Exploration Quality By Design In Pharmaceutical Industries

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Abstract

Quality by Design (QbD) were introduced in international guidelines intended for the pharmaceutical industry between 2009 & 2012. Joseph M. Juran developed the concept of quality by design. Quality by design is a strategic approach employed in various industries including pharmaceuticals, manufacturing, product development, to endure the consistent delivery of heigh quality product. The "Research & Development Quality by Design" model has been developed on input from the pharmaceutical industry, regulatory agencies, and patient feedback. The QbD is a systematic scientific approach aimed at meeting the needs of the patient in the desired and targeted quality and aiming to produce the same quality pharmaceutical product in this direction.

Keyword: *Analytical technology, Risk management techniques, Risk assessment.*[1]

1. Introduction

The International Conference on Harmonization (ICH) definition of the design space [1] expresses the view that if a process is not managed to account or input variability, it will affect the quality of the final product (output). The ICH has issued regulations such as ICH Q12, ICH Q11, ICH Q10, ICH Q9, and ICH Q8, that specify the requirements for creative and scientific design as well as quality perception in order to ensure consistent product quality [1].

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2. Control Strategy

A carefully around control system that guarantees (exceptional) process efficiency and product quality. Based on familiarity with the latest technologies, practices. A few of the numerous elements and criteria that are covered in controls include drug substances, ingredients, equipment, operational conditions, in-process controls, product specifications, monitoring methods, and frequency (ICH 2008b, 2008a).

3. Design Space

It has been demonstrated that quality assurance can be provided by the interaction of process parameters and multidimensional combination and input elements (such as material characteristics) in design space (ICH, 2008B) [1].

4. Principles of QbD

The QbD principles emphasize a methodical procedure that begins with predetermined objectives and incorporates scientific knowledge and risk management techniques while creating new medications. Based on this emphasis, the current paper explores approaches to analytical method development and QbD principles. Quality by design (QbD) is a complete research methodology that focuses to improve product quality. It is thorough, methodical, scientific, risk-based and comprehensive.

5. QbD

Design-based quality is a systematic approach to manufacturing that starts with clearly defined goals and prioritizes understanding the product and process. Modern technology and risk management are its cornerstones (ICH, 2008a) [1].

6. Critical elements of QbD - PAT education and training

Although they can be mixed and matched as needed, the general module (GM1) ought to be required for all training programs. To guarantee that there is enough, the technical modules include a large amount of "hands on" content [9].

7. Manufacturing processes

Every product is the outcome of a particular manufacturing process, and it is important to thoroughly comprehend how each affects the final quality features. Typically, a manufacturing process comprises of multiple unit operations, all of which produce copious amounts of multivariate data. This section's primary goal is to analyze which manufacturing unit processes were examined more frequently in the bibliographic corpus and to pinpoint pertinent discoveries that fall under the purview of QbD [3].

