www.pharmaerudition.org

ISSN: 2249-3875

# International Journal of Pharmaceutical Erudition

Research for Present and Next Generation

AUG 2026

Vol: 16 Issue:02

(6-20)

ISSN 2249-3875

International Journal of Pharmaceutical Erudition

Received: 15.8.26 Revised: 2.9.26 Accepted: 12.9.26

**Review Article**

# AUDIT AND SELF-INSPECTION IN THE PHARMACEUTICAL INDUSTRY: REGULATORY PERSPECTIVES, PRINCIPLES, AND QUALITY IMPROVEMENT STRATEGIES

**BHAVIKA SONI, APARNA ARORA, ANJU GOYAL**

**Bhupal Nobles' College of Pharmacy, Udaipur, Bhupal Nobles University Udaipur (313001)**

The pharmaceutical industry works under strict regulatory requirements to make sure that medicines are safe, effective, and of good quality. Audit and self-inspection are important parts of the Pharmaceutical Quality System because they help organizations check their activities, maintain Good Manufacturing Practices (GMP), and identify areas that need improvement. This review aims to bring together and compare different regulatory guidelines related to audit and self-inspection and present their common requirements in a simple and clear manner. It focuses on their classification, basic principles, regulatory requirements, importance, advantages, limitations, and practical challenges. An audit is a systematic and independent evaluation used to check whether an organization follows regulatory requirements and its own procedures, while self-inspection is an internal review carried out by trained and qualified personnel to identify gaps and ensure continued GMP compliance. Regulatory bodies such as WHO, USFDA, and EU GMP give importance to proper audit programs, accurate documentation, clear classification of observations, and timely corrective and preventive actions (CAPA). Effective audit and self-inspection help organizations maintain compliance, reduce risks, improve supplier management, strengthen quality systems, and remain prepared for regulatory inspections. When these activities are properly planned and documented, they also help improve transparency, build a strong quality culture, and support continuous improvement within the pharmaceutical organization.

**KEYWORDS:** Audit; Self-Inspection; GMP; Quality Assurance; CAPA; Regulatory Compliance; Pharmaceutical Industry.

## INTRODUCTION

The pharmaceutical industry is strictly regulated because medicines have a direct impact on public health and patient safety. To ensure that products are safe, effective, and of high quality, regulatory authorities mandate compliance with Good Manufacturing Practices (GMP).[1]

In this context, audit and self-inspection serve as structured and systematic tools to evaluate whether pharmaceutical operations are being carried out in accordance with regulatory requirements as well as established internal procedures.[2]

Self-inspection is considered one of the key components of the pharmaceutical quality system.The gaps in identifying both known and potential non-compliances related to processes, procedures, equipment, storage conditions, utilities, and other operational areas. The purpose of self-inspection is to detect gaps and ensure that they are corrected in accordance with current Standard Operating Procedures (SOPs) and regulatory

requirements. Generally, self-inspection should be conducted at least once a year; however, depending on the nature and severity of previous observations, the frequency may be increased to quarterly or even monthly reviews. These inspections should be carried out by subject matter experts who possess adequate technical knowledge and understanding of regulatory expectations in the irrespective areas.[3]

An audit can be defined as a systematic analysis of a system or process to determine whether it meets specified requirements. According to the International Organization for Standardization (ISO), an audit is a systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which established criteria are fulfilled.[4]

**Importance of Audit and Self-Inspection**.

Audit supports pharmaceutical organizations in several important ways. It helps in evaluating compliance with applicable regulatory standards and ensures that operations are aligned with established requirements. Audits also verify the accuracy and completeness of documentation, assess whether procedures are being properly implemented, and identify potential weaknesses within the system. In addition, they contribute significantly to the strengthening and continuous improvement of the Quality Management System (QMS).Self-inspection, on the other hand, is regarded as one of the most effective internal monitoring mechanisms. It enables organizations to regularly review their own processes, maintain ongoing compliance, and promote continuous quality improvement. [5,6].

