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Review Article

From concept to compliance: The role of QbD in modern product development

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ABSTRACT

Pharmaceutical development is revolutionized by the Quality by Design (QbD) strategy, which replaces conventional trial-and-error procedures with a systematic, science-based approach that ensures product quality, safety, and efficacy. This article offers a comprehensive description of the key elements and instruments required to execute QbD, as specified by regulatory recommendations like ICH Q8 (R2) and ICH Q9. The construction of a Target Product Quality Profile (TPQP), which acts as a dynamic summary of the quality attributes required to achieve the intended product quality, safety, and efficacy, is the basic concept of quality-based development (QbD). Critical quality attributes, or CQAs that are, are important qualities that need to be maintained within specified limits in order to ensure the quality of the final product. These are connected to Critical Process Parameters (CPPs) and Critical Material Attributes (CMAs) via risk assessment techniques like Fault Tree Analysis (FTA) and Failure Mode Effects Analysis (FMEA). An essential component of Quality-Based Development (QbD) is Quality Risk Management (QRM), which offers a framework for evaluating and controlling risks over the course of a product's existence. To identify and reduce potential risks, a variety of tools are used, such as Hazard Analysis and Critical Control Points (HACCP), FMEA, and FTA. The foundation of Quality-Based Design (QbD) is the idea of Design Space, which is described as the multifaceted collection of variable inputs and process factors that ensures quality assurance. Another crucial element of QbD is Control Strategy, which consists of a series of planned controls based on knowledge about present products and processes. The concepts of lifecycle management and continuous improvement highlight the significance of implementing a pharmaceutical quality system at every stage of the product lifecycle in order to encourage innovation and continuous improvement while assuring regulatory compliance. The principles of Quality by Design (QbD) are applied with the use of several technologies, including Process Analysis Technologies (PAT) and Design of Experiments (DOE). These technologies allow for the real-time monitoring and management of critical process parameters, which reduce manufacturing unpredictability and increase product quality.

1. Introduction

The process of developing formulations and manufacturing techniques ensuring predefined product attributes is known as "quality by design," or QbD. Through several initiatives,

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such as ICH Q8[1], Q9[2], and Q10[3] , as well as the new regulation papers Process Analytical Technology (PAT)[4], FDA's cGMP for the 21st Century[5], and others, the pharmaceutical sector is presently implementing the quality by design (QbD) idea. Quality by design, or QbD, was designed as an integrated strategy to achieve the USFDA's goals of offering qualities-enriched and streamlined drug development processes with rapid modifications and better scaled-up post market reviews. For this process, the Guidelines Q8, Q9, and Q10 provided an integrated structure. ICH Q8 is mainly concerned with laying out the foundations of QbD.[6]

Since cGMP regulations aim to replace the FDA's chemical, manufacturing, and control (CMC) review procedure, QbD was incorporated into the agency's systematic scientific and risk-based pharmaceutical quality assessment system.[7]

2. ICH Guidelines

1. ICH Q8 (R2) – Pharmaceutical development.
2. ICH Q9 – Quality risk management (QRM).
3. ICH Q10 – Pharmaceutical quality system.

Here, Figure 1 illustrates how the previously mentioned rules function as strict specifications for maintaining product quality and production procedures in order to reach the intended QbD state. "Quality cannot be tested or inspected into a finished product; rather, it must be built into a product or manufacturing process," in accordance with ICH Q8 (R2).[8]

2.1. Definition [ICH Q8 (R1)]

A methodical approach to development that begins with predefined objectives, concentrates on comprehending the product and the process, and uses high-quality risk management and excellent science to govern the process.[9]

3. Definition [FDA PAT Guidelines, Sept. 2004]

A strategy for organizing, assessing, and overseeing manufacturing in order to ensure the final product's safety by promptly monitoring critical aspects of new and in-process materials and procedures' performance and quality.[9,10]

According to ICH Q9, "The degree of formality, documentation, and effort required by the QRM process should correspond to the degree of risk, and the assessment of the risk to quality should be based in scientific knowledge that ultimately relates to patient safety".

