International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 1, January 2025 **ijppr.humanjournals.com** ISSN: 2349-7203

A Review on Quality by Design

Jadhav D.A.*[1], Birajdar M.J. [1], Patil S.S[1]., Satpute K.L. [1]

1. Department of Pharmaceutical Quality Assurance, DES Dayanand College of Pharmacy, Latur- 413512, Maharashtra, India.

Received: 2025-1-07 Revised: 2025-1-19 Accepted: 2025-1-25

ABSTRACT

Quality by Design (QbD) is a systematic approach to pharmaceutical development and manufacturing that emphasizes the integration of quality into every stage of the product lifecycle. Rooted in the principles outlined in the International Council for Harmonisation (ICH) guidelines Q8, Q9, and Q10, QbD aims to ensure that pharmaceutical products are designed and produced with a focus on achieving consistent quality, safety, and efficacy. The approach begins with defining the Quality Target Product Profile (QTPP), which outlines the desired characteristics of the final product. From there, Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) are identified, and a robust process is developed to control variability and ensure product quality. Risk management tools are employed throughout the development process to identify potential risks and mitigate them proactively. QbD shifts the focus from end-product testing to a more holistic, process-oriented strategy that emphasizes understanding and controlling variability in both the formulation and manufacturing processes. This approach leads to improved product quality, reduced costs, and greater regulatory compliance by ensuring that all aspects of the product's design and production are scientifically grounded and well-controlled. By incorporating continuous monitoring, validation, and optimization, QbD also allows for more flexibility and efficiency in manufacturing. Ultimately, Quality by Design represents a paradigm shift towards a more predictive and proactive framework for ensuring the quality of pharmaceutical products, ultimately benefiting both manufacturers and patients.

Keywords: Quality by Design (QbD), Process Analytical Technology (PAT), Quality target product profile, and Critical quality attributes.

1. INTRODUCTION

Quality: In Quality by Design, the word "quality" is essential. Quality is defined as "standard or suitability for the intended use." Qualities like potency, purity, and identity are all included in this word.

Quality by Design: The International Council Harmonization (ICH) and the US FDA have supported a number of methods for developing pharmaceutical products and then producing them. "A systematic approach to development that begins with a predefined objective and emphasizes product and process understanding and process control, based sound science and quality risk management" is the description of the "Quality by Design" (qbd) methodology.

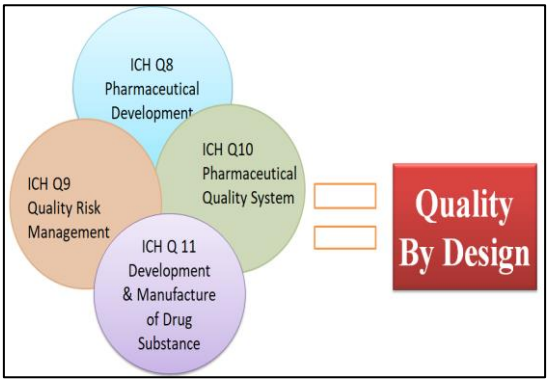


Figure 1: Designed Quality Content

The standard, security, and effectiveness of the pharmaceutical products are important considerations for the industry. Product quality has increased through the use of scientific techniques known as quality by design, or qbd. From the creation of products to their production, scientific procedures can yield enough and clear information. These QBD tools will improve output and quality while reducing risk.

The QBD technique has been effectively applied to the creation of standard formulations in recent years. For pharmaceutical goods having both immediate and extended release, as well as biotechnology, the USFDA has issued particular quality control criteria. Regulatory bodies are constantly putting forward regulations for adoption, including Q8, Q9, Q10, and Q11. Throughout the development phase, the "Quality by Design" (QbD) concept encompasses the following topics: enhancing scientific knowledge of important processes and product attributes; creating controls and tests according to scientific knowledge boundaries; and using the knowledge gained over the course of the product's life-cycle to work on an environment of continuous improvement. Quality by Design (QbD) is a pharmaceutical development technique that addresses formulation design, development, and manufacturing processes to maintain the required degree of product quality.