**Definition and Concept of Audit**

An audit evaluates both the strengths and weaknesses of quality assurance processes within an organization. The findings of an audit help in identifying gaps, improving existing processes, and developing a more robust quality system for the overall benefit of the company. In the pharmaceutical industry, audits may cover activities ranging from design qualification (DQ) to performance qualification (PQ).They also include the review of Standard Operating Procedures (SOPs), regulatory guidelines, validation policies, and other quality-related documentation.[7]

An audit can be defined as the systematic examination of a system or process to determine whether it meets specified requirements.

1. According to the International Organization for Standardization (ISO), an audit is a systematic independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which established criteria are fulfilled [8,9]

ISSN 2249-3875

International Journal of Pharmaceutical Erudition

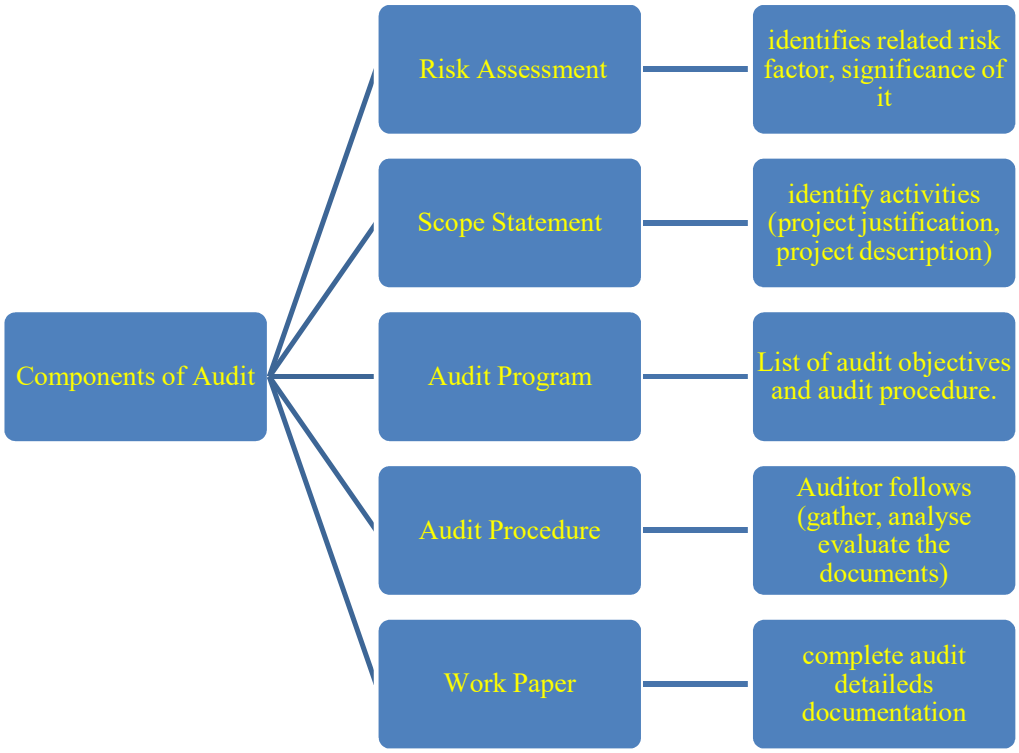



**Fig 1: Components of Audit**

**Audits Evaluate**

Audits evaluate the following key areas within a pharmaceutical organization:

1. Effectiveness of qualitysystems
2. Accuracy and completeness of documentation practices
3. Operational compliance with established procedures
4. Supplier qualification and vendor management

Adherence to applicable regulatory requirements[10]

**Objectives of Pharmaceutical Audit**

The main objectives of a pharmaceutical audit are to evaluate the effectiveness of the quality system in meeting established quality requirements and objectives and to ensure compliance with GMP guidelines and other applicable regulatory requirements. An audit also provides an opportunity for the audit team to identify areas for improvement within the Quality Management System (QMS). It helps maintain a documented record or register of audited and approved companies, determine conformity or non-conformity with specified quality system standards, and assess and improve the performance and reliability of

vendors. In addition, audits are conducted to verify the proper implementation of and adherence to approved documents and procedures.[11]

**Classification of Audits**

Pharmaceutical audits can be broadly classified into the following categories:

**Internal Audit**

An internal audit is conducted within the organization to evaluate its own systems and processes. It focuses on monitoring and regulating the internal systems of the pharmaceutical company and reviewing company policies to assess their practical implementation. Internal audits also involve analyzing records to verify their accuracy and identify possible errors or irregularities. In addition, they help identify and prevent errors and deficiencies, safeguard company assets, and support the smooth functioning of the organization's internal control system.[12]

**ExternalAudit**

An external audit is conducted by customers, clients, or third-party organizations. It helps strengthen confidence and transparency between business partners, ensures that agreed requirements are properly understood and fulfilled, and reduces the risk of quality failures and compliance issues.[13]

**Regulatory Audit**

A regulatory audit is conducted by a regulatory authority or an independent regulatory body to verify compliance with legal and regulatory requirements. Such audits may be performed for licensing, approval, or product registration purposes and are generally conducted by regulatory authorities such as the Medicines Control Authority (MCA) and the USFDA. After the audit, a formal report is issued to the organization. In MCA inspections, verbal feedback is generally provided during the exit meeting, whereas USFDA inspections may issue observations through Form 483, highlighting areas of non-compliance that require corrective action.[14]

**Concept of Self-Inspection**

The present review focuses on the requirements of self-inspection as described in various regulatory guidelines, including WHO,Schedule M of the Drugs and Cosmetics Act,USFDA, MHRA and TGA.Each regulatory authority outlines self-inspection requirements under specific sections of their guidelines. Although the structure may vary slightly among guidelines, the fundamental purpose remains the same -to ensure continuous compliance with GMP standards.[15]

**Definition and Purpose of Self-Inspection**

Self-inspection is a periodic internal review carried out by company personnel to assess compliance with GMP requirements and

established company procedures.

Detect deficiencies at an early stage.

1. Recommend appropriate corrective and preventive actions.
2. Prevent potential regulatory non-compliance.

Self-inspection should be conducted by qualified and experienced personnel who possess adequate technical knowledge. Ideally, the inspectors should be independent of the area being evaluated to ensure objectivity and unbiased assessment.[16]

**Areas Covered During Self-Inspection**

Self-inspection covers all major areas of a pharmaceutical organization that can directly or indirectly affect product quality, safety, and GMP compliance. Personnel are evaluated by reviewing their training records, job descriptions, hygiene practices, and qualification status to ensure that employees are properly trained, competent, and following the required procedures. Premises and facilities are inspected to verify cleanliness, environmental conditions, HVAC monitoring, and pest-control measures, as these factors can influence the quality and safety of pharmaceutical products. Equipment is reviewed by checking calibration records, maintenance logs, and cleaning validation to ensure that equipment remains accurate, properly maintained, and suitable for its intended use.[17]

self-inspection. It includes checking SOP control, proper version management, record retention, and completeness of logbook entries to ensure that activities are properly documented and traceable. In the production area, batch manufacturing records, line clearance, and in-process controls are reviewed to confirm that manufacturing activities are performed according to approved procedures and that necessary controls are maintained during production.

Quality Control activities are assessed through the review of test method validation, stability data, and analytical records to ensure that testing procedures and quality-related data are reliable and properly maintained. Finally, complaints and recalls are evaluated by reviewing complaint-handling procedures, recall mock drills, and investigation reports. This helps the organization assess its ability to identify, investigate, and appropriately respond to product-related quality issues. Overall, these areas help identify deficiencies at an early stage and support timely corrective and preventive actions (CAPA). [18]

**Regulatory Frame work: Detailed Comparative Analysis**

**WHO GMP Requirements**The World Health Organization (WHO) emphasizes that pharmaceutical organizations should maintain a written self-inspection procedure and appoint .