Facilitate continuous medication product improvement, create and uphold a condition of control, and achieve product realization are the three primary objectives of ICH Q It offers a thorough model for an effective quality system for pharmaceuticals based on ISO standard ideas, as well as relevant GMPs.[11]

1. Quality by Design (QbD) procedures are gaining popularity among regulators and the pharmaceutical industry, as outlined in ICH standards Q8–11. QbD is a knowledge system that makes pre-defined features for product quality and process control possible.
2. Real-time process modifications within predetermined quality limits and in a way that can be applied to various products and facilities are made possible by QbD and process analytical technology (PAT). Compared to traditional end-product testing, these in-process control techniques can offer a higher degree of quality assurance and enable real-time release testing of pharmaceutical products.[12]

Figure 1: ICH Concepts for QbD

4. QbD Concept's Historical Aspects

The emphasis on quality implementation in the pharmaceutical industry is a result of the key works in quality development and inspection done by Joseph M. Juran, W. Edwards Deming, Dr. Kaoru Ishikawa, and Phillip B. Crosby. In the early 1970s, American engineer and pioneer Joseph M. Juran published his well-known book "Juran on Quality by Design," which set the objective of quality preplanning as opposed to its accidental occurrence. The principles of quality management in processes and products were outlined by Juran in his theories of Juran's triology.[13] A product's quality may be summed up in two words, according to Juran: "features that meet customer satisfaction" and "freedom from deficiencies."[14]

Juran's triology concept is seen in Figure 2.

Building and developing products and procedures to satisfy client needs is a component of quality planning.

Figure 2: Juran's triology

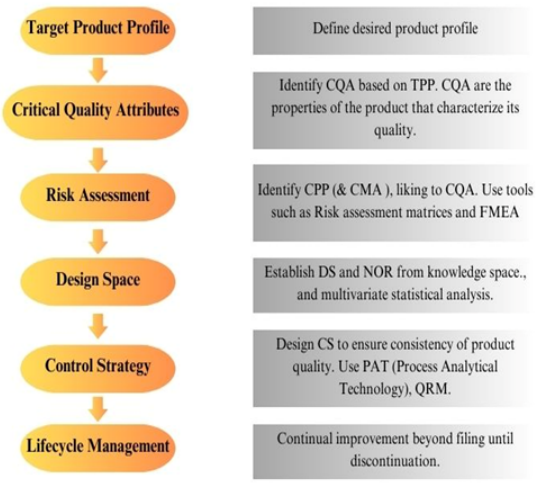

Figure 3: Components of drug development [ICH Q8 (R2)]

Comparing, assessing, and identifying quality performance and goals are all part of quality control. Raising quality performance to meet customer needs and satisfaction is the process of quality improvement.

In order to meet the predetermined goals for product quality, it basically requires planning and creating the product as well as the manufacturing process.[15] From the perspective of the patient, QbD finds qualities that are crucial to quality and transforms them into the CQAs (critical quality attributes) that the product must have. It also defines the boundaries, or design space, for the significant material attributes (CMAs) and key process parameters (CPPs) that have an impact on the CQAs. It is decided to calculate the CMAs and CPPs using the new risk-based method. The technique is invariant inside the design space and produces the intended outcome.[16] [18] Design of experiment (DoE), a statistical method for enhancing CMA and CPP variable choices, is used to obtain design space. Making use of this data results in a manufacturing procedure that is flexible and adaptive and can consistently manufacture a product over time.

QBD includes the following essential components:

1. The TPQP, or Target Product Quality Profile
2. Ascertain the essential qualities (CQAs).
3. Perform risk analysis and link process parameters and raw material properties to CQAs.
4. Risk Assessment.
5. Develop a design space.
6. Design and implement a control strategy.
7. Oversee the life cycle of a product, including ongoing development.