Rules related to models in mathematics are utilized to make sure that information about the topic is developed along with used in a unique and consistent manner.

2. Advantages about QBD

a. QbD has achieved success.

b. Remove batch failures.

c. Decrease the frequency of variations and expensive inquiries.

d. Prevent issues with adherence to regulations

e. An organization's internal acquiring knowledge is an investment in the future. QbD is a good science.

f. Improved options for technical staff empowerment and progress.

3. Prospects

- A system that is efficient, adaptable, and flexible
- Improve efficiency in production by cutting expenses, waste, and product cancellations.
- Create a scientific database for every product you sell.
- Enhanced exchange of information between industry and science
- Include risk management and ensure that the information is consistent.

The steps involved in designing products for quality

- New molecular entity development
- Preclinical research
- A nonclinical investigation
- A clinical investigation
- Increase in scale
- Request for Acceptance into the market

- Producing the Area of Planning
- Analytical Technologies for Processes
- Control of Quality in Real Time
- Strategy for Control
- A choice based on risk
- Constant Enhancement
- Product effectiveness

The Seven Steps for a Quality by Design Start-Up Plan

a. Employ a self-employed Quality by Design specialist.

b. With the help of an expert doing a gap analysis, audit your company and procedures.

c. All of your staff should participate in a basic design-based quality program.

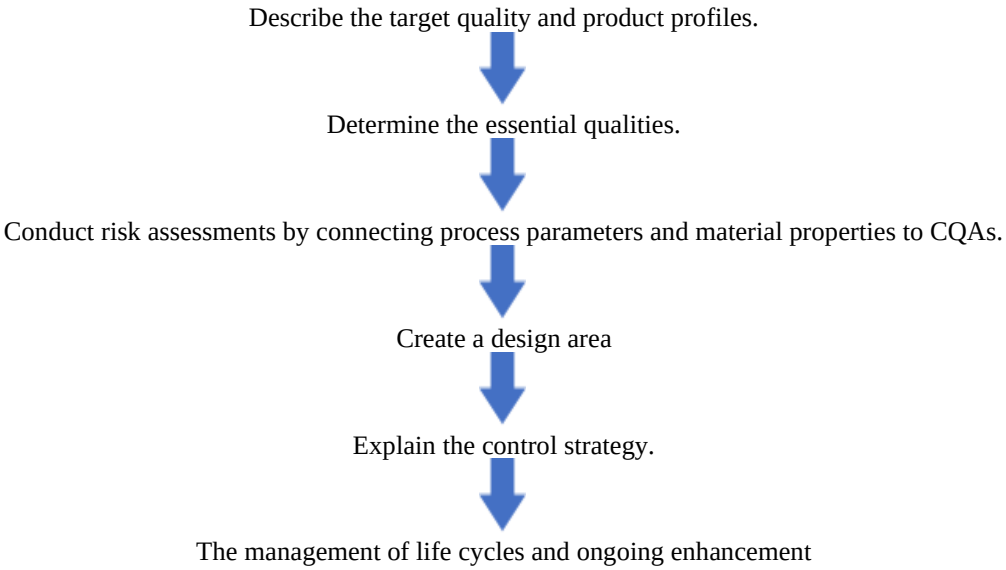
d. Review the expert's conclusions and recommendations.

e. Establish a timetable, financial plan, and execution approach.

f. Distribute the resources or get a different worker.

g. Keep the outside specialist on as your counselor for "Project Assurance."

➢ **Flow of Quality By Design**



QbD, or quality by design, and clearly defined products and procedures. Every significant source of variability has been located and described. The process controls variability. It is possible to accurately and reliably predict features of the product quality by using the area of the design made regarding the components utilized ambient elements, parameters of the process, and more situations. For the purpose of better understanding how a product performs across a variety of material grades, manufacturing process alternatives, and process parameters while taking into account the proper application of quality risk management concepts.

Pharmaceutics' QbD approach

Despite prioritizing quality, the pharmaceutical industry has not been able to match Different industries in terms of effectiveness and manufacturing efficiency.

