World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(RESEARCH ARTICLE)

Check for updates

An Overview on Pharmaceutical Pillars with Reference to Case Study Analysis

Padwal Prachi Nandkumar [1,*], Ghode Seema Vikas [2], Lokhande Rahul Prakash [3], Bhalekar Sachin Mahadu [4] and Lamkhade Ganesh Jayram [4]

[1] *Assistant Professor, Department of Quality Assurance Technique, Samarth institute of pharmacy, Belhe, Pune, Maharashtra.*
[2] *Student, Samarth institute of pharmacy, Belhe, Pune, Maharashtra.*
[3] *Assistant Professor, Department of Pharmaceutical Chemistry, Samarth institute of pharmacy, Belhe, Pune, Maharashtra.*
[4] *Assistant Professor, Department of Pharmaceutics, Samarth institute of pharmacy, Belhe, Pune, Maharashtra.*

World Journal of Biology Pharmacy and Health Sciences, 2025, 24(01), 364-372

Publication history: Received on 10 September 2025; revised on 19 October 2025; accepted on 22 October 2025

Article DOI: https://doi.org/10.30574/wjbphs.2025.24.1.0910

Abstract

Creating quality standards, creating processes, and offering training are all part of quality assurance (QA). auditing and ongoing surveillance. guarantees that, in order to continuously produce high-quality products, all stages of the product development life cycle from planning to production and maintenance—follow efficient procedures.[1] Methods like Processing Analytical Technology (PAT) and Quality by Design (Q50) improve control and clarity when developing dosage forms. The goal of quality control (QC) is to find variations or flaws in the finished product through testing and inspection.[3] Activities include conducting product testing, checking manufactured goods, testing software for faults, and frequently performing instrumental analysis at the conclusion of it. Both are essential for guaranteeing the quality, safety, and effectiveness of pharmaceutical products, but they take different approaches. [4] QC is concerned with identifying and fixing flaws prior to product release, whereas inspection is usually carried out during the inspection phase, often during production, even if the product satisfies predetermined specifications. [6] The FDA, USFDA, WHO, MHRA, TGA, and CDSCO are among the regulatory agencies that have documentation, validation, certification, and calibration requirements. [8] Pharmacopeia standards compliance guarantees that pharmaceutical dosage forms, instruments, and processes are safe and effective.[10] Validated techniques, including Thin Lap Chromatography (TIC), High-Performance Liquid chromatography (HPLC meter), UV-Visible spectroscopy, and potentiometry, are used in the instrumental analysis of product to enforce guidelines and produce safe and effective results. [11] The significance of QA and QC in preserving openness and enhancing safety management systems is demonstrated by case studies on patent analysis and pharmaceutical audits. [14] For instance, the commonly used medication paracetamol, which is mild to pain, shows therapeutic efficacy.[2] But excessive dosage can cause serious harm or even death, which emphasizes the necessity of strict quality standards.

Keywords: Quality Control; Quality Assurance; Regularity Bodies; Analytical Analysis; Drug Qualification; Raw Material

1. Introduction

QC focuses on finding and fixing flaws in the finished product, QA focuses on preventing problems through methodical processes. Similar rules are used in the pharmaceutical industry to maintain quality standards.

* Corresponding author: Padwal Prachi Nandkumar

1.1. [15] Good Laboratory Practices (GLP)

GLP consists of recognized guidelines for reliable laboratory data. These guidelines offer a structure for organizing and carrying out research while guaranteeing the accuracy and reproducibility of the findings.

1.2. Good Manufacturing Practices (GMP) and Current GMP

GMP regulations guarantee reliable production and product quality assurance. Strong systems for planning, observing, and overseeing manufacturing processes and facilities in accordance with quality requirements are emphasized by GMP.

1.2.1. [17] ICH CSEM Guidelines

Guidelines on City (0) Safety (5) May and Multidisciplinary (M) aspects of pharmaceutical development are provided by the International Council for Harmonization (ICH). With a focus on quality, aims to standardize requirements for worldwide drug registration in order to guarantee high-quality, safe, and effective medications.