5. The TPQP, or Target Product Quality Profile

TPQP is defined as "prospective and dynamic summary of the quality aspects of a drug product that, in an ideal world, will be achieved" and is used to guarantee that the intended level of quality, which leads to the drug product's safety and effectiveness are realized. This covers the pharmacokinetic properties (like dissolution and aerodynamic performance) appropriate for the dosage form being developed, the dosage form and route of administration, the strength(s) of the dosage form, the purpose of therapeutic moiety release or delivery, and the drug product quality criteria (like sterility and purity) appropriate for the intended marketed product. The QbD paradigm introduces new ideas to the TPP concept and its application.[4]

TPP provides the following framework[17] for product design:

1. Dosage form;
2. Route of administration
3. Strength, maximum, and minimum drug release/delivery; and
4. Pharmacological characteristic.
5. Standards for drug product quality
6. The grace of pharmaceuticals

6. Critical Quality Attributes (CQA)

The definition of CQA provided in ICH Q8 is "a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality." To construct a final product with the intended CQAs, one needs comprehend the concepts of critical material attributes (CMAs) and critical process parameters (CPPs), which are described by the QbD method.[18] A CMA is an

attribute or feature of an input material that is physical, chemical, biological, or microbiological, and that need to be contained within a certain distribution, range, or limit. to ensure the required degree of output material quality.

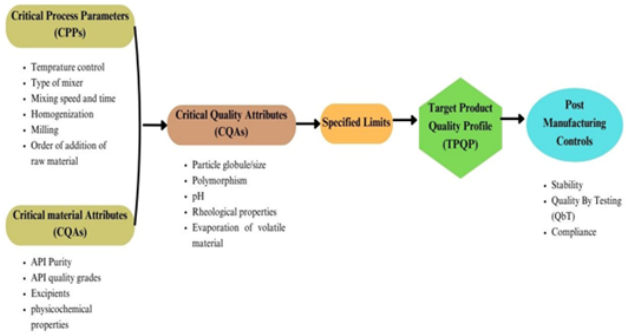

Figure 4: Factors affecting drugproduct CQAS

7. Quality Risk Management (QRM)

The manufacturers for the study that will be conducted must be chosen carefully. It aids in connecting process characteristics and quality features to CQAs. The assessment of the quality risk ought to be established in both scientific understanding and the therapeutic advantage to the patient.[19] A quality risk management approach that offers a framework for starting the risk process is provided by the ICH Q9 recommendations. There can be a high degree of assurance that the analytical method will fulfill the TPQP in all use circumstances with the implementation of QRA, a science-based procedure that may help identify CPPs and hence eliminate risk. As a result, based on prior experience and initial testing, many parameters can be safely eliminated by using QRA techniques, such as failure mode effects analysis (FMEA) and Ishikawa diagrams.

7.1. Failure mode effects analysis (FMEA)

A failure mode and effects analysis (FMEA) assigns a risk priority number (RPN) to each element based on its likelihood of occurrence (probability), impact on pharmaceutical findings (severity), and detectability (difficulty of detection). Subsequent studies can then assess factors whose RPN is higher than a certain threshold, while factors whose RPN is lower can be excluded from additional research.[2] Ishikawa diagrams divide hazards into various groups, such as those related to measurements, equipment, materials, procedures, human factors, and laboratory environment.

7.2. Fault tree analysis (FTA)

As shown in Figure, a fault tree analysis is performed to connect a possible failure mode and likely causes to the possibly essential quality characteristic "content uniformity." The four main causes—raw and intermediate material quality, processing parameters, equipment and design parameters, and environmental factors were carefully listed to build an Ishikawa diagram.[20]

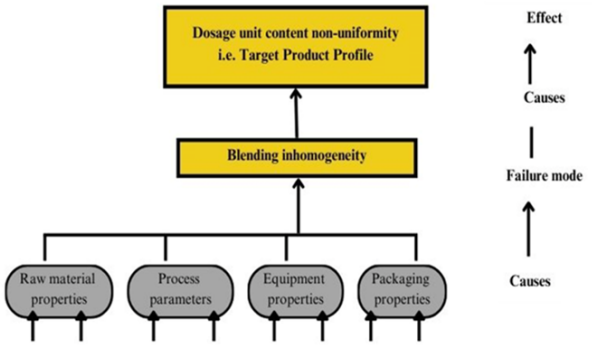

Figure 5: Variable content uniformity fault tree analysis for risk identification