The current state of the pharma sector:

- Analysis of offline data for during, necessity-based
- The revalidation cost
- Specifications of the product such the main control mechanism
- Variable Scale-up Problems
- Lack of comprehension of failures
- A systematic approach to expansion:
- That begins with pre-established objectives.
- focuses on understanding products and processes.
- Control of the process

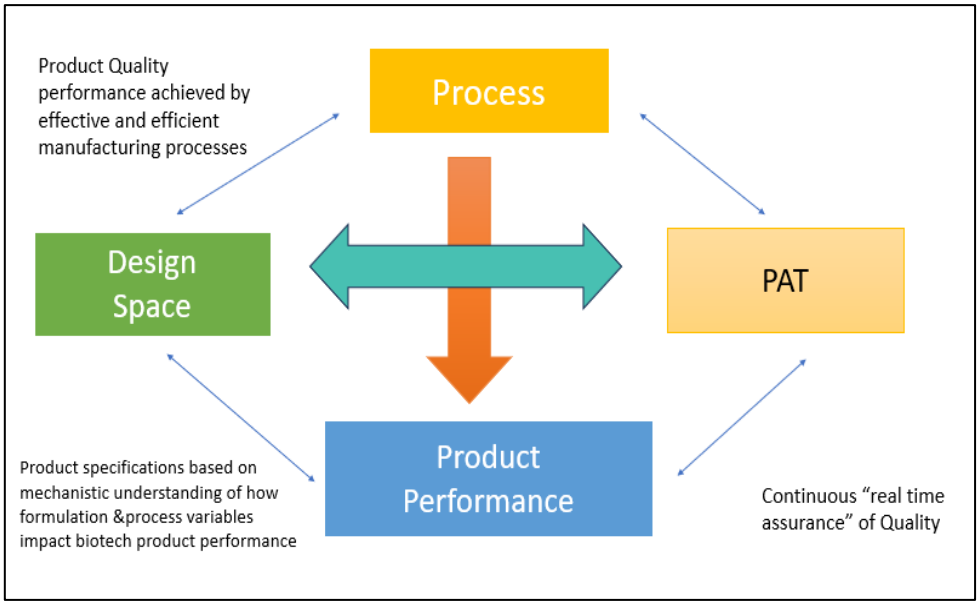


Figure 2: Process, Quality, Design and PAT

4. ELEMENTS OF QbD

A. QTPP (Quality Target Product Profile):

It covers things like dose form, administration methods, and dosage strength or strengths. In addition to the qualities that influence pharmacokinetic characteristics (such as dissolution and aerodynamic performance) and drug product quality criteria (such as sterility, purity, stability, and drug release) necessary for the intended marketed product, this is a prospective summary of the quality characteristics of a drug product to be achieved. The definition of QTPP is a "prospective and dynamic summary of the quality characteristics of a drug product that ideally will be achieved" in order to make sure that the intended of effectiveness, and hence the effectiveness and protection a pharmacological product, is realized. In addition to drug product-quality standards (such as

sterility and purity) appropriate for the intended marketed product, this also includes pharmacokinetic characteristics (such as dissolution and aerodynamic performance) appropriate for the drug product dosage form under development, the formulation and path of administration, the dosage form strength or strengths, and the release or delivery of the therapeutic moiety. As a tool for "quality planning" of the therapeutic product with "the end in mind," the target product profile (TPP) gives a summary of the drug development program as it is given in relation to the objectives of prescription information.

The term QTPP is a logical TPP expansion for quality of product. A QTPP is a pharmacological product's or drug substance's quality needed to provide the intended treatment outcome. QTPP is a predefined synopsis of the features of the medication that are ideally necessary to guarantee the desired standard of quality with regard to the product's effectiveness and safety. Throughout the course of drug development, these preset QTPP may change to take into account new information as supported by continuing clinical research, including toxicity and dosage impact data. A logical progression of TPP for good product quality is the Quality Target Product Profile (QTPP).