1.2.2. [16] Analysis of Materials

In sectors like pharmaceuticals, this procedure is essential for confirming that raw materials fulfill precise physical, chemical, and microbiological requirements. Material analysis preserves quality and efficacy, avoids production problems, and guarantees product safety.

Figure 1 Quality Control and Quality Assurance

1.3. [18] Authorities in Charge of Regulation

1.3.1. FDA Regulations

Deals with medications, medical devices, biologics, food, cosmetics, and radiation-emitting goods are safe, effective, and secure.

1.3.2. USFDA Regulations

In order to guarantee the safety and efficacy of products, the USFDA establishes and enforces rules for clinical studies, manufacturing procedures, labelling, and advertising.

In order to encourage evidence-based practices, the World Health Organization (WHO) creates global guidelines. WHO guidelines cover a wide range of information products that offer recommendations for public health policy or clinical practice. In order to get the best possible individual or group health outcomes, these guidelines help end users make well-informed decisions regarding therapeutic interventions, diagnostic procedures, or public health initiatives.

1.3.3. [20] Records in the pharmaceutical sector

A systematic, interdisciplinary method to developing novel drugs to address unmet medical needs is drug discovery and development. It involves multiple crucial phases, aided by cutting-edge technology like high-throughput drug design. Identification and validation of the target. Finding and identifying a biological target, illness cause, or prospective treatment is the main goal of this first step.

1.3.4. Lead Discovery

Screening procedures are used to uncover compounds with potential drug molecules (leads).

1.3.5. potential for therapy

are improved to improve their pharmacokinetic, safety, and effectiveness characteristics.

1.3.6. Preclinical Development

Analytical and laboratory research is conducted to assess the biology, safety, and effectiveness of product.

A crucial component of Good Manufacturing Practices (GMP), validation is a documented process that scientifically verifies that a system, process, method, or piece of equipment consistently produces results that meet predetermined quality and regulatory standards. It ensures drug safety, efficacy, and quality by confirming that processes are repeatable, patient risks are minimized, and regulations from organizations like the EMA are followed.

1.4. [25] Why is validation crucial?

1.4.1. Assures Product Quality and Safety

It confirms that medications are regularly potent, pure, and sold for medical purpose.

1.4.2. Regulatory Compliance

Pharmaceutical firms must verify their procedures to adhere to international regulatory standards, such as those set forth by the FDA and WHO.

Figure 2 Process of Validation

1.4.3. Patient and manufacturing risk reduction

Reduces the possibility of product recalls and possible harm to

1.4.4. Process Consistency

It proves that production procedures are repeatable.

1.4.5. Stakeholder Trust

By demonstrating a dedication to quality, a robust validation program increases credibility and trust among patients, healthcare providers, and regulators.

1.5. Crucial elements of validation

1.5.1. Documentation

To produce unbiased, recorded proof, it entails gathering and assessing product lifecycle data.

1.5.2. Scientific Evidence

The procedure demonstrated that gathering and evaluating evidence in a way that is scientifically sound can supplying a high-quality item Characteristics of Quality: Validation assesses important factors such dose precision, efficacy, and stability.

1.5.3. Effective risk mitigation

lowers the risks connected to industrial systems and processes.

1.5.4. Continuous Improvement

Validation is a continuous procedure that enables constant observation, evaluation, and

1.6. [26] Validation types

1.6.1. Validation of the process

Affirms that production procedures invariably result in goods that fulfill predetermined quality standards.

Validation of Equipment confirms that the equipment fits the standards and functions consistently.

1.6.2. Analytical Method Validation

Verifies the accuracy and dependability of analytical testing techniques.

1.6.3. Cleaning Validation

Shows that residues are successfully removed by cleaning methods, avoiding cross-contamination.

1.6.4. Computer System Validation

Verifies the functionality of computer systems used in quality assurance and manufacturing.

1.7. [30] Calibration (accurately and consistently Adjustment)

Pharmacological calibration and quality assurance Verifying and modifying the accuracy of the tools used in the production process guarantees consistent and trustworthy measurements, supporting patient safety and product quality.

