International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Quality Risk Management in Pharmaceutical Industry

Manali C. Asare[1], Jiterdra A. Kubde[2], Ravindra L. Bakal[3], Pooja R. Hatwar[4]

[1,2,3,4]Shri Swami Samarth Institute of Pharmacy, At, Parsodi Dhamangaon Rly. Dist-Amravati (444709) Maharashtra, India

Abstract:
The pharmaceutical sector functions under a highly regulated environment where patient safety and product quality are of utmost importance. Maintaining product consistency, ensuring regulatory compliance, and promoting continuous improvement all depend on a strong quality management system (QRM). The basic principles, elements, and legal framework that control QMS in the pharmaceutical industry are examined in this paper. Good Manufacturing Practices (GMP), risk management, GLP, TQM, QC and QA, maintenance, GLP and GMP, and auditing procedures are among the essential components that are highlighted.

Keywords: Quality management, Audits, maintenance.

Introduction:

The complicated environment in which the pharmaceutical sector operates is characterised by strict regulatory constraints, quick technical breakthroughs, and a never-ending need for innovation. The importance of QRM in this situation is clear since it acts as a proactive method to detect and control risk [1]. Every piece or thing that is used can be of high quality, whether it be a domestic product, appliance, or aid, machinery purchased from the market, a vehicle for personal or commercial use, food and food commodities, or medication for human and animal consumption. QA is a technique or trick of technique for the integrity of the product to meet with the quality standards, so no one needs to compromise on any product quality [2]. The quality, safety, and effectiveness of pharmaceutical goods are all dependent on current good manufacturing practices, or cGMP. The U.S. Food and Drug Administration (FDA) and other regulatory bodies enforce these policies, which are crucial for upholding the strict standards needed in the pharmaceutical sector [3]. The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension of the Pharmaceutical Inspection Convention (PIC) of 1970. The "European Free Trade Association" founded it in 1970. With a number of objectives, the organisation seeks to advance efficient and cooperative efforts in the field of “Good Manufacturing Practice (GMP)”. Among these objectives are the establishment, development, and application of standardised GMP procedures and guidelines for pharmaceutical quality auditors. In addition, the program encourages cooperation and communication between pertinent regulatory agencies and local and international organisations to build trust. Within the scheme, all decisions are decided by consensus [4].

The quality, safety, and effectiveness of pharmaceutical goods are all dependent on current good manufacturing practices, or cGMP. The U.S. Food and Drug Administration (FDA) and other regulatory bodies enforce these policies, which are crucial for upholding the strict standards needed in the pharmaceutical sector [3]. The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension of the Pharmaceutical Inspection Convention (PIC) of 1970. The "European Free Trade Association" founded it in 1970. With a number of objectives, the organisation seeks to advance efficient and cooperative efforts in the field of "Good Manufacturing Practice (GMP)"[5].

Every pharmaceutical plant's main goal is to consistently produce goods with the required qualities and attributes at the most competitive costs. The pharmaceutical sector has long carried out validation studies, however to get such a quality, the industry is currently interested in a range of perspectives. The term "validation" first appeared in the United States in 1978 [6].

With the introduction of artificial intelligence, the pharmaceutical sector has experienced previously unheard-of technological breakthrough, signalling a fundamental change in the paradigms around drug development. Large biological datasets, complex algorithms, and enhanced computing power have all come together to generate new avenues for innovation in pharmaceutical research and development. Traditional drug development procedures, which usually take ten to fifteen years and cost more than $2.5 billion, are being transformed by AI-driven methods [7]. The Pharmacy Commission was created by the Ghana Pharmaceuticals Act 1994 to oversee and authorise pharmacies and professional pharmacies in Ghana; however, the existing legislation ignores the growing concerns around automation- and artificial intelligence (AI) technologies. Despite the growing globalisation of AI pharmaceutical systems, Ghanaian law makes a clear distinction between liability discrimination and quality control. AI tools for healthcare have expanded quickly in recent years. AI pharmacy solutions can automate inventory control, drug distribution [8].

One of the sectors with the highest levels of regulation worldwide is the pharmaceutical sector. Documentation is essential to ensuring pharmaceutical companies adhere to the stringent rules and regulations established by many regulatory bodies, including the FDA, EMA, and WHO. Research and development, manufacturing, quality control, and distribution of pharmaceutical goods are all supported by the documentation employed in the pharmaceutical sector. Additionally, documentation is essential for handling changes in the pharmaceutical sector. To manage modifications to processes, methods, or equipment that could affect a product's quality or safety, change control paperwork is utilised. This includes change requests, change control plans, and change control records. To make sure that modifications are handled properly and that the product keeps up with legal standards, these documents need to be kept up to date on a regular basis. In the pharmaceutical sector, validation documentation is also very important. Plans, procedures, and reports that show that the machinery, systems, and procedures utilised in the production of pharmaceutical products continuously yield goods that satisfy predetermined quality requirements are examples of validation documentation. To assure that the validation is thorough and satisfies regulatory criteria, the documentation procedure for validation must be strict [9].