In the above continuously deliver the therapeutic benefit that the label promises, the medication product needs to possess specific quality qualities. Formulation scientists are guided by the TPQP in developing formulation strategies and maintaining the efficiency and focus of formulation efforts. The label's identification, stability, pureness, dosage form, and testing are all associated with TPQP. Physical, chemical, and biological characteristics are examples of biopharmaceutical qualities of drug compounds.

The usual QTPP for the components of an oral solid dose form with instant release would be:

Features of the Tablet: Similarity, Testing, and Identification

Stability, Dissolution, and Impurity/Pureness

In the context of QbD, the idea of TPP in this form and its use are new. The following are some ways that TPP serves as the foundation for product design.

Administration method for the dose form

Maximum, minimum, & ability

Delivery/release among the medication A pharmacological feature

Requirements for drug product quality

Elegant pharmaceuticals

B. CQA, or critical quality attribute:

It includes the final therapeutic product as well as the an output material's chemical, physical, biologically and microbial properties. The QTPP and previous data are familiar with inform the development of the product and procedure, and possible drug product CQAs are used to guarantee the intended level of product quality. There must be a proper restrict, range, or dispersion for these CQAs. After determining TPP, Finding the relevant CQAs is the next stage.

A CQA can be described as "a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distributed to ensure the desired product quality" CQAs are identified by risk assessment, in accordance with ICH guidance Q9. These risk assessments require prior product knowledge, such as the entire laboratory, nonclinical, and clinical experience with a certain product-quality attribute. Book and pertinent information from related compounds can also provide such kind of information. This data supports the idea that product safety and efficacy are related to the CQA. The QbD paradigm is unique in that it uses robust risk assessment techniques to identify CQAs. Whether they are physical, chemical, biological, or microbiological, critical quality traits are those that need to be managed to guarantee a product's quality. According to ICH Q8, CQAs are attributes that, in order to guarantee the required level of product quality, must fall within a specific range, limit, or distribution. These characteristics could be biological, chemical-based, microbial, or mechanical. CQA has been used by some to define TPQP components and by others to explain the mechanical elements that influence product performance. Thus, CQA describes both product performance variables and attributes. Finding the pertinent CQAs comes next after TPQP has been determined.

A CQA is described as "a physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distributed" in order to guarantee the intended product excellence. ICH guidance Q9 states that CQAs are identified through risk assessment. These risk assessments require prior product knowledge, such as the entire laboratory, nonclinical, and clinical experience with a certain product-quality attribute. Books and pertinent information from related compounds can also provide this kind of information. This data supports the idea that product safety and efficacy are related to the CQA. The QbD paradigm is unique in that it uses robust risk assessment techniques to identify CQAs. CQAs that affect the product's strength, stability, drug release, and purity are typically found in solid oral dosage forms. More product-specific factors, such as adhesion qualities for transdermal patches, sterility for parenteral, and aerodynamic qualities for inhaled goods, can also be included in CQAs for various delivery modalities. The CQAs for therapeutic compounds, raw materials, and intermediates can also incorporate the factors (such bulk density and particle size distribution) that affect the CQAs of drug products.

C. Critical Materials Attributes (CMAs):

An input substance's physical, chemical, biological, or microbiological characteristics make up this. CMAs must fall within a suitable range, limit, or distribution in order to guarantee that the medicinal component, excipient, or in-process material has the required quality.

D. CPPs (Critical Process Attributes):

The final product's yield, impurity, and appearance are greatly influenced by the parameters that are monitored before or during a procedure. In contrast to CQAs, CMAs are recognized as a component of product engineering and comprehension throughout the QbD process. Drug compounds, excipients, and in-process materials are examples of input materials; CQAs are for output products. It is possible for an intermediate's CQA to be converted into its CMA for a subsequent manufacturing process. Even though recognizing CPPs & having a film understanding of the scale concepts are also necessary for process design and comprehension, connecting CMAs and CPPs to CQAs is very crucial. Since, according to QbD, CMAs and CPPs can differ within the authorized Design Space without substantially influencing CQAs, the final product's quality will fulfill the QTPP.