ISSN 2249-3875

International Journal of Pharmaceutical Erudition

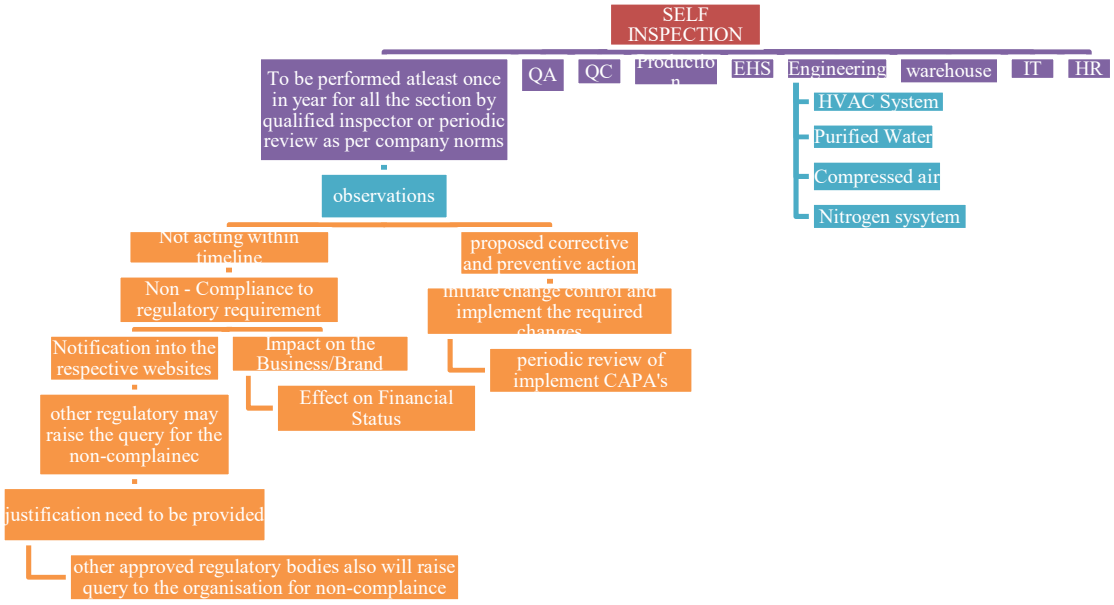
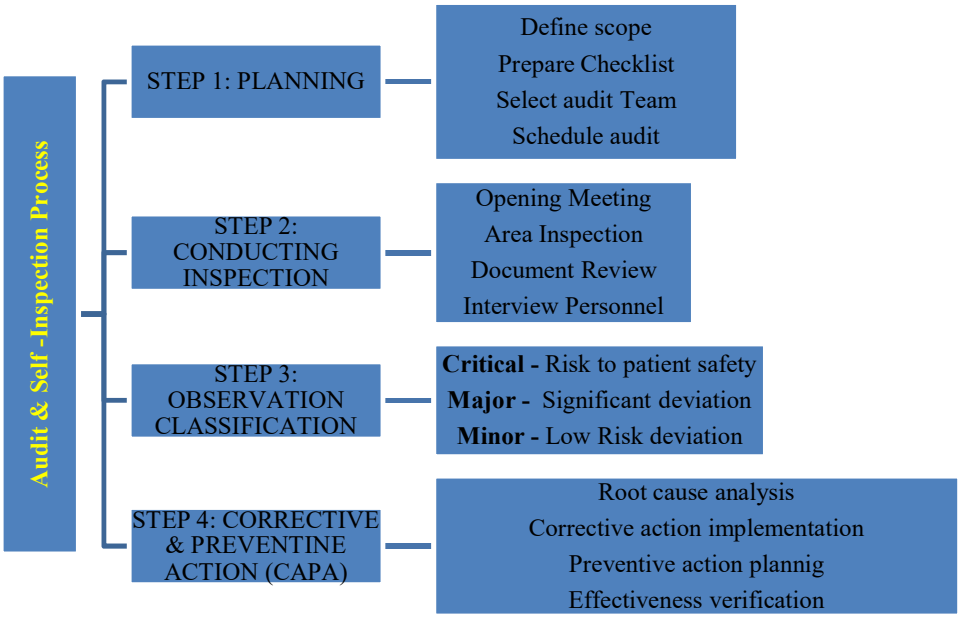