[35] Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (CQ), and Performance Qualification (PQ) are the four official phases of the industry. In accordance with industry standards and laws, these phases guarantee that systems and equipment are developed, implemented, upgraded, and maintained to fulfill their intended uses.

A methodical, science-based approach to product creation, **Quality by Design**

(Qbd) focuses on integrating high-quality goods from the outset rather than depending just on post-production testing. It entails establishing precise quality goals, defining the product's Critical Quality Attributes (COA), and identifying the Critical Process Parameters (CPP) that affect them.

QbD creates a design space and control strategies to guarantee consistent quality by using statistical analysis and risk assessment.

This proactive approach, which is popular in sectors like pharmaceuticals, minimizes failures, lowers returns, and launches products on schedule.

Figure 3 Quality by Design

1.8. The Design Principle and History of Quality

The idea behind Quality by Design (CBD) is to incorporate quality into products by means of methodical design and process management, rather than depending solely on post-production testing. According to the International Council for Harmonization (ICH) principles, specifically ICH Q8, quality must be included into a product from the beginning and cannot be tested into it.

QbD has its roots in race-back standards. Scientific research examined novel design ideas in a variety of industries, including computer networking and aerospace, by the 170s, when Toyota was at the forefront of this approach in the automobile industry, setting standards for quality in the 1980s and 1990s. The FDA emphasized the significance of QbD in pharmaceuticals in 2002 when it released recommendations on QbD in the context of the 21st century (GMP current Manufacturing Practices).

1.9. [44] Intellectual Property

Works of literature, art, inventions, designs, names, symbols, and pictures used in trade are all considered forms of intellectual property (IP). Patents, copyrights, trademarks, and trade secrets are examples of intellectual property laws that provide producers exclusive rights for a predetermined amount of time, encouraging innovation and creativity while making financial gains possible.

1.9.1. Principal Categories of Intellectual Property

- **Patents:** Protect innovations and technical breakthroughs by giving creators the sole authority to stop others from copying, utilizing, or selling their creations for a predetermined period of time.
- **Copyrights:** Give authors the sole right to reproduce, distribute, and display their original works of authorship, including software, music, art, and books.
- **Trademark:** Secure names, symbols, or logos that set one company's products or services apart from another are known as trademarks.

1.10. [45] Investigations into pharmaceutical patents

1.10.1. Background

The gamma-crystalline form of an active ingredient, which was covered by a valuable Vietnamese patent that the European company possessed in 2015, was discovered by two Vietnamese distributors of pharmaceuticals.

This was the first instance of a crystalline structure of a copyrighted substance being implicated in a patent infringement lawsuit in Vietnam; previously, pharmaceutical patent disputes had only involved the medicine itself.

Vietnam's poor testing capabilities meant that X-ray diffraction investigation was used in France to evaluate the violation.

A French scholar and the Research Institute (VIPR) offered expert opinions regarding the possible patent infringement.

The court issued its final verdict on July 17, 2013, concluding that the defendant had violated the patent by manufacturing and selling the infringing products while the patent was in effect. The matter went to trial on October 5, 2018.

The defendant was directed to remove all illegal pharmaceuticals from the market and conduct a recall.