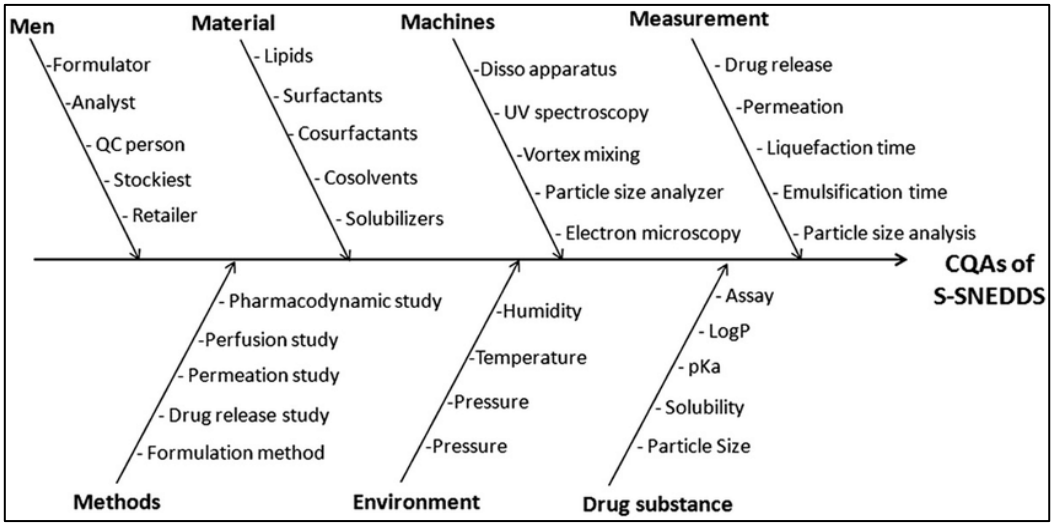


Figure 3. Ishikawa fish-bone diagram

E. Risk management

In a risk management process, risk assessment is the methodical process of arranging data to support a risk decision. It entails recognizing risks and evaluating the risks associated with exposure to such risks. Along with risk review and control, this is the initial phase in the quality risk management process. Decisions to accept or minimize hazards are part of risk control. Reducing the risk to a reasonable level is the aim of risk control. In order to integrate fresh information and experience, the output and outcomes of the risk management process should be evaluated at its completion. Every stage of the risk management process should include ongoing risk communication, or the exchange of information about risk and risk management between the parties (industry and the patient, regulators and industry, inside a firm, industry or regulatory authority, etc.).

The existence, type, form, likelihood, seriousness, acceptability, control, management, detectability, and other aspects of quality risks may be covered by the information provided. Finding and forecasting the causes of manufacturing process variability, or which material characteristics and process variables influence the CQAs of pharmaceutical products, is one of the primary goals of risk assessment in pharmaceutical development. This makes it possible to put in place an appropriate control mechanism that ensures the CQAs fulfill the desired criteria. Throughout the development process, critical material qualities and critical process parameters (CPP) are determined repeatedly. The categorization is primarily based on information that is currently available in the early stages of development since there is a lack of process or product understanding of the product being produced.

As a result, the risks that are initially identified are perceived risks; the actual risks become clearer with the acquisition of further process or product knowledge, enabling the development of a more successful management strategy.

The three components of risk assessment are risk identification, risk analysis, and risk assessment.

Risk identification represents the systematic use of the facts, such as theoretical analysis, historical knowledge, stakeholder concerns, and informed opinions, to determine possible causes of harm (hazards) associated with the risk inquiry or problem description;

The process of applying risk assessment to recognized threats is known as risk analysis.

Risk evaluation is the process of utilizing the method of evaluating risks involves using calculated risk in relation to preset risk criteria in order to assess the risk's significance.

