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Review Article

The Role of GMP Audits in Ensuring Drug Quality and Safety in Drugs

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ABSTRACT

The importance of GMP audits in ensuring the quality, safety, and efficacy of pharmaceuticals is unmistakable. These audits are systematic appraisals of facilities, processes, personnel, documentation, and quality management systems that assure compliance with regulatory standards both nationally and internationally. The agencies that govern the regulatory framework for GMP compliance auditing are the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the World Health Organization (WHO), and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Key aspects of GMP auditing include quality management systems, facility and equipment maintenance, training for personnel, raw material control, process validation, laboratory testing, and documents. Unfortunately, several of those have affected the effectiveness of GMP auditing. They include inconsistency in global regulations, resource constraints, a continuously changing cloud of expectations regarding compliance, data integrity issues, and complexities found in the supply chain. The pharmaceutical sector is increasingly relying on the benefits of adopting digital technologies like Artificial Intelligence (AI), blockchain, and predictive analytics to improve audit processing efficiency and transparency in real-time monitoring of compliance. The future of GMP audits will be driven by automation, regulated harmonization, virtual inspection, and sustainable manufacturing practices to ensure proactive risk management. The strength of GMP audits is necessary for the realization of pharmaceutical quality, thus protecting public health from a continuously changing regulatory environment.

Keywords: GMP audits, Pharmaceutical quality, Drug safety, Regulatory compliance, Quality management system, AI, Predictive compliance, Pharmaceutical manufacturing.

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INTRODUCTION

Conducting Good Manufacturing Practice (GMP) audits means systematically reviewing pharmaceutical manufacturing facilities to ensure they meet established regulatory standards (World Health Organization) 2021). This mandatory audit system is established by regulatory agencies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), World Health Organization (WHO), and Pharmaceutical Inspection Co-operation Scheme (PIC/S) to ascertain whether manufacturers adhere to stringent quality control guidelines throughout the entire production lifecycle. GMP guidelines cover how the manufacturers should operate, quality management systems, training of personnel, control of raw materials, hygiene of facilities, validation of equipment, and documentation practices (U.S. Food and Drug Administration, 2023). The primary purpose of GMP audits is to identify deviations from these criteria, mitigate the risk of substandard or contaminated drugs, and the enforcement of corrective actions to maintain compliance. Pharmaceutical manufacturing technologies evolve at an increasingly high speed, and so are drug supply chains becoming globalized. The GMP audit scope has therefore expanded widely to include a risk-based approach, real-time and digital compliance systems, and AI-analytics technologies for efficient and effective inspection. Remote and hybrid audits have appeared to complement this new form of auditing, which is especially practical after the COVID outbreak when regulators now virtually assess compliance oversight (European Medicines Agency, 2022). Although they are significant, GMP audits also face numerous practical challenges such as regulatory ends associated with various countries, inspection processes that consume too many resources, integrity of data, and complex supplier networks. As the industry moves into a digitized, globally harmonized regulatory environment, these challenges must be tackled to facilitate the achievement of consistent compliance levels and quality/safety standards in medicines (Pharmaceutical Inspection Co-operation Scheme [PIC/S], 2023). This review paper explains the GMP audit on drug quality and safety concerning its regulatory framework, key components, challenges, and future

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perspectives. This shows the changing scenario of pharmaceutical quality assurance along with ongoing strengthening of compliance mechanisms in a rapidly transforming industry by analyzing new trends and innovations in GMP audits (International Council for Harmonisation [ICH], 2021).

REGULATORY FRAMEWORK

In Figure 1, GMP compliance is the core objective of pharmaceutical regulation, which is backed by major international bodies: the FDA in the U.S., the EMA in the EU, the WHO for global guidelines, and the PIC/S and ICH for the harmonization of standards. These organizations, via cooperative enforcement and oversight, bring about uniform drug quality and safety and regional regulatory alignment. GMP compliance is a basic stipulation for drug manufacturing in any part of the globe to produce an acceptable quality standard for any given drug. Various regulatory agencies enforce GMP guidelines, with every region having its specific setup. These regulations differ in several aspects but carry a common objective: the preservation of public health by guaranteeing the quality, safety, and efficacy of pharmaceutical goods. The following highlights the key regulatory bodies and their GMP guidelines:

U.S. Food and Drug Administration (FDA)

In the United States, GMP regulations are specified under Title 21 of the Code of Federal Regulations (CFR), Parts 210 and 211. The Current Good Manufacturing Practice (cGMP) provides emphasis on quality management, solid documentation, validation of manufacturing processes, and exercising rigorous quality control. The FDA routinely inspects domestic and foreign pharmaceutical manufacturing facilities to ensure compliance. These inspections generally identify non-compliance issues that may result in warning letters, import refusals, or product recalls (International Society for Pharmaceutical Engineering [ISPE], 2022).