7.3. Hazard analysis and critical control points (HACCP)

For the purpose of managing and observing by using certain parameters, HACCP offers detailed documentation that demonstrates product or process understanding. Any concerns regarding the quality and safety of a product or method goes into the concept of risks. It includes risk assessment, selecting key management objectives, setting critical boundaries, creating a framework for monitoring key management objectives, and creating a system for maintaining records. Biological, chemical, and physical hazard risk can be established and managed with this.[18]

8. Design Space (DS)

Design space is defined by ICH Q8 (R2) as, “the multidimensional collection of input factors (material characteristics) and process parameters that can ensure quality assurance”.[1] Design space explains how process inputs and CQAs are related. The ICH efforts provide that working inside a design space does not require post-approved modifications. Therefore, the applicant can operate under a design space without undergoing additional regulatory review or approval by submitting an appropriate design space to the FDA.

Changes that are made outside of the design space are often regarded as changes and would start the post-approval change procedure. Note that QbD and design space are not interchangeable words. Although a formal design space establishment is not a prerequisite for a successful QbD implementation, it is still possible to obtain and apply knowledge of the product and process. Figure 6 provides

an overview of design space. All factors related to the product and process, as well as their impact on CQAs throughout the various operational units involved in the manufacturing process, should be known in the design space. In simpler terms, the design space must to provide comprehensive details regarding the established acceptable ranges of every CPP and the corresponding CQAs. Design space would typically depend on the equipment and scale up, showing more differences between laboratory and commercial scales. Design space is typically established through the use of proper experiment design in multivariate analysis between CPPs and CQAs. The allowable operating region may be severely constrained if a greater number of CPPs have an effect on several CQAs. The critical processes of product conceptualization and appropriate TPQP identification are required for the design space development.

Research on procedure development and risk assessment should demonstrate the relationship between input components and CQAs. It gives selecting the factors to include in the design space and developing a variety of factors that ensure a uniform level of product quality. The information required to develop a design space is provided by established acceptable ranges obtained from univariate experimentation data. During the design space creation process, multivariate mathematical models can be utilized to prospectively analyze historical production data for goods that are already in production.

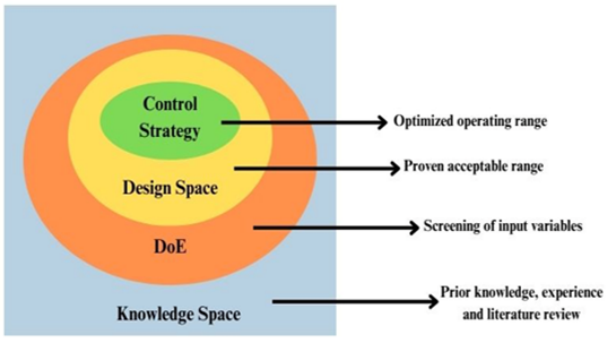

Figure 6: Design space

9. Control Strategy (CS)

The definition of "control strategy" is "a planned set of controls that ensures process efficiency and product quality, derived from current product and procedure understanding." It helps to maintain expected quality and prevent errors.[21]

The following components in the control strategy:

1. Protocol safeguards.
2. Process monitoring;
3. Lot release testing; and
4. In-process controls.
5. Testing for characterisation
6. Testing for comparability, and
7. Testing for stability.

It takes an organized approach with a multidisciplinary team of professionals to design a Control Strategy. It also involves building controls for process equipment and connecting pharmaceutical development to production.