The following is an incomplete list of nine typical risk management instruments provided by ICH Q9:

(1) fundamental techniques for facilitating risk management, like as check sheets, flowcharts, and the Ishikawa fishbone diagram;

(2) analysis of fault trees;

(3) Risk classification and screening;

(4) Initial hazard assessment;

(5) Risk assessment and crucial points of control;

(6) Analysis of Failure Mode and Effects (FMEA);

(7) Analysis of Failure Mode, Effects & Criticality (FMECA);

(8) Analysis of hazard Operatability; and

(9) Statistical tools for support.

The QbD implementation states that risk assessment is more important than DoE. Whether used separately or in tandem, FMEA and the Ishikawa fishbone diagram are two popular methods for evaluating risk. As an example, the Ishikawa diagram for creating extruded particles is displayed. Although the Ishikawa fishbone diagrams categorize risk variables into broad groups, and the FMEA analysis could be able to identify the failure modes that are most likely to cause a product to fail. As a result, the following is a ranking of each of the factors in the fishbone diagrams. As a result, each of the variables in the fishbone diagrams will be ranked subsequently. Using the FMEA method, the quantitative risk assessment may be performed to identify which CQAs have the highest potential to cause product failure. Risk priority numbers (RPN) are produced by an FMEA for each possible incidence likelihood, detection chance, and failure mode severity combined.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 1, January 2025 ijppr.humanjournals.com ISSN: 2349-7203

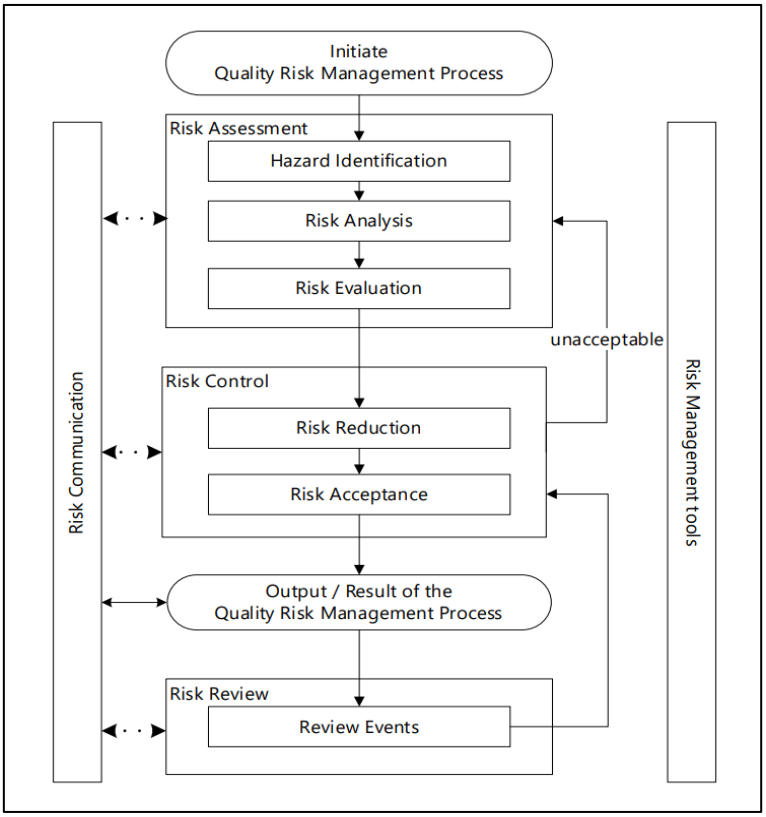


Figure 4. Quality Risk Management

F. Design of Experiment (DoE):

The risk assessment ought to come first in the experiment's design. A systematic, planned strategy to determining how factors influencing a process connect to its final outcome is known as "Design of Experiments" (DoE). DoE is a fantastic technology that allows pharmaceutical specialists to systematically change variables in line with a preset plan. Effective production process management and a deep comprehension of the product form the basis of a strong design. Mechanism-based studies work in tandem with DoE research to enhance our comprehension of products and processes.