1.11. An analysis of an audit case

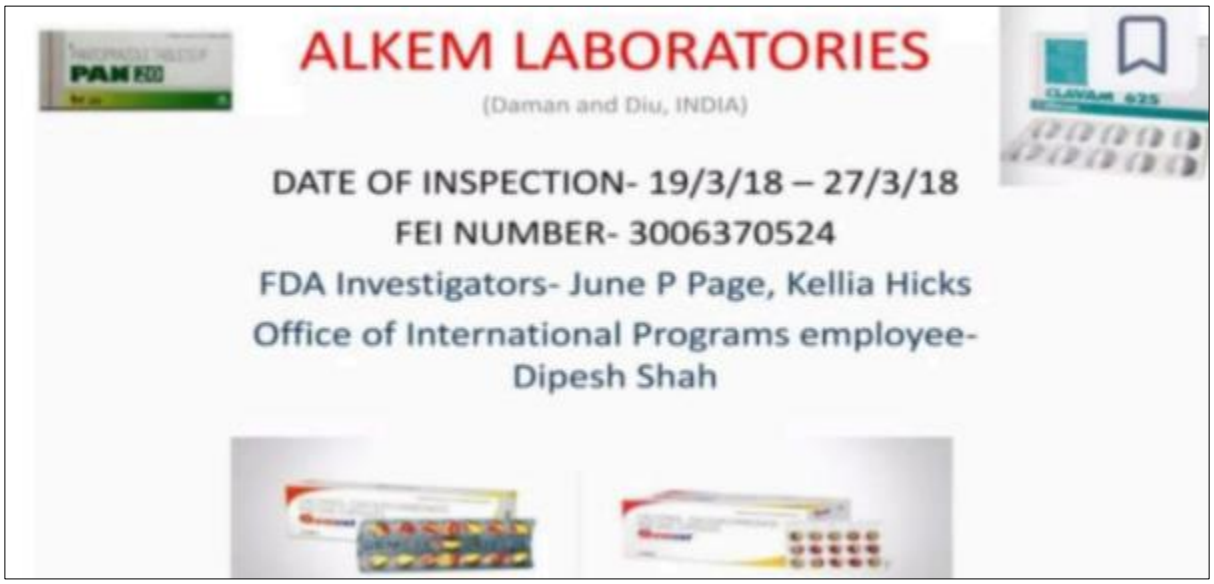

Figure 4 Audit Case Study

1.12. Goals of the Audit

Verifying conformance or determining whether the quality meets the requirements to assess how well the quality system in place is accomplishing the established quality goals.

To offer tam chances to improve the quality system to guarantee adherence to legal requirements.

To make it possible for the quality system of the audited organization to be included into a register.

In 2017, QA and specification A were confirmed by the quality unit. But according to the product testing release certificate of analysis month batch of P tablets meant for market release, which was certified by the QC chiefs on November 13, the tablets were distributed prior to the remedy these errors, the logbook recording the January incorrect analytical results system suitability was deleted, according to the firm's OC analyst, reviewer, and assistant QC manager.

This problem was resolved via logbooks for housekeeping, DA, QC, and maintenance processes. which were destroyed.

1.13. Suggestions for Reducing Problem

Create a strong quality control department to guarantee reliable supervision.

Maintain accurate and comprehensive records.

Improve stability studies to guarantee product conformity and dependability.

1.13.1. ALKEM Audit news

Alkem stated that it would prepare a comprehensive report "with adequate corrective id prevents measures to address the US FDA Observations and send it to the FD/within the agency's stipulated timeframe," without providing any specifics about the findings.

Observations regarding the Daman facility The FDA Performs an Unexpected Audit at the ALKEM Iab Daman Plant of Alkem Lab.

1.14. [43] Problems with quality assurance and quality control(challenges)

- Challenges with Regulation and Compliance
- Integrity of Data
- Challenges in Analysis and Testing
- Provide the Quality of Cham Raw Material

2. Conclusion

On basis of Peer reviews from articles, references we can conclude that Quality by design structure, an calibration, validation parameters are the building blocks of our pharma industry and it has been proven by means of studies on various case study for the same above.

[44] Future Extent

The quality assurance (QA) and control (QC) sectors of the pharmaceutical business are poised for expansion due to digital revolution.

Big data, blockchain, machine learning, and Al usage are changing these domains and necessitating the use of expert digital tools and technology.

Recognition

The authors would like to extend their sincere gratitude to the advisor for his invaluable advice, inspiration, and unwavering support during the writing of this review paper. They are also grateful to the faculty and staff of Samarth Institute of Pharmacy, Belhe, Pune, for giving us the tools we needed to create an inspiring learning environment. Finally, we would like to express our profound gratitude to our friends, family, and peers for their unwavering moral support and encouragement, which were crucial to the work's successful completion.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] Kumar S, Singh P., Pharmaceutical Quality Assurance: A Review on Regulatory and Ethical Aspects, Journal of Clinical and Diagnostic Research, 2020:14(12):1-5

[2] Sharma A, Gupta N., Pharmaceutical Quality Control and Good Manufacturing Practices (GMP) In Drug Development, Current Drug Safety, 2020:15(4):309-315.