Principle:

Improving overall responsiveness, cutting lead times, and increasing efficiency are the main goals of QRM in the pharmaceutical sector. These are the main QRM concepts used in the pharmaceutical industry [1].

- Pay attention to time as a factor of competition.
- Organization-Wide Commitment and Understanding.

- Work cells that are tailored.
- Batch sizes are being reduced.
- Batch sizes are being reduced.
- cutting down on setup time.
- interdisciplinary teams.
- proactive control of risks.
- Flexible Capacity.
- ongoing development.

QA and QC are crucial for:

Adherence to regulations pharmaceutical firms is more likely to adhere to rules when quality assurance and control are in place. By supplying safe and effective medications, public safety quality assurance and control contribute to public safety. Pharmaceutical firms are assisted in preserving their reputation for dependability and honesty by reputation quality assurance and control. By making sure that medications contain the right ingredients, liability quality assurance and control help to reduce liability. Good manufacturing practices should be considered while producing, distributing, and marketing pharmaceutical products [10]. To guarantee that the user and outside parties are confidence in the quality of the data acquired, a QA/QC program's objective is to track the data quality from field sampling to the creation of the final findings [11]. QA is a method that ensures that quality standards are consistently followed during the compounding process [12].

Quality Control:

Choosing the right IQC material is essential to the effectiveness of a quality control program. First, IQC material should closely resemble the composition of patient samples to minimise matrix influences on analyte measurement [13]. QC uses inspections, testing, and evaluation to identify and address defects [14]. While the inventory is being built, its quality is monitored and managed by a system of routine technical duties known as quality control.

The quality control system's objectives are to:

- To guarantee the correctness, completeness, and integrity of the data, conduct regular, routine tests.
- Find and correct mistakes and omissions.
- Keep track of all Quality Control actions and document and maintain inventory items [10].

The most crucial element in an organization's success and the main factor propelling its expansion into both domestic and foreign markets is quality. For this reason, to compete in a free market, every company strives to improve its products. To improve the quality of their products, manufacturers have introduced a number of advances as technology has developed [15].

Figure 1: Eight Quality System Parameters [10]

Quality Assurance:

To assess the quality of the inventory and identify areas for improvement, an objective review is required for excellent practice in quality assurance operations. One could look at the list as a whole or in parts[10]. In the pharmaceutical sector, the Quality Control (QC) department is essential to guaranteeing the manufacture and distribution of high-quality medications. Its duties include a variety of tasks to ensure that every facet of the production process complies with legal requirements and fulfils the requirements required to ensure patient safety and treatment effectiveness [16]. Proactive measures are given priority in QA in order to avoid issues and ensure consistency [14].

QUALITY RISK MANAGEMENT:

Quality risk management, or QRM, is the systematic process of recognising, mitigating, communicating, and assessing risks to the quality of pharmaceuticals. This process is crucial for ensuring patient safety and product quality across the whole product lifecycle, from research and manufacturing to post-market operations [14]. The manufacturing and usage of pharmaceuticals, including its component elements, are always fraught with risk. The risk to its quality is only one aspect of the whole risk. It's important to understand that making sound risk-based decisions over the course of a product's lifecycle guarantees that the characteristics that are essential to the medication's (or medicinal product's) quality are maintained, and that the product remains safe and effective [17].

Four primary principles of QRM [18]

- The evaluation of quality risk should be grounded in scientific understanding and ultimately connected to patient safety.
- QRM ought to be adaptable, dynamic, and iterative.
- The degree of risk should be reflected in the QRM process's effort, formality, and documentation.
- The QRM process should incorporate the opportunity for ongoing improvement and development.

Good Laboratory Practices GLP:

The uniformity, consistency, dependability, reproducibility, quality, and integrity of products being developed for human or animal health (including pharmaceuticals) are all assured by good laboratory practice (GLP), a quality system of management controls for research labs and organisations [19].

TQM in GLP involves following points [20]:

1. It tightly regulates the use of animals in lab experiments.
2. Prepares protocol or master schedule sheet for the study
3. Keep a copy of the protocol, which is necessary to carry out laboratory research.
4. Regular examination of the tools used for the study.
5. Documentation if the study's approved protocol changes, there should be documentation explaining the change's justification.

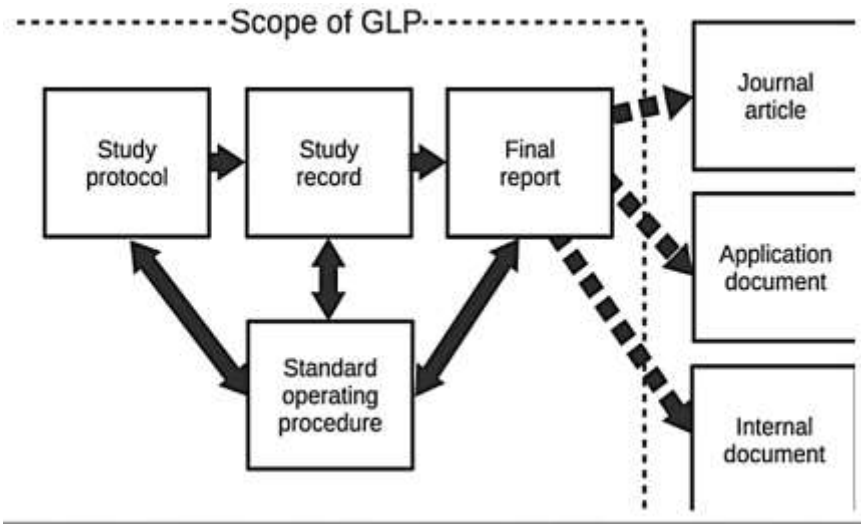

Figure 2: Scope of GLP [19].

Current Good Manufacturing Practices (cGMP):

To produce safe and high-quality meals, good manufacturing practices (GMPs) are essential working and environmentally friendly conditions that guarantee the safe handling of products, materials, and packaging in conjunction with food processing in a suitable setting [21].

Regulatory Affairs:

A company's regulatory affairs operations have a significant financial impact. Millions of euros, dollars, or pounds may be spent on the research of a new medication, and even a three-month delay in launching it can have a big financial impact. The regulatory affairs division serves as the initial point of contact between the government agency and the corporation. The company's strategic decisions are influenced by the regulatory affairs division's information on the government's viewpoint. Since even a small delay might have an effect on the company's financial health, regulatory affairs help to assurance the drug hits the market on time [24]. Guidelines for process validation have been released by regulatory bodies like the FDA and EMA. These standards include crucial requirements and suggestions for guaranteeing the safety and quality of products [25].

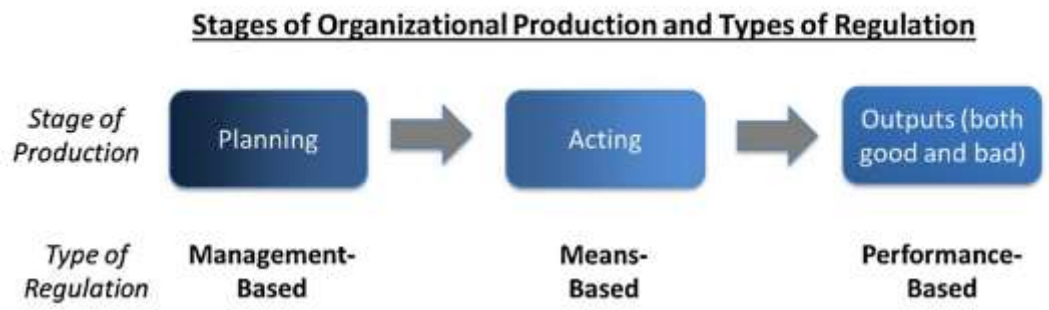

Figure 3: Stages of organizational production and types of regulation[24]

Standard Operating Procedures (SOPs):

Standard Operating Procedures (SOPs) are a set of written instructions that specify how to perform a routine or recurrent operation inside an organisation. The terms protocols, instructions, and worksheets are sometimes used interchangeably with "SOP" [25].

Purpose of SOPs [25]:

- SOPs describe the routine work procedures carried out in an organisation, guaranteeing reliable data and constant adherence to technical and quality standards.
- They cover a wide range of jobs, such as basic programming, specialised operations like analytical processes, and equipment calibration and maintenance.
- SOPs help with quality control, assurance, and regulatory compliance because they are customised for the organisation or facility.
- SOPs that are badly worded are ineffectual; well-crafted ones are essential. Management monitoring, ideally by direct supervisors, is necessary since even the best SOPs are useless if they are not followed.
- To ensure their efficacy, SOPs must be readily available, up-to-date, and in print or electronic format for individuals carrying out the responsibilities.

Management of materials:

The word "materials management" describes the process of controlling the kind, amount, location, movement, and schedule of various commodities that industrial businesses employ in their manufacturing. Ten key aspects of materials management are depicted in Figure 3. It is the process of organising, directing, tracking, and coordinating the activities related to inventory and material specifications, from their inception to their integration into the manufacturing process.

1. Maintaining accurate inventory,
2. Facilitating Just in Time (JIT) inventory management,
3. Maximising freight costs, and
4. Enhancing quality control are the four primary justifications for the significance of materials management [26].

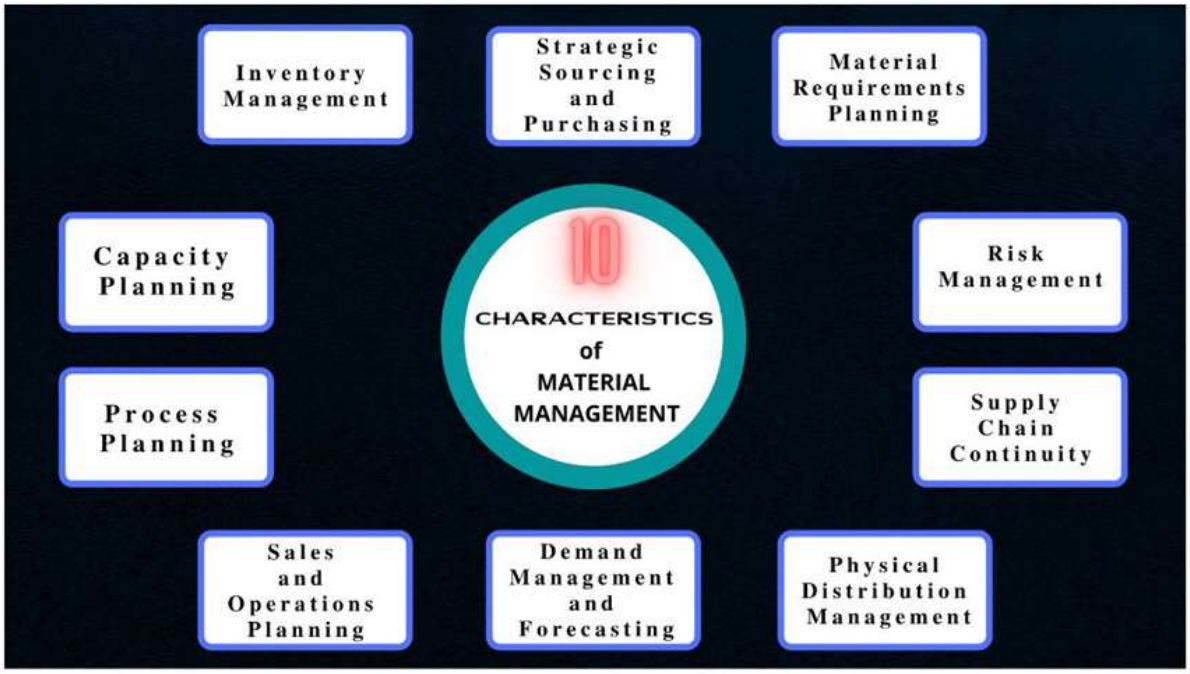

Figure 3: Ten characteristics of Materials Management [26].

Implementation and maintenance:

Audits are conducted to assess the internal oversight of a system and ascertain the quality and reliability of the data. It provides management with information on how well the pharmaceutical business maintains quality control over its manufacturing processes and final goods. All stakeholders involved are guaranteed to be aware that the program operates in accordance with accepted standards of practice thanks to the audit's conclusions and the remedial actions taken [27].

Conclusion:

Pharmaceutical products must have a strong Quality Management System (QMS) in place to guarantee its efficacy, safety, and quality. Pharmaceutical firms can reduce risks, increase product consistency, and gain the trust of consumers and regulatory agencies by implementing a systematic approach to quality planning, assurance, control, and improvement. To modify QMS frameworks to address upcoming difficulties, it will be essential to incorporate digital tools, data analytics, and a culture of quality. In the end, a robust and adaptable pharmaceutical business is supported by a well-structured QMS.

Reference:

1. Bais SK, Rathod PR. Quality Risk Management in Pharmaceutical Industry. 2024; 1(2): 811-830.
2. Yadav KK, Kushwaha SK, Verma J. A review on advacement in quality assurance practices in pharmaceutical manufacturinge. 2024 14(7): 1639-1654.
3. Ahmed R. The role of CGMP in the manufacturing unit of a pharmaceutical industry. Radinka Journal of Health Science. 2024; 2(2): 242-53.
4. Kamaraj R, Balakumar P. Pharmaceutical inspection co-operation scheme: an overview. Cureus. 2024; 16(9): 1-12.
5. Likhitha B, Bhuvana C, Swathika B, Aroon A. Equipment qualification and maintenance in pharmaceutical manufacturing: Strategies for efficiency and compliance. 2024;13(11): 298-306.

6. Jagtap S, Jadhav PB, Bairagi V. Pharmaceutical validation: a review. Int J Pharm Sci. 2024; 2(1): 399-409.
7. Uriti SV. A review on progress and potential of machine learning and ai in pharmaceutical development. Journal of pharma insights and research. 2025; 3(2): 019-30.
8. Mensah GB, Mijwil MM, Adamopoulos I. Analyzing ghana's pharmacy act, 1994 (act 489) regarding quality control and negligence liability measures for artificial intelligence pharmacy systems. Babylonian Journal of Artificial Intelligence. 2024; 14-9.
9. Thanuja R, Kumar KV, Sree BD, Karthick S, Reshma T. A comprehensive review on documentation practices in the pharmaceutical manufacturing industry. Jordan Journal of Pharmaceutical Sciences. 2024; 17(4): 829-47.
10. Lengare RR, Arjun YN, Bais SK. A review on quality control and quality assurance in pharmaceuticals. 2024; 2(4): 2507-2520.
11. Piercey SJ. Modern analytical facilities 2: A review of Quality Assurance and Quality Control (QA/QC) procedures for lithogeo-chemical data. Geoscience Canada. 2014; 41(1): 75-88.
12. Hossain MF. Quality assurance in pharmaceutical compounding (qa part 1): verification of certificate of analysis (CoA). Journal of Pharmaceutical Compounding and Therapeutics Open Access. 2024; 1(1): 2996-3753.
13. Kinns H, Pitkin S, Housley D, Freedman DB. Internal quality control: best practice. Journal of clinical pathology. 2013; 66(12): 1027-32.
14. Waghmode G, Mane SR. Introduction to the Back Bone of Excellence: Exploring QA & QC.2025; 3(1): (3193-3208).
15. Naveen RS, Meyyanathan SN, Sowbarnika S, Dash A, Abhishek R. Innovative approaches to capa and change control in the pharmaceutical industry. 2025; 31(1): 200-225.
16. Ahmed R. Ensuring Quality Medicine Is Not A Single Event But Rather Combines Effects of A Pharmaceutical Company. Radinka Journal of Health Science. 2024; 2(2): 226-41.
17. Dey S, Dutta S, Ray J. A review article on an existing schedule m vs revised schedule m. 2025; 16(3): 663-669.
18. Reddy VV, Vishal Gupta N, Raghunandan HV, Nitin Kashyap U. quality risk management in pharmaceutical industry: a review. international journal of pharm tech research. 2014; 6(3): 908-14.
19. Devmare SB, Bais SK. A Review: Good Laboratory Practices. 2025; 3(1): 3491-3506.
20. Jain AA, Mane-Kolpe PD, Parekar PB, Todkari AV, Sul KT, Shivpuje SS. Brief review on total quality management in pharmaceutical industries. International Journal of Pharmaceutical Research and Applications. 2022; 7(05): 1030-6.
21. Mishra S. Applications of Management Practices in Food Processing Industries: An Overview. EC Nutrition. 2024; 19: 01-5.
22. Sireesha B, Haritha S. A review on regulatory affairs and regulatory requirements for new drug approval. International Journal of Health Care and Biological Sciences. 2024; 5(4): 22-28.
23. Nishad M, Prasad P, Kushwaha Sk. Review on Process Validation of Optimized Formulation of Delamanid In Tablet Dosage Form. 2024;13(13): 145-158.
24. Lawrence XY, Kopcha M. The future of pharmaceutical quality and the path to get there. International journal of pharmaceutics. 2017; 528(1-2): 354-9.
25. Chingale ND, Walunj SD, Kikale MS, Devade OA, Redasani V. Documentation Essentials In The Pharmaceutical Industry: A Regulatory Perspective. 2024;13(11): 116-130.

26. Ammar M, Haleem A, Javaid M, Walia R, Bahl S. Improving material quality management and manufacturing organizations system through Industry 4.0 technologies. Materials Today: Proceedings. 2024; 45: 5089-96.
27. Verma S, Javed M, Pandey S. Exploring Auditing Practices in Pharmaceutical Microbiology Laboratories: An Overview. 2024; 9(4): 1524-1533.