DoE is a sensible technique for figuring out how a process's inputs and outputs relate to one another. CMAs, CPPs, ideal conditions, and eventually the Design Space can all be found with its assistance. A Design Space for multivariate experiments can be effectively created using DoE. It has been said that supplements that update (for example, expand) the FDA's acceptance criteria do not need to be submitted if the changes are made inside the Design Space. An organized and controlled approach to figuring determine how various components impact a process's outputs is called design of experiments, or DoE. It has been proposed that DoE can provide returns in a fraction of the time that are four to eight times higher than the expense of conducting the tests. In his revolutionary book, Ronald A. Fisher presented a methodology for constructing experiments. Experiments: Their Design (1935). In QbD, DoE makes it easier to extract as much information as possible from the fewest number of experiments. Factors include input material characteristics and process parameters (like speed and duration), where as the outputs are important quality qualities including mix friability testing its thickness, uniformity, and hardness of tablets when DoE is employed in a pharmaceutical process.

It is not possible to conduct an empirical analysis of all the numerous input and output variables and process factors that are involved in each unit operation. Scientists will determine the main input and output variables and process components that DoE will be examining based on their past experience and risk management skills.

In addition to facts like the presence of interactions and synergies between components, DoE results can assist in identifying ideal circumstances and the crucial elements that most affect CQAs and those that do not. Experiment design, one factor at a time.

G. Design Space:

Design space, as defined by ICH Q8, is the intricate interplay and fusion of input elements (material characteristics) and process parameters that have been shown to result in quality. Since leaving the design space is seen as a change, a regulatory post-approval change process would typically be started. The applicant proposes the design space, which must be approved by the regulatory body. The design space created at the laboratory size might not be suitable for the process at the commercial scale because of the potential for scale and equipment dependence. Therefore, until it is established that the design space is scale-independent, design-space verification at the commercial scale becomes crucial. Sponsors of generic medications are being given information on permissible ranges for particular CPPs and CMAs at pilot or laboratory scales. It has been demonstrated that quality assurance can be achieved through the complex interplay and a mix of process parameters and input variables.

Design space is the intricate interaction and combination of input elements (material attributes) and process parameters that have been shown to generate quality, according to ICH Q8 (R1). Since leaving the design space is seen as a change, a regulatory post-approval change process would typically be started. The design space is suggested by the applicant and needs regulatory authority approval. The design space created at the laboratory size might not be appropriate for the method at the commercial scale because it may vary on scale and equipment. Therefore, until it is established that the design space is scale-independent, design-space verification at the commercial scale becomes crucial. Sponsors of generic medications are now given information on permissible ranges for particular CPPs and CMAs at pilot or laboratory scales.

H. Process Analytical Technology (PAT):

"A system for designing, analyzing, and controlling manufacturing through measurements, during the processing of critical quality and performance attributes of raw and in-process materials and processes, to ensure final product quality" is exactly how PAT is defined. The objective of PAT is to "enhance understanding and control the manufacturing process, which is consistent with our current drug quality system: quality cannot be tested into products; it should be built-in or should be by design."

The important and crucial process parameters found in process characterization studies, along with their permissible ranges, make up the design space. These factors are primarily the subject of online, in-person, and online PAT applications. Real-time PAT evaluations have the potential to strengthen the process' resilience and serve as the foundation for ongoing feedback. In order to reduce the quantity of product release testing, PAT and RTRT (Real Time Release Testing) benefit from the use of NIR, which tracks particle size, blend uniformity, granulation, content uniformity, polymorphism, dissolution, and process monitoring.

5. PAT is an essential QbD tool.

The PAT refers to "Tools and systems that utilize real-time measurements, or rapid measurements during processing, of evolving quality and performance attributes of in-process materials to provide information to ensure optimal processing to produce a final product that consistently conforms to established quality and performance standards".

PAT is used to guarantee that the process stays inside a designated Design Space, according to ICH Q8. The idea was born out of the regulators' wish to move control over product quality toward a science-based strategy that specifically aims to lower patient risk by regulating production in accordance with process knowledge.