[3] Patel H, Shah R, Pharmaceutical Quality Control: A Comprehensive Review of Methods and Regulatory Standards, International Journal of Research in Pharmaceutical Sciences, 2021: 12(4):1102-1108.

[4] Singh P. Choudhary, Key Considerations in Pharmaceutical Quality Assurance and Control in New Drug Development, Pharmaceutical Regulatory Affairs, 2017:6(2):35-41.

[5] Vyas M, Jain S., Quality Control and Assurance in Pharmaceutical Industry: A Comprehensive Review, Journal of Pharmacy Research, 2019:13(1):42-47.

[6] Dey A, Saha R., Improving Quality Control Systems in The Pharmaceutical Industry: Trends and Challenges, Drug Development and Industrial Pharmacy, 2020:46(9):1456-1462

[7] Choudhary R, Sharma P, Best Practices in Pharmaceutical Quality Assurance and Control: An Industry Overview, International Journal of Quality Control and Assurance, 2021:8(1):19-26.

[8] Patel K, Shah S., Pharmaceutical Quality Control: Techniques, Regulatory Frameworks, And Applications, Pharmaceutical Technology, 2021:45(2):58-65

[9] Singh A, Agarwal R, Advances in Pharmaceutical Quality Control: Regulatory and Technological Perspectives, Drug Research and Development, 2020:32(3):95-104.

[10] Kumar A, Mishra S., Pharmaceutical Quality Assurance and Control: A Step Towards Enhancing Product Quality and Safety, International Journal of Pharmaceutical Research, 2019:11(1):56-63.

[11] Chauhan N. Meena S., Pharmaceutical Quality Control: Principles and Practices, Asian Journal of Pharmaceutical Science and Technology, 2020:10(5): 113-118.

[12] Gupta S, Arora S., Current Approaches in Pharmaceutical Quality Control and Assurance Systems. Journal Of Pharmaceutical Quality Assurance, 2019:7(2):27-32.

[13] Tiwari M, Verma A., Pharmaceutical Manufacturing: Integrating Quality Assurance and Quality Control for Continuous Improvement, Quality Assurance and Quality Control in Pharmacy, 2018:12(1):42-49.

[14] Chauhan R, Kumari S., Exploring Quality Control Systems in Pharmaceutical Product Development, Pharmaceutical Regulatory Affairs, 2021:6(3):14-20.

[15] Rao N. Dey A., Modern Techniques in Pharmaceutical Quality Control and Good Manufacturing Practices (GMP), International Journal of Drug Regulatory Affairs, 2020:18(2):110-115.

[16] Soni H, Kumar S., Quality Control in Pharmaceutical Industries Key Insights and Techniques, Pharmaceutical Manufacturing and Technology, 2020:8(4):34-39

[17] Woodcock J. The concept of pharmaceutical quality. American Pharmaceutical Review, 7(6), 2004, 10-15,

[18] Quality Risk Management. ICH Harmonized Tripartite Guidelines. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2006.

[19] Q10: Pharmaceutical Quality System, ICH Tripartite Guidelines. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use 2007

[20] Lionberger RA, Lee IS. Lee L, Raw A Yu IX, Quality by design: Concepts for ANDAS, The AAPS Journal, 10, 2008, 268-276

[21] FDA Guidance for Industry and Review Staff: Target Product Profile A Strategic Development Process Tool (Draft) Guidance).

[22] 08 (R1) Pharmaceutical Development, Revision 1, ICH Harmonized Tripartite Guidelines, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2007.

[23] Sharma A, Saini S; Process Validation of Solid Dosage Form: A Review. International Journal of Research in Pharmacy and Science, 2013; 3 (2): 12-30.