European Medicines Agency (EMA)

EudraLex - Volume 4 describes the existing GMP regulations for the European Union in great detail-repairing the manufacturing and quality assurance of medicinal products. While inspections of GMP compliance are conducted within Europe and in third countries which export pharmaceuticals to the EU, the EMA works with the national regulatory agencies of EU member states. The EU also specifies Good Distribution Practice (GDP) as a requirement to ensure that the handling and storage processes are implemented effectively throughout the supply chain (Sarvari and Johnson, 2022).

World Health Organization (WHO)

Based on the WHO GMP guidelines with universal acceptability, countries with no regulatory systems can benefit from their usage around the world. They have been intensely adopted in developing countries and used as a reference in the Prequalification of Medicines Programme (PQP) for medicines procured by international organizations under high-quality medicines standards (Kumar and Patel, 2021).

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

PIC/S began in 1972 and was established in Brampton, Ontario to improve international cooperation and mutual recognition of their GMP inspection systems. Established by more than 50 different member authorities, some from Europe and North America to Asia, it finally becomes an answer to the increasing need for harmonization in GMP and inspection procedures in the global context (Sikdar and Kapoor, 2022).

Harmonization Efforts

Supplying chains of pharmaceuticals usually have an aspect of the world today therefore, harmonization of regulations becomes more and more increasing. Membership with organizations like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has related, to having GMP requirements unified across regions, one stating it provides ICH Q7, which generally contains GMP conditions with regards to active pharmaceutical ingredients, so applying to all the countries where medicines are manufactured. This dynamic nature of regulatory compliance means that agencies never rest on their laurels but are always making the GMP requirements better able to cope with newly emerging risks and also with changing technologies and advancements in the best practices of the industry. GMP audits are, therefore, the principal means to ensure that manufacturers comply with the ever-evolving standards and, thus, drug safety and quality assurance for the patient (Haque and Sharma, 2021).

KEY COMPONENTS OF GMP AUDITS

In Figure 2, Almost all the elements of a GMP audit in the image include control of processes, quality systems, raw materials, documentation, laboratory testing, facilities, and personnel training. Each area-such as batch records, equipment calibration, and supplier qualification-ensures compliance, safety, and quality across the pharmaceutical manufacturing environment and thus highlights the overall intent of regulatory oversight.

Quality Management System

Underpinning the entire GMP compliance imperative is an effective QMS. Thus, GMP audits evaluate the extent of GMP compliance in manufacturers based on the effectiveness of the QMS within the facility by looking at documentation practices, change control processes, and CAPA. It reviews the SOPs and other critical documentation, including batch records and training logs, to ensure that it has been recently updated and properly followed. In such a case, on a very structured QMS,

the manufacturing deviation, product complaints, and recalls would be dealt with appropriately and efficiently, reducing the risk of defective products in the market. Audits further verify if a company has a Quality Risk Management (QRM) strategy to proactively identify and mitigate anticipated risks with potential hazards in the production process (Guan and Lee, 2022).

Facilities and Equipment

The design, maintenance, and cleanliness of manufacturing facilities preclude contamination and ensure product consistency. The GMP audit checks the production areas for adherence to regulatory standards, such as air filtration, cleanroom classifications, temperature, humidity, etc., (Rahman and Choudhury, 2021). Auditors check whether the equipment is well calibrated, validated, and regularly maintained to ensure its operation within the required specifications. Facility layout and workflow design are also assessed to prevent cross-contamination between production areas and for smooth production processes. It is a critical factor in detecting and controlling microbial contamination, especially in sterile drug manufacturing environments (Piccirillo and Zhang, 2022).

Personnel and Training

Competence and hygiene among personnel are critical GMP aspects. The auditor checks if the employee was adequately and continuously trained in GMP to understand regulatory requirements, quality control measures, and safety measures. Training records are also reviewed to ascertain that staff have undergone training on current best practices and changes to procedures. The audit assesses compliance with standards for personal hygiene for instance gowning, handwashing, and restricted access to critical production areas. Non-compliance with training and hygiene levels can lead to cross-contamination, inconsistent quality of products, and regulatory breaches (Pfizer, 2023).

Raw materials and supply chain management

The raw material quality gives the final product safety and efficacy. The GMP audit assesses the manufacturer's supplier qualification programs to comply with raw materials, Active Pharmaceutical Ingredients (APIs), and excipients against predetermined quality standards. Supplier audits, Certificates of Analysis (CoA), and raw material testing records are checked by the auditors for verification and compliance (McKinsey and Company, 2022). Systems of proper storage and handling of materials, correct labelling, and traceability are examined to avoid mix-ups and to make sure that only approved raw materials are used for manufacture. Supply chain security is another important aspect as poor supply chain controls would allow counterfeit or substandard materials into the manufacturing process Haque and Sharma (2021).