6. PAT REGULATORY APPROACH

This guideline aims to adapt the Agency's standard regulatory review process to PAT-based advancements that

1. strengthen the scientific foundation for developing regulatory requirements;

2. Encourage ongoing development;

3. Increase output without sacrificing or compromising the ultimate product's quality.

Manufacturers should rapidly address such technological difficulties and share pertinent scientific knowledge with the Agency in order to accomplish this. Our objective is to support a uniform scientific regulatory evaluation across several Agency offices with different functions. This guideline offers a comprehensive viewpoint on our suggested PAT regulatory strategy. A fundamental element of this strategy will be close contact between the Agency's PAT review and inspection personnel and the manufacturer. As a product progresses through its life cycle, we expect that manufacturers and the Agency will continue to communicate through meetings, phone calls, and written letters.

Any changes, additions, or marketing applications must be sent to the relevant CVM or CDER division in compliance with regular practice. Manufacturers may want to offer ideas for a potential regulatory path in addition to particular PAT plans when speaking with the Agency.

Together with other process experts, research on an existing process can provide information that can be utilized to create and distribute implementation plans to Agency personnel. Plans for implementing PAT should generally be risk-based. Where appropriate, we are suggesting the following implementation options: The use of PAT is allowed under the facility's quality system. Before or after PAT adoption, the PAT Team or a PAT-certified investigator may conduct CGMP inspections.

7. Quality By Design Applications

I. Regarding the Chromatographic Method

a) In identifying impurities

b) When a chromatography column is being screened

c) Developing the HPLC method for the substance of drug goods

d) In electrophoresis of capillaries

e) In research on stability

f) In HPLC

II. For hyphenated technique

a) In the Development of the LC-MS method

III. When developing bioanalytical methods

IV. In investigations on dissolution

V. To measure spectroscopically

(a) Mass Spectroscopy

(b) IR Spectroscopy

(c) When managing intricate

VI. In products with changed releases

VII. During the tableting procedure

VIII. Making a nanosuspension

IX. In the examination of excipients and API

X. In pharmaceutical companies.

8. Conclusion

A well-defined method development project aims to provide a high-assurance, dependable approach that, when used within specified parameters, consistently yields data that satisfies predetermined criteria. It is possible to use QbD in the creation and assessment of analytical techniques. A few instances of AQbD tools include Continuous Method Monitoring (CMM), Method Validation, Method

Development and Optimization using ATP, CQA, DoE, MODR, Control Strategy with Risk Assessment, and Continuous Improvement.

In addition to having the correct ATP, QbD also calls for risk assessment, the use of the suitable tools, and doing the right amount of work in the right amount of time. To ensure product quality, the pharmaceutical industry mostly depends on the creation and verification of analytical techniques through QbD. Understanding is the outcome of AQbD from the creation of the product to its commercial manufacturing. Scientists can successfully determine the risk at the beginning to enhance quality. In the future, there may be much more regulatory freedom thanks to this new QbD procedure. The method performance requirements may be registered in place of the actual method. The employed strategy may be regarded as an illustration to satisfy the intended technique performance requirements. Any changes made to this approach would be subject to internal change control protocol.

Conflict of Interest: No conflict

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International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 1, January 2025 **ijppr.humanjournals.com** ISSN: 2349-7203

How to cite this article:
Jadhav D.A et al. Ijppr.Human, 2025; Vol. 31 (1): 56-67.

Conflict of Interest Statement: All authors have nothing else to disclose.

Image **Author -1**	Author Name – Jadhav Dnyaneshwari Asaram Department of Pharmaceutical Quality Assurance DES Dayanand College of Pharmacy, Latur- 413512, Maharashtra, India.
Image **Author -2**	Author Name- Birajdar Mahesh J. DES Dayanand College of Pharmacy, Latur- 413512, Maharashtra, India.
Image **Author -3**	Author Name- Patil Shivamala Subhash Department of Pharmaceutical Quality Assurance DES Dayanand College of Pharmacy, Latur- 413512, Maharashtra, India.
Image **Author -4**	Author Name- Satpute Kranti L. Department of Pharmacognacy DES Dayanand College of Pharmacy, Latur- 413512, Maharashtra, India.