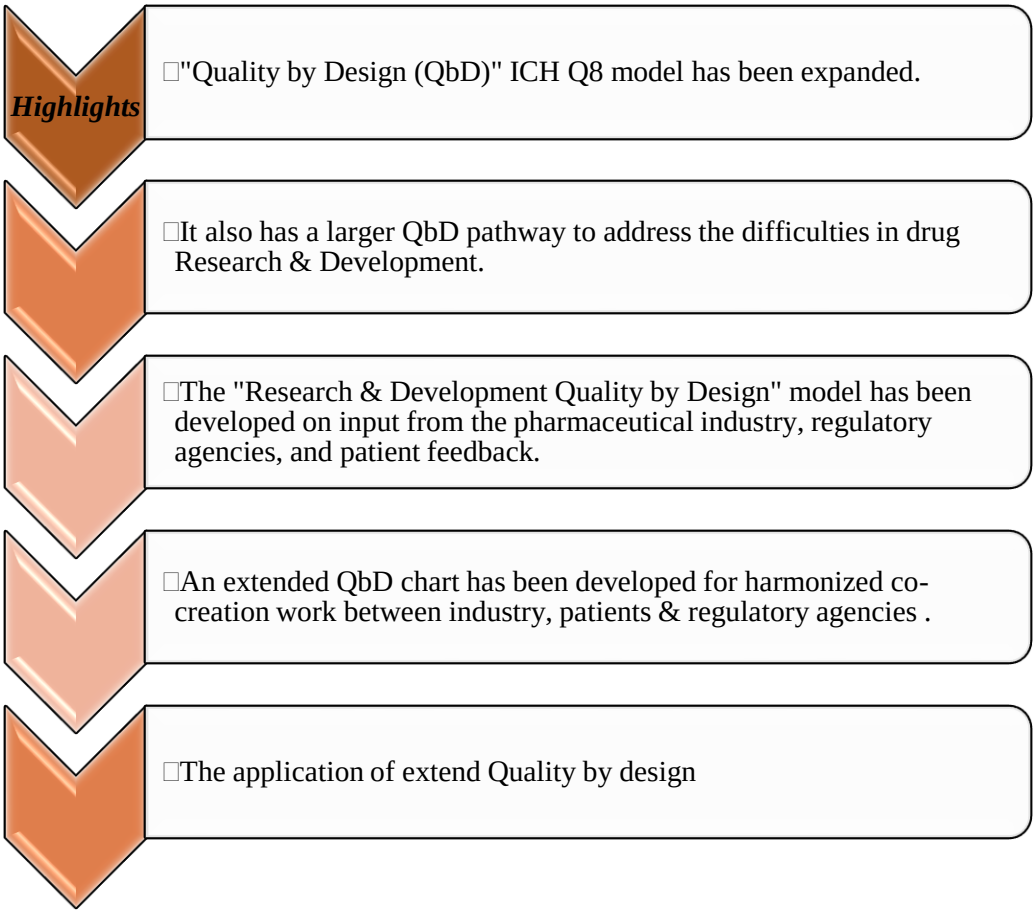

Figure 1. Highlights of Quality by Design [2].

8. Quality By Design steps

Finding the product's intended use and the right quality to fulfill it is the first stage in the design and quality approach. The data and information required for identify essential quality attributes are assessed in second step. Developing process is assessed using ideas like risk management, analytical technology, and experimental design at the next step. Furthermore, in this step, a design area that guarantees quality is established. The design and identification of control plan come next. A final phase provides life cycle and continuous improvement through the integration of product process information and quality risk management [6].

9. Process Analytical Technology

Design, evaluating, & managing the essential performance quality attributes of processes and materials in the process using real time measurements to the guarantee quality of finished product is what FDA (2004) defines as process analytical technology. In this technique, the phrase "analytical" often refers to an integrated application of risk analysis, mathematics, chemistry, physics, and microbiology [6].

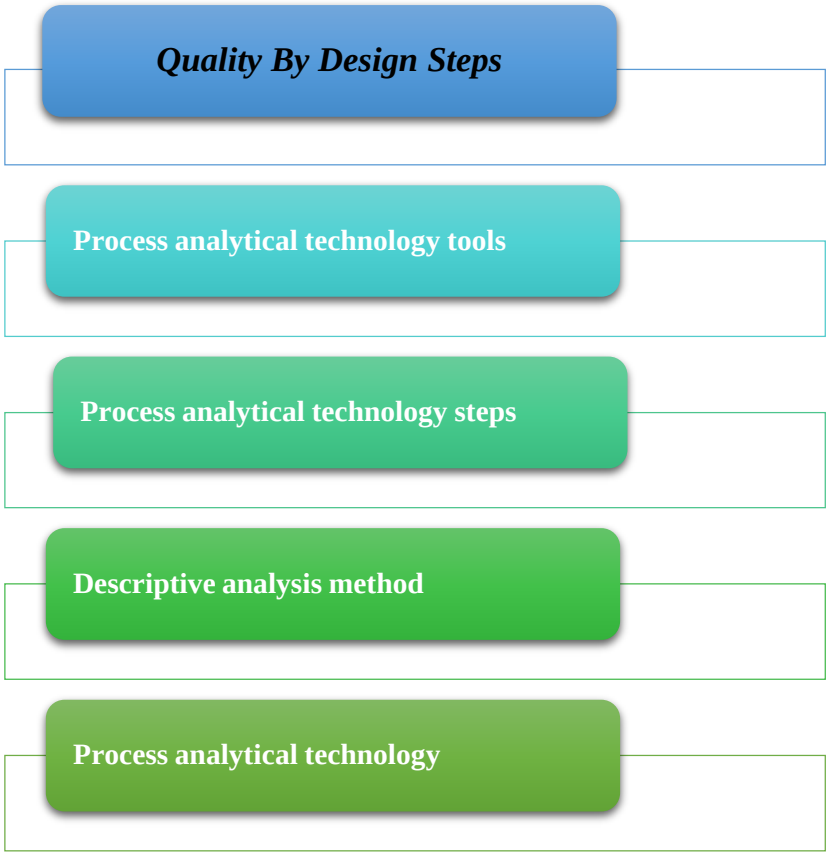

Figure 2. Steps involved in Quality by Design [6].

11. Process Analytical Technology Tools

PAT tools comprise highly variable data acquisition, information management and continuous improvement tools and process analyzers and process control tools, tools for data collecting and analysis. In PAT applications, the pharmaceutical industry commonly uses (RAMAN) Raman Spectroscopy, (NIRS) Near Infrared Spectroscopy, (UV-VIS) Ultraviolet-Visible Region Spectroscopy, & Nuclear Magnetic Resonance Spectroscopy (NMR). When producing solid oral dosage forms, NIRS is very useful for determining process parameters, limit compliance, optimal value, & process termination points in a variety of units, including drying, mixings, granulations, and coating [6].

12. Descriptive analysis method

Our concept is to use common quality characteristics, including quality target, quality variation, and dangers, to characterize the end products of different process parameters, notwithstanding the complexity and diversity of production processes, from the perspective of QbD laws [7].

13. Conclusion

In order to increase product quality from the beginning of manufacturing to the conclusion, quality by design is a crucial technique in the business. It is extremely important to make sure that the ICH guidelines serve as the foundation for new product development. All crucial formulation characteristics and process factors must be identified, and the degree to which any deviation may affect the final product's quality must also be established, according to QbD .

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