e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:11/November-2024 Impact Factor- 8.187 www.irjmets.com

QUALITY BY DESIGN

Ankita Jambe*1, Nirmal Sujata*2

*1.2Department Of Medicinal Chemistry Vidya Niketan Institute Of Pharmacy And Research Centre, Bota, Tal-Sangamner, Dist- Ahmednagar, Maharashtra, India.

ABSTRACT

QbD is a systematic approach to product development that aims to build quality into the product and its manufacturing process. Quality by design (QbD) is an essential part of the modern advance to pharmaceutical quality. Quality has been given an importance by all regulatory body for pharmaceutical products. Quality means customer satisfaction in terms of service, products, and process. QbD is best key to build a quality in all pharmaceutical products. This paper gives idea about the Pharmaceutical Quality by Design (QbD) and describes use of Quality by Design to ensure quality of Pharmaceutical Analysis. Under this concepts of be throughout design and growth of product, it is important to identify desire product performance report Target product profile (TPP), Quality Target product profile (QTPP) and identify critical quality attributes (CQA). [1] To recognize the impact of raw material critical material attributes (CAM), critical process parameters (CPP) on the CQAs and identification an control sources of changeability. USFDA launched a pilot programmer in 2005 to permit participating firms a prospect to submit chemistry, manufacturing, and controls (CMC) of NDA information representing application of QbD.

Keywords: Quality By Design, Critical Quality Attributes, Pharmaceutical Analysis, Design Of Experiment, And Pharmaceutical Quality By Design.

I. INTRODUCTION

Quality by design (QbD) is a concept first developed by the quality pioneer Dr. Joseph M. Juran . Dr. Juran believed that quality should be designed into a product, and that most quality crises and problems relate to the way in which a product was designed in the first place. Woodcock, defined a high-quality drug product as a product free of contamination and reliably delivering the therapeutic benefit promised in the label to the consumer. The US Food and Drug Administration (FDA) encourage risk-based approaches and the adoption of QbD principles in drug product development, manufacturing, and regulation. FDA's emphasis on QbD began with the recognition that increased testing does not necessarily improve product quality. Quality must be built into the product.[2] Pharmaceutical QbD is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and control based on sound science and quality risk management . The goals of pharmaceutical QbD may include the following:

1. To achieve meaningful product quality specifications that are based onclinical performance
2. To increase process capability and reduce product variability and defects by enhancing product and process design, understanding, and control
3. To increase product development and manufacturing efficiencies
4. To enhance root cause analysis and post approval change management

Under QbD, these goals can often be achieved by linking product quality to the desired clinical performance and then designing a robust formulation and manufacturing process to consistently deliver the desired product quality.QbD uses a systematic approach to product design and development. As such, it enhances development capability, speed, and formulation design. Furthermore, it transfers resources from a downstream corrective mode to an upstream proactive mode. It enhances the manufacturer's ability to identify the root causes of manufacturing failures. Hence, increasing product development and manufacturing efficiencies is the third objective of pharmaceutical QbD.

The final objective of QbD is to enhance root cause analysis and post approval change management. Without good product and process understanding, the ability to efficiently scale-up and conduct root cause analysis is limited and requires the generation of additional data sets on the proposed larger scale. FDA's change guidance provide a framework for post approval changes.

e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:11/November-2024 Impact Factor- 8.187 www.irjmets.com

II. ELIMENTS OF QUALITY BY DESIGN

In a pharmaceutical QbD approach to product development, an applicant identifies characteristics that are critical to quality from the patient's perspective, translates them into the drug product critical quality attributes (CQAs), and establishes the relationship between formulation/manufacturing variables and CQAs to consistently deliver a drug product with such CQAs tothe patient. QbD consists of the following elements:

1. A quality target product profile (QTPP) that identifies the critical quality attributes (CQAs) of the drug product
2. Product design and understanding including the identification of criticalmaterial attributes (CMAs)
3. Process design and understanding including the identification of critical process parameters (CPPs) and a thorough understanding of scale-up principles, linking CMAs and CPPs to CQAs
4. A control strategy that includes specifications for the drug substance(s), excipient(s), and drug product as well as controls for each step of themanufacturing process
5. Process capability and continual improvement Quality Target Product Profile that Identifies the Critical Quality Attributes of the Drug Product[3]

QTPP is a prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product. QTPP forms the basis of design for the development of the product. Considerations for inclusion in the QTPP could include the following:

- Intended use in a clinical setting, route of administration, dosage form, anddelivery system(s)
- Dosage strength(s)
- Container closure system
- Therapeutic moiety release or delivery and attributes affecting pharmacokinetic characteristics (*e.g.*, dissolution and aerodynamic performance) appropriate to the drug product dosage form being developed
- Drug product quality criteria (*e.g.*, sterility, purity, stability, and drug release) appropriate for the intended marketed product[4]

Quality Target Product Profile (QTPP)

A Quality Target Product Profile (QTPP) is a document that outlines the quality characteristics of a drug product. It's created early in the development process and serves as the basis for the product's design. The QTPP is important because it helps ensure the drug's desired quality, while also taking into account its safety and efficacy.