[24] Kaur H, Singh G, Seth N; Pharmaceutical Process Validation: A Review. 2013; 3 (4): 189-194.

[25] Thaduvai R. Rao BS, Jeybaskaran M; Process Validation of Pantoprazole 40 mg Tablets: The Pharma Innovation. 2012; 1 (5): 50-52.

[26] Kavita, Khurana G. Chaudhary S; Process. Validation of Solid Dosage Form: A Review. Pharma Science Monitor, An International Journal of Pharmaceutical Sciences, September 2013; 4 (4): 390-391.

[27] Chapman K. G. A History of Validation in the United States. Part 1. Pharma Technology. November 1991; 39-98.

[28] Nash R. A., Wachter A. H: In Pharmaceutical Process Validation. Third Edition; Revised and Expanded, Marcel Dekker Inc., New York, 1993.

[29] Pordar MA; Pharmaceutical Quality Assurance. 2nd Edition, Nirali Prakashan, 2009: 8.6-8.20.

[30] WHO Expert Committee on Specifications for Pharmaceutical Preparations. WHO technical report, series no. 863. 34 report, Annex 6 GMP: Guidelines the validation of manufacturing processes: 4-7.

[31] ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: 33.

[32] Potdar MA; Current Good Manufacturing Practices for Pharmaceuticals. 2nd Edition, PharmaMed Press Publication, Delhi, December 2007: 8.2-8.3.

[33] Singh P. Chaudhuri, Key Considerations in Pharmaceutical Quality Assurance and Control in New Drug Development Pharmaceutical Regulatory Affairs, 2017:6(2):33-41

[34] Was M. Jain 5. Quality Control and Assurance in Pharmaceutical industry. A Comprehensive Review, Journal of Pharmacy. Research, 2019:13(1):42-47

[35] Dey A, Saha R, Improving Quality Control Systems in The Pharmaceutical industry: Trends and Challenges, Drug Development and industrial Pharmacy, 2020-4619):1456-1462

[36] Choudhary Sharma P. Best Practices in Pharmaceutical Quality Assurance an industry Overview, Interna 26 Control: sal Journal of Quality Control Assurance, 20218(1): 19

[37] Patel K, Shah 5, Pharmacntical Quality Control Techniques, Regulatory Frameworks, And Applications, Pharmaceutical Technology, 2021-45/2158-45

[38] Singh A, Agarwal R ances pharmaceutical Quality Control Regulatory and Technological Perspectives, Drug Research Development, 2020:32(3):95-104.

[39] Kumar A, Mohra 5, Pharmaceutical Quality Assurance and Control. A Stop Towards Enhancing Product Quality and Safety, International journal of Pharmaceutical Research, 2019:11:11:55-63.

[40] Chauhan N. Meena 5, Pharmaceutical Quality Control: Principles and Practices. Asian Journal of Pharmaceutical Science and Technology, 2020:10(5)

[41] Gupta 5, Arora S., Current Approaches in Pharmaceutical Quality Control and Assurance Systems Journal Of Pharmaceutical Quality Assurance, 2015:702):27-32

[42] Tiwari M, Verma A., Pharmaceutical Manufacturing, Integrating Quality Assurance and Quality Control for Continuous Improvement Quality Assurance and Quality Control in 25. 43.Gupta 5, Arora 5, Current Approaches in Pharmaceutical Quality Control Assurance Systems Of Pharmaceutical Quality Assurance, 2019:21:27-32

[43] Tiwari M. Verma A, Pharmaceutical Manufacturing: Integrating Quality Assurance and Quality Control for Continuous improvement, Quality Assurance and Quality Control in Pharmacy, 2018 12/1/42-49

[44] Chauhan, Kumari S, Exploring Quality Control Systems in Pharmaceutical Product Development, Pharmaceutical Regulatory Affairs, 2021-6(3):14 20.

[45] Modern Techniques in Pharmaceutical Quality Control and Good Manufacturing Practices (SMP national Journal of Drug Regulatory Affairs, 2020-18(2):110-115.