10. Lifecycle Management and Continual Improvement

According to ICH Q10, applying Q10 across a product's lifespan should promote innovation and ongoing improvement while strengthening the relationship between the manufacturing and pharmaceutical development processes. Changes to the design space's processes won't need to be reviewed or approved under the QbD paradigm. With fewer post-approval submissions, process gains in terms of consistency and throughput could therefore occur within the product life cycle. A deeper understanding of the manufacturing procedure would enable ICH Q9-compliant risk assessments that is more informed about the consequences of process alterations and manufacturing variations (excursions) on product quality, in addition to offering regulatory flexibility.[1,2]

11. Tools of Quality by Design

11.1. Design of experiment (DOE)

In order to ascertain the extent of the impact of each input or combination of inputs, DOE refers to an organized analysis in which inputs are altered and differences or variations in outcomes are measured.[22] It's a methodical and structured way to figure out how different elements affect a process's results. When DOE is used in a pharmaceutical process, the parameters of the process (such as speed and duration) and the characteristics of the raw materials (such as particle size) are the factors, and the outputs are the critical attributes (CQA) (such as blend homogeneity, tablet hardness, thickness, and friability). It is not feasible to experimentally study every one of the numerous input, output, and process parameter combinations that each unit operation contains. Using their prior knowledge and expertise in risk management, scientists must choose significant output and input variables as well as process components for DOE investigations.

The results of DOE can be utilized to ascertain the ideal conditions, the significant components that impact CQAs most and least, as well as specifics like the existence of interdependencies and factor synergy. The permitted range of CQAs can be used to determine the design space of CPPs. Before thinking about scale-up, extra testing may be

required to confirm that the model developed at the small level is predictive at the large scale. This is because certain important variables are size-dependent while others are not. The operational range of scale-dependent critical process parameters will need to be adjusted for scale-up. Given that the majority of pharmaceutical companies frequently employ the same technology and excipients, previous experience may be crucial in this situation. Pharmaceutical scientists can often define crucial material characteristics, processing parameters, and their performance ranges by using past experience.[23]

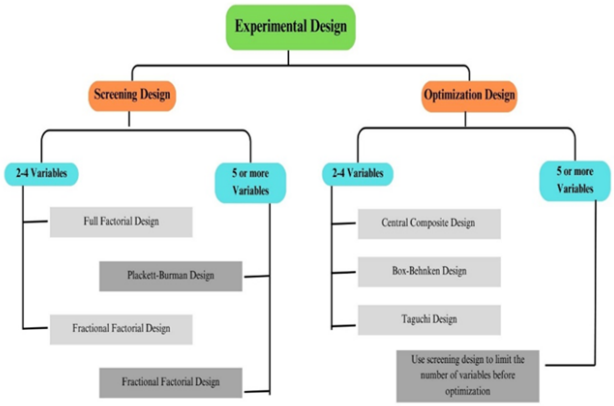

Figure 7: Categorization of severalexperimental design types

12. Process Analytical Technology

The concept came about as a result of regulators' desire to shift control over product quality to a scientific method that aims to clearly reduce patient risk by regulating manufacturing according to process knowledge.[24,25]

Estimating the impacts of CPPs on the finished product is difficult, hence process analytical technology (PAT) is intentionally used in QbD as a tool to optimize the production process. PAT is characterized as a crucial component of QbD because, even in cases when the complex interactions between process changes and their effects are unpredictable, it nevertheless permits extensive testing, monitoring, analysis, and changing of the manufacturing processes to fully control and enhance the efficacy of drug products.

PAT could refer to a more comprehensive change in pharmaceutical production that involves many dynamic approaches instead than only static batch production. It entails processing the instrumentation's CPPs, producing a product that influences the product's CQAs, and controlling these CPPs at predetermined intervals. This helps producers to deliver goods of a regular standard and also contributes to a reduction in waste and total costs.[26] This waste reduction and consistent product quality manufacturing method makes a strong case for the use of continuous production technology.

12.1. Proses analytical technology steps

The three main, interconnected procedures that make up PAT are design, analysis, and control (Figure 2). Determining the degree to which every stage of the process and the beginning material have an impact is crucial when evaluating the end product's quality during the design phase. In the analysis step, real-time use of direct or indirect analytical techniques is made for determining the quality characteristics of the raw materials and process materials. Finally, the final stage evaluates the harmony among all the outputs attained by a control process.[27]

Figure 8: Process analytical steps

12.2. Proses analytical technology tools

PAT tools include information management tools for data collection and analysis, process analyzers, process control tools, and tools for continuous improvement. Pharmaceutical companies frequently use Raman (RAMAN), near-infrared (NIRS), ultraviolet-visible-spectrum region (UV-VIS), and nuclear magnetic resonance (NMR) spectroscopy (NMR) for process analytical technology (PAT) applications. Process characterisation studies identify the essential and crucial process parameters, along with their permissible ranges, which define the design space. Applications for on-, in-, or at-line PAT are primarily focused on these criteria. In theory, continuous feedback could be based on real-time PAT assessments, which would increase process durability NIR is useful in real-time release testing (RTRT) and as a tool for polymorphism and dissolution testing (PAT). It tracks multiple parameters, including particle size, mix uniformity, granulation, content uniformity, polymorphism, and dissolution. NIR reduces the amount of product release testing by keeping an eye on these metrics offline, at the line, and online.[5]

Real-time release testing (RTRT), which involves in-process and/or real-time testing when making pharmaceutical products, is an essential part of Quality by Design (QBD). This strategy seeks to guaranty of the final product throughout the production process.

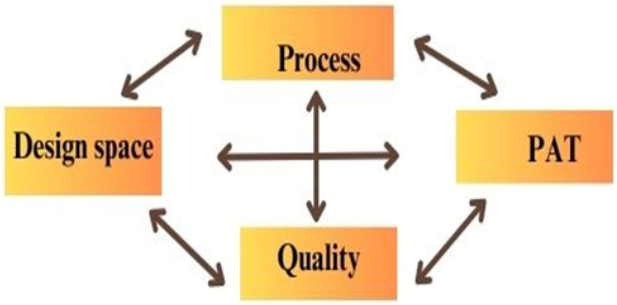

Figure 9: Process, quality, design and PAT

13. Regulatory Perspective

The QbD component of regulatory applications is receiving more attention from regulatory bodies, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). QbD is becoming an essential component of the drug manufacturing procedure.

Authorities in charge of regulations believe that ensuring quality throughout the design phase will help businesses by lowering errors or deviations during the later phases of product development. For organizations, lowering the duration of time for effective product development is an additional advantage. Recent changes in regulations will increase demand for the integrated use of quality and QbD. These days, regulatory bodies only place emphasis on QbD rather than on "Quality by Testing" or "Quality by Chance."[28]

14. Conclusion

Quality by Design (QbD) has revolutionized the pharmaceutical and biotechnology sectors by introducing a systematic, science-driven approach to product development. Through its principles—such as defining Quality Target Product Profiles (QTPP), identifying Critical Quality Attributes (CQAs), and establishing a Design Space—QbD enables manufacturers to proactively design quality into products rather than relying on final-product testing. This approach helps ensure consistent quality, enhances process understanding, and reduces production variability. The QbD framework is built on robust risk management, process control strategies, and continuous improvement, allowing manufacturers to adapt efficiently to changes in materials, methods, or regulatory requirements. Regulatory bodies like the FDA and EMA strongly support QbD, as it aligns with their goals of advancing patient safety, improving drug efficacy, and reducing approval timelines. As regulators increasingly encourage QbD implementation, manufacturers benefit from greater flexibility and efficiency, reduced production costs, and streamlined regulatory processes. In conclusion, QbD is more than a methodology; it represents a forward-thinking commitment to product quality and patient safety. By adopting QbD, companies can achieve superior product performance, regulatory compliance, and sustainable innovation, fostering confidence in both industry stakeholders and patients.

15. Source of Funding

None.

16. Conflict of Interest

None.

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