A QTPP includes details on the following:

- Active substance
- Finished product specifications
- Packaging documentation
- Clinical use
- Route of administration
- Formulation
- Delivery system
- Content
- Container and packaging
- API release or delivery

The QTPP is updated as the product's development progresses and more information becomes available.[5]

CRITICAL MATERIAL ATTRIBUTES (CMAs)

Critical material attributes (CMAs) are the physical, chemical, microbiological, or biological characteristics of a material. CMAs can affect the quality of a product, the consistency of a process, and pharmaceutical operations.

In the development and manufacturing of drug products, the U.S. Food and Drug Administration (FDA)

e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:11/November-2024 Impact Factor- 8.187 www.irjmets.com

emphasizes quality by design (QbD) principles. QbD elements include: Identifying CMAs, Identifying critical process parameters (CPPs), and Linking CMAs and CPPs to CQAs.[6]

ADVANTAGES OF QbD

1. Reduced costs: QbD can lead to reduced costs and process downtime.
2. Better consistency: QbD can lead to better consistency in drug quality andefficacy.
3. Shorter time to market: QbD can lead to a reduced time to market for newdrugs.
4. Less regulatory oversight: QbD can lead to less intensive regulatoryoversight.
5. Better understanding: QbD can lead to a better understanding of theprocess and product.[7]

DISADVANTAGES OF QbD

1. Cost: The initial cost of new equipment and training can be a challenge.
2. Resources: QbD requires a significant investment of time and resources to conduct scientific studies, establish a design space, and implementanalytical techniques.
3. Knowledge and expertise: QbD requires a high level of scientific knowledge and expertise to understand product attributes and processparameters.
4. Regulatory compliance: While regulatory agencies encourage QbD, navigating the regulatory landscape can be challenging.
5. Communication: A lack of communication between teams can lead to miscommunication and incorrect evaluations.[8]

APPLICATION OF QbD

1. Quality by Design (QbD)- is a philosophy that uses statistical analysis and empirical study to design efficient processes. It has many applications, including:
2. Connecting stages of development - QbD can help connect the stages of product development, from molecule design to clinical performance.
3. Control strategy - A control strategy is an important feature of an analytical method that ensures the method performs as intended.
4. Residual moisture - QbD can help control the residual moisture content and head space gas composition of products that are sensitive to residual water.
5. Formulation parameters - QbD can be used to develop and assess methods of formulation.
6. Experimental design - QbD emphasizes the value of thorough intellectual planning before starting laboratory studies.
7. Lifecycle approach - QbD can be applied throughout the product lifespan, from development to post-approval and marketing.
8. Risk assessment - Risk assessment is an important part of developingQbD.[9]

III. CONCLUSION

1. The conclusion of Quality by Design (QbD) is that it can be a promising approach to improve the pharmaceutical industry by:
2. Reducing development time: QbD can reduce development and validationtime by 30% or more.
3. Improving product quality: QbD can help ensure that the desired productquality is consistently achieved.
4. Increasing efficiency: QbD can help increase product development andmanufacturing efficiencies.
5. Improving patient safety: QbD can help focus on patient safety andproduct efficacy.
6. Reducing risk: QbD can help mitigate risks by identifying and addressing potential quality issues early on.
7. Facilitating continuous improvement: QbD can provide a framework for ongoing process optimization and innovation.

IV. REFERENCES

[1] Yu, Lawrence X. "Pharmaceutical quality by design: product and process development, understanding, and control." Pharmaceutical research 25 (2008): 781-791.

[2] Beg, S., & Hasnain, M. S. (Eds.). (2019). Pharmaceutical quality by design: principles and applications. Academic Press.

[3] Namjoshi, Sarika, Maryam Dabbaghi, Michael S. Roberts, Jeffrey E. Grice, and Yousuf Mohammed. "Quality by design: Development of the quality target product profile (QTPP) for semisolid topical products." Pharmaceutics 12, no. 3 (2020): 287.

[4] Benetti, Camillo, and Ayca Altay Benetti. "Quality by Design in Formulation Development." Introduction to Quality by Design (QbD) From Theory to Practice. Singapore: Springer Nature Singapore, 2024. 139-159.

[5] Patil, Tulshidas S., and Ashwini S. Deshpande. "Development of an innovative quality by design (QbD) based stability-indicating HPLC method and its validation for clofazimine from its bulk and pharmaceutical dosage forms." Chromatographia 82.2 (2019): 579-590.

[6] Bhutani, Hemant, Moolchand Kurmi, Saranjit Singh, Sarwar Beg, and Bhupinder Singh. "Quality by design (QbD) in analytical sciences: an overview." Quality Assurance 3 (2004): 39-45.

[7] Bhutani H, Kurmi M, Singh S, Beg S, Singh B. Quality by design (QbD) in analytical sciences: an overview. Quality Assurance. 2004 Sep;3:39-45.

[8] Mishra, V., Thakur, S., Patil, A., & Shukla, A. (018). Quality by design (QbD) approaches in current pharmaceutical set-up. Expert opinion on drug delivery, 15(8), 737-758.

[9] Beg, S., Hasnain, M. S., Rahman, M., & Swain, S. (2019). Introduction to quality by design (QbD): fundamentals, principles, and applications. In Pharmaceutical quality by design (pp. 1-17). Academic Press..