Manufacturing and Process Control

Consistency and reproducibility of the manufacturing process are key parameters for producing high-quality pharmaceuticals. GMP audits evaluate batch production records, process validation reports, and In-Process Quality Control (IPQC) measures to ensure compliance with established specifications. Process validation has also been highlighted, which ensures that the production processes are capable of yielding products conforming to predetermined quality attributes consistently (World Economic Forum, 2023).

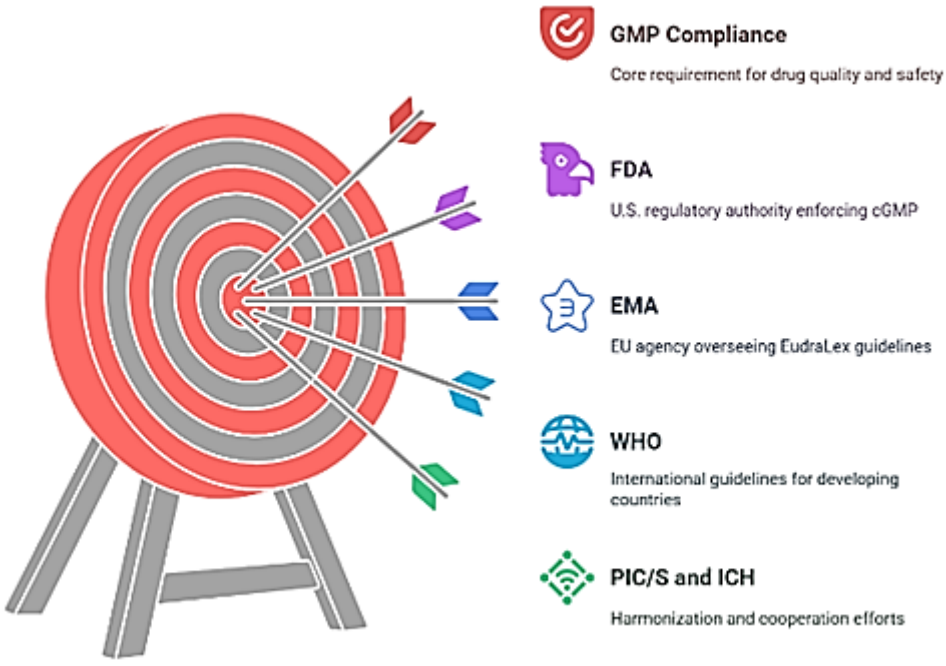

Figure 1: Regulatory Framework.

Auditors also assess the real-time monitoring of the manufacturing systems where deviations can be detected early and corrective actions be taken. Audits also review if cleaning validation was documented to avoid cross-contamination between different batches or products (Guan and Lee, 2022).

Laboratory Controls and Testing

Through laboratory testing, pharmaceutical products are assessed for safety, efficacy, and stability before being released to the market. These audits assess the validation of analytical methods, calibration of laboratory instruments, and compliance testing with pharmacopeial standards (e.g. USP, Ph. Eur., JP). The performance of microbiological testing, sterility assurance, and endotoxin testing is particularly relevant for sterile products. Stability studies are reviewed to ensure that the drug is effective and safe during the claimed shelf life. Data integrity in laboratory records is another major area of concern that would be looked at during audits, as regulatory agencies have strict guidelines to avoid the falsification, manipulation, or errors of analytical data (Rahman and Choudhury, 2021).

Documentation and Record Keeping

Accurate and complete documentation is a behavioural requirement for GMP compliance. Auditors examine batch records, deviation reports, laboratory notebooks, and equipment logbooks for proper maintenance according to ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available). Record-keeping has provided more room for new electronic systems, and audits evaluate records maintained in these systems for GMP compliance with 21 CFR Part 11 (for electronic records and signatures) (World Health Organization, 2022).

CHALLENGES IN GMP AUDITS

While GMP audits are critical in assuring pharmaceutical quality and safety, many challenges can obstruct their successful implementation. These challenges include inconsistent regulations, resource constraints, evolving expectations for compliance, and data integrity issues. It is essential to tackle these challenges to develop a strong pharmaceutical quality system (U.S. Food and Drug Administration, 2023).

In Figure 3, Navigation Complexities and Challenges in GMP audits: limited resources, global regulatory variances, changing expectations, data integrity, and complexity of the supply chain. Uncertain compliance is engendered by the different resources used, variability of regulations, technological changes, data security way of thought, interlaced nature of global supply chains, and so on.

Global Regulatory Variations

The biggest hindrance posed to GMP audits is the variation in regulatory requirements of the different countries and regions. While the International Council for Harmonisation (ICH) and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are