**Fig 2: Self-Inspection Process and Areas Covered During Self-Inspection**



ISSN 2249-3875

International Journal of Pharmaceutical Erudition

**Fig 3: Audit and Self-Inspection Process**

**Table 1: Comparison between Audit and Self-Inspection**

| Parameter | Audit | Self Inspection |
|---|---|---|
| Conducted by | Internal/External | Internal |
| Purpose | Compliance Verification | Continue Monitoring |
| Frequency | Scheduled/Trigger | Periodic |
| Regulatory | Possible | NotDirect Involvement |

qualified, independent internal inspectors Self-inspections should follow a predefined and periodic schedule, with findings documented in a formal report and followed by appropriate Corrective and Preventive Actions (CAPA). Management should review the findings to ensure effective implementation, while continuous quality improvement and transparency in documentation practices should be maintained. [19]USFDA RequirementsUnder 21 CFR Parts 210 and 211, the USFDA requires pharmaceutical manufacturers to establish an independent Quality Control Unit (QCU), implement effective internal control systems for GMP compliance, conduct scientifically justified investigations of deviations and failures, and maintain proper documentation with effective Corrective and Preventive Action (CAPA) systems. In the past decade, FDA warning letters have frequently identified deficiencies such as inadequate investigations, weak CAPA systems, data integrity problems, and incomplete or missing audit trails. FDA inspections follow a risk-based approach, with strong emphasis on documentation accuracy, traceability, and data authenticity to ensure the reliability and integrity of pharmaceutical quality systems. [20,21]

**EU GMP**

According to EU GMP Chapter 9 (Self-Inspection), pharmaceutical manufacturers should establish a structured and well-documented self-inspection program conducted by independent and competent inspectors. The inspection should have a clearly defined scope covering all GMP-relevant areas, and the findings should be documented in written inspection reports. Appropriate follow-up actions and re-evaluation of corrective measures should be performed to ensure effective resolution of identified deficiencies. EU GMP also emphasizes the integration of Quality Risk Management (QRM) principles, implementation of a Pharmaceutical Quality System (PQS) aligned with ICH Q10, and qualification and auditing of suppliers to ensure consistent quality and regulatory compliance. [22,23]

**PIC/S Guidelines**

ISSN 2249-3875

International Journal of Pharmaceutical Erudition

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) aims to harmonize GMP standards and inspection practices among participating regulatory authorities worldwide. Its guidelines emphasize the adoption of risk-based inspection approaches, structured training programs for inspectors, and standardized audit and inspection methodologies. PIC/S also places strong emphasis on international regulatory harmonization and consistency in GMP implementation. Through these approaches, PIC/S contributes to improving the quality and consistency of pharmaceutical inspections and facilitates greater mutual confidence and recognition of regulatory inspection outcomes among participating countries. [24]

**Supplier and Vendor Audits**

Supplier qualification and vendor auditing are important components of pharmaceutical quality systems because the quality of raw materials, packaging materials, and other components can directly influence the safety, efficacy, and quality of finished pharmaceutical products. Supplier audits are conducted to evaluate the quality of materials supplied, assess compliance with applicable GMP requirements, verify the adequacy of manufacturing and process controls, and review the supplier's documentation and quality management systems. Effective supplier auditing helps pharmaceutical manufacturers identify potential risks within the supply chain and establish confidence in the reliability and consistency of approved suppliers. [25,26]

**Supplier Audit Process**

The supplier audit process generally begins with the distribution of a pre-audit questionnaire to obtain preliminary information about the supplier's facilities, manufacturing activities, quality systems, and regulatory status. Based on the information obtained, a risk assessment is performed to determine the need, frequency, and scope of the audit. Where necessary, an on-site audit is conducted to evaluate actual manufacturing and quality practices. Audit observations are classified according to their significance, commonly as critical, major, or minor. Identified deficiencies are followed through an appropriate CAPA process, and the final decision regarding supplier approval, conditional approval, or rejection is based on the overall audit findings and risk assessment. Effective vendor audits help reduce the risks associated with contamination, substandard raw materials, inadequate manufacturing controls, and supply-chain disruptions. [27]

**CAPA System in Audit Management**

The Corrective and Preventive Action (CAPA) system is an essential component of pharmaceutical audit management because it ensures that deficiencies identified during

audits are systematically investigated, corrected, and prevented from recurring. CAPA implementation generally begins with the identification and documentation of a non-conformity, followed by Root Cause Analysis (RCA) to determine the underlying cause of the problem. Appropriate corrective actions are then developed to eliminate the identified deficiency, while preventive actions are established to minimize the possibility of recurrence. The approved actions are implemented within defined timelines, and their effectiveness is subsequently evaluated. All CAPA activities should be properly documented, reviewed, and formally closed only after adequate evidence confirms that the identified issue has been effectively addressed.[28]

**Quality Culture and Management Responsibility**

Modern pharmaceutical regulatory systems increasingly emphasize the importance of a strong quality culture, in which quality and compliance are integrated into everyday organizational activities rather than being treated merely as regulatory requirements. Management has a critical responsibility in establishing and maintaining such a culture by actively supporting audit and self-inspection programs, providing adequate resources for quality activities, ensuring appropriate training of auditors and personnel, and regularly reviewing audit findings and quality performance. Management should also monitor CAPA trends and continuous improvement activities to identify recurring problems and systemic weaknesses. A strong quality culture encourages employees to report problems openly and view audit findings as opportunities for improvement rather than as regulatory burdens. Consequently, effective management commitment and employee participation are essential for maintaining a sustainable pharmaceutical quality system and achieving continuous improvement in product quality and patient safety.[29]

**Common Regulatory Observations (Trend Analysis)**

Analysis of regulatory inspection findings over recent years shows that certain deficiencies repeatedly appear across pharmaceutical manufacturing and quality systems. These recurring observations indicate that regulatory expectations are increasingly focused not only on compliance with written procedures but also on the effectiveness, reliability, and integrity of the overall Pharmaceutical Quality System (PQS). The major recurring areas of concern include data integrity, documentation practices, deviation and failure investigations, process validation, and quality risk management.[30]

Data integrity and documentation deficiencies

are among the major concerns identified during regulatory inspections. Issues may include inaccurate, incomplete, manipulated, or unreliable records, as well as weaknesses in audit trails and data management. Backdated or falsified records can compromise the reliability of manufacturing and laboratory data and may prevent regulators from determining whether processes were properly controlled. Therefore, pharmaceutical organizations are expected to maintain complete, accurate, traceable, and authentic records throughout the product lifecycle. The increasing regulatory focus on data integrity demonstrates that quality decisions must be based on trustworthy and scientifically reliable information.[31]

Inadequate deviation investigations are another frequently observed deficiency. A deviation should be investigated systematically to determine its actual or potential impact on product quality and patient safety. However, investigations may sometimes focus only on the immediate or obvious cause without identifying the underlying root cause. Weak investigations can result in ineffective corrective and preventive actions (CAPA), allowing similar problems to occur repeatedly. A robust investigation should therefore include appropriate root cause analysis, assessment of product and process impact, implementation of suitable corrective and preventive actions, and verification of their effectiveness.[32]

**DISCUSSION**

Audit and self-inspection systems have undergone significant transformation over the past decade. Regulatory authorities have gradually shifted their focus from simple verification of documentation to a more comprehensive evaluation of the entire quality system. Modern inspections now emphasize data integrity, risk management, process understanding, and the overall effectiveness of the Pharmaceutical Quality System (PQS).[33]

Large pharmaceutical companies have increasingly adopted structured, risk-based audit approaches supported by digital quality management systems. These systems allow better tracking of observations, CAPA monitoring, and trend analysis.[34]

In contrast, many small and medium-sized pharmaceutical industries still depend largely on manual documentation and traditional audit practices, which may lead to compliance gaps and delayed corrective actions.[35]

The COVID-19 pandemic further accelerated changes in auditing practices. Remote and hybrid audit models were introduced, demonstrating the importance of digital documentation, electronic quality management systems, and centralized data control. These developments indicate that digitalization and automation will play a critical role in the future

of pharmaceutical audit and self-inspection programs.[36]

1. Measuring the actual effectiveness of audit programs.
2. Establishing globally harmonized audit performance metrics.
3. Evaluating the practical implementation of AI-based compliance monitoring systems.

Future research should therefore focus on developing predictive compliance tools, automation strategies, and data-driven quality systems that enhance proactive risk management in pharmaceutical industries.[37]

**CONCLUSION**

Audit and self-inspection are essential components of an effective Pharmaceutical Quality System and should not be considered merely as regulatory or compliance-related activities. This review highlights that well-planned and systematically conducted audits and self-inspections provide pharmaceutical organizations with an opportunity to evaluate the effectiveness of their quality systems, identify deficiencies at an early stage, assess compliance with GMP requirements, and implement appropriate corrective and preventive actions (CAPA). Their effective implementation can therefore contribute to improved process control, reduced regulatory risk, better supplier management, and continuous improvement in overall pharmaceutical operations.

The review also indicates that regulatory expectations have progressively shifted from simple verification of documented procedures toward a broader assessment of data integrity, risk management, process effectiveness, investigation quality, and the overall performance of the Pharmaceutical Quality System. Recurring regulatory observations related to documentation, data integrity, inadequate deviation investigations, process validation, and weak CAPA systems demonstrate the need for organizations to focus on the effectiveness of their quality practices rather than only on procedural compliance.

Management commitment, competent personnel, independent auditors, accurate documentation, effective root cause analysis, and timely CAPA implementation are therefore critical for establishing a strong quality culture. In addition, the increasing use of electronic quality management systems, remote audits, data-driven monitoring, and risk-based approaches is transforming traditional audit practices.

Overall, pharmaceutical organizations that integrate audit and self-inspection into their routine quality management activities can achieve stronger GMP compliance, improved inspection readiness, and more sustainable

quality performance. Future development should focus on harmonized audit performance metrics, predictive compliance tools, automation, and data-driven approaches to support proactive risk management and ultimately enhance product quality and patient safety.

**REFERENCE**

1. World Health Organization. WHO good manufacturing practices for pharmaceutical products: main principles. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-eighth report. Geneva: World Health Organization; 2014. WHO Technical Report Series No. 986, Annex 2, Section 8: Self-inspection, quality audits and suppliers' audits and approval. p. 98-100.

2. Government of India, Ministry of Health and Family Welfare. Drugs Rules, 1945: Schedule M—Good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products. New Delhi: Government of India.

3. U.S. Food and Drug Administration. Current good manufacturing practice for finished pharmaceuticals: 21 CFR parts 210 and 211. Part 211, Subpart B: Self-inspection. Silver Spring (MD): U.S. Food and Drug Administration; 2016.

4. Medicines and Healthcare products Regulatory Agency. Rules and guidance for pharmaceutical manufacturers and distributors (The Orange Guide). London: MHRA; relevant edition. Section: Self-inspection.

5. Therapeutic Goods Administration. Australian code of good manufacturing practice for medicinal products. Canberra: Australian Government Department of Health and Aged Care; relevant edition. Requirements: self-inspection and quality management.

6. Pharmaceutical Inspection Co-operation Scheme. Guide to good manufacturing practice for medicinal products. PE 009. Geneva: PIC/S; relevant edition. Chapter 9: Self-inspection.

7. Ghose A, Koliadis G. Auditing business process compliance. In: Krämer BJ, Lin KJ, Narasimhan P, editors. Service-oriented computing—ICSOC 2007. Berlin: Springer; 2007. p. 169-180. doi:10.1007/978-3-540-74974-5_14.

8. Karapetrovic S, Willborn W. Generic audit of management systems: fundamentals. Manag Audit J. 2000;15(6):279-294.

9. Karapetrovic S, Willborn W. Quality assurance and effectiveness of audit systems. Int J Qual Reliab Manag. 2000;17(6):679-703.

10. Arter DR. Quality audits for improved performance. 3rd ed. Milwaukee (WI): ASQ

Quality Press; 2003. 142 p. ISBN: 978-0-87389-570-5.

11. World Health Organization. WHO good manufacturing practices for pharmaceutical products: main principles. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-eighth report. Geneva: World Health Organization; 2014. WHO Technical Report Series No. 986, Annex 2. p. 82-122.

12. World Health Organization. WHO good manufacturing practices for pharmaceutical products: main principles. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-eighth report. Geneva: World Health Organization; 2014. WHO Technical Report Series No. 986, Annex 2, Section 8: Self-inspection, quality audits and suppliers' audits and approval. p. 97-100.

13. World Health Organization. WHO guidance on good data and record management practices. Geneva: World Health Organization; 2016.

14. World Health Organization. WHO guidelines on quality risk management. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013. WHO Technical Report Series No. 981, Annex 2. p. 62-78.

15. World Health Organization. WHO good practices for pharmaceutical quality control laboratories. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-eighth report. Geneva: World Health Organization; 2024. WHO Technical Report Series No. 1052, Annex 4. 88 p.

16. World Health Organization. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Geneva: World Health Organization.

17. U.S. Food and Drug Administration. Current good manufacturing practice for finished pharmaceuticals: 21 CFR parts 210 and 211. Silver Spring (MD): U.S. Food and Drug Administration.

18. U.S. Food and Drug Administration. Data integrity and compliance with drug CGMP: questions and answers: guidance for industry. Silver Spring (MD): U.S. Food and Drug Administration; 2018.

19. U.S. Food and Drug Administration. Remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities: guidance for industry. Silver Spring (MD): U.S. Food and Drug Administration; 2023.

20. U.S. Food and Drug Administration. Compliance program guidance manual. Silver Spring (MD): U.S. Food and Drug Administration.

21. U.S. Food and Drug Administration. Quality systems approach to pharmaceutical current good manufacturing practice regulations. Silver Spring (MD): U.S. Food and Drug Administration; 2006.

22. U.S. Food and Drug Administration. Quality systems approach to pharmaceutical CGMP regulations: guidance for industry. Silver Spring (MD): U.S. Food and Drug Administration; 2006.

23. U.S. Food and Drug Administration. Investigating out-of-specification (OOS) test results for pharmaceutical production: guidance for industry. Silver Spring (MD): U.S. Food and Drug Administration; 2022.

24. U.S. Food and Drug Administration. Contract manufacturing arrangements for drugs: quality agreements: guidance for industry. Silver Spring (MD): U.S. Food and Drug Administration; 2016.

25. European Commission. EudraLex: the rules governing medicinal products in the European Union. Volume 4: EU guidelines for good manufacturing practice for medicinal products for human and veterinary use. Chapter 9: Self-inspection. Brussels: European Commission.

26. European Medicines Agency. Guidance on good manufacturing practice and good distribution practice: questions and answers. Amsterdam: European Medicines Agency.

27. European Commission. EudraLex Volume 4: EU guidelines for good manufacturing practice for medicinal products for human and veterinary use. Chapter 4: Documentation. Brussels: European Commission.

28. European Commission. Guidelines of 5 November 2013 on good distribution practice of medicinal products for human use. Off J Eur Union. 2013;C343:1-14.

29. Pharmaceutical Inspection Co-operation Scheme. PIC/S guide to good manufacturing practice for medicinal products. PE 009. Geneva: PIC/S.

30. Pharmaceutical Inspection Co-operation Scheme. PIC/S inspection risk assessment model. Geneva: PIC/S; relevant edition.

31. International Council for Harmonisation of echnical Requirements for Pharmaceuticals for Human Use. ICH harmonised guideline Q9(R1): quality risk management. Geneva: ICH; 2023.

32. Pharmaceutical Inspection Co-operation Scheme. PIC/S inspector training programme. Geneva: PIC/S.

33. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonised guideline Q9(R1): quality risk management. Geneva: ICH; 2023. p. 1-13, Annex I. p. 15-21.

34. International Council for Harmonisation of Technical Requirements for Pharmaceuticals

for Human Use. ICH harmonised tripartite guideline Q10: pharmaceutical quality system. Geneva: ICH; 2008. p. 1-17.

35. Pharmaceutical Inspection Co-operation Scheme. PIC/S guide to good manufacturing practice for medicinal products. PE 009-17, Part I. Geneva: PIC/S; 2023. Chapter 9: Self-inspection. p. 54.

36. Pharmaceutical Inspection Co-operation Scheme. PIC/S guidance on remote assessments. PI 056-1. Geneva: PIC/S.

37. Pharmaceutical Inspection Co-operation Scheme. Good practices for data management and integrity in regulated GMP/GDP environments. PI 041-1. Geneva: PIC/S; 2021.

**Conflict of Interest**

The authors declare that they have no conflict of interest