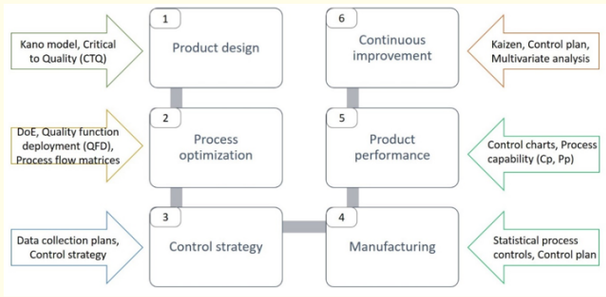

Figure 1: QbD framework with tools and techniques to be used at various stages for pharmaceutical drug product development.

Quality function deployment (QFD) is a tool that helps connect voice of customer or quality target product profile to the technical requirements and to better understand the processes. Failure Mode and Effect Analysis (FMEA) is a technique to identify and eliminate potential failures. It prioritizes the risk of failure based on its severity, occurrence and detectability.

Many researchers use QbD and Design of experiments (DoE) interchangeably. QbD is not DoE, it is much more than that. DoE is a technique widely used in formulation development and analytical research that helps to perform structured experiments. A quick search on scholar with the key word 'design of experiments' and 'design of experiments + quality by design' give 6,530,000 and

5,370,000 results respectively. The numbers indicate that more than 80% of the articles use the term quality by design with design of experiments. Application of DoE during is helpful in drug product development. In addition to DoE, other techniques should be explored and routinely used to better develop the quality drug products [1,6].

Sustainability is very critical aspect in manufacturing. Process capability is the ability of a process to consistently deliver the product with intended quality. Process capability indices (short term- Cp and Cpk; long term- Pp and Ppk) might be of great help to determine the process performance over time.

As a healthcare community, how do we see the future of QbD? On one hand, we want to develop better, faster, and affordable drug products that can improve the patient's quality of life, on the other hand, implementation of pharmaceutical QbD demands resources that makes the drug development process challenging. We must balance both aspects without compromising the safety and therapeutics of drug products using scientific approach and implementation of best practices of quality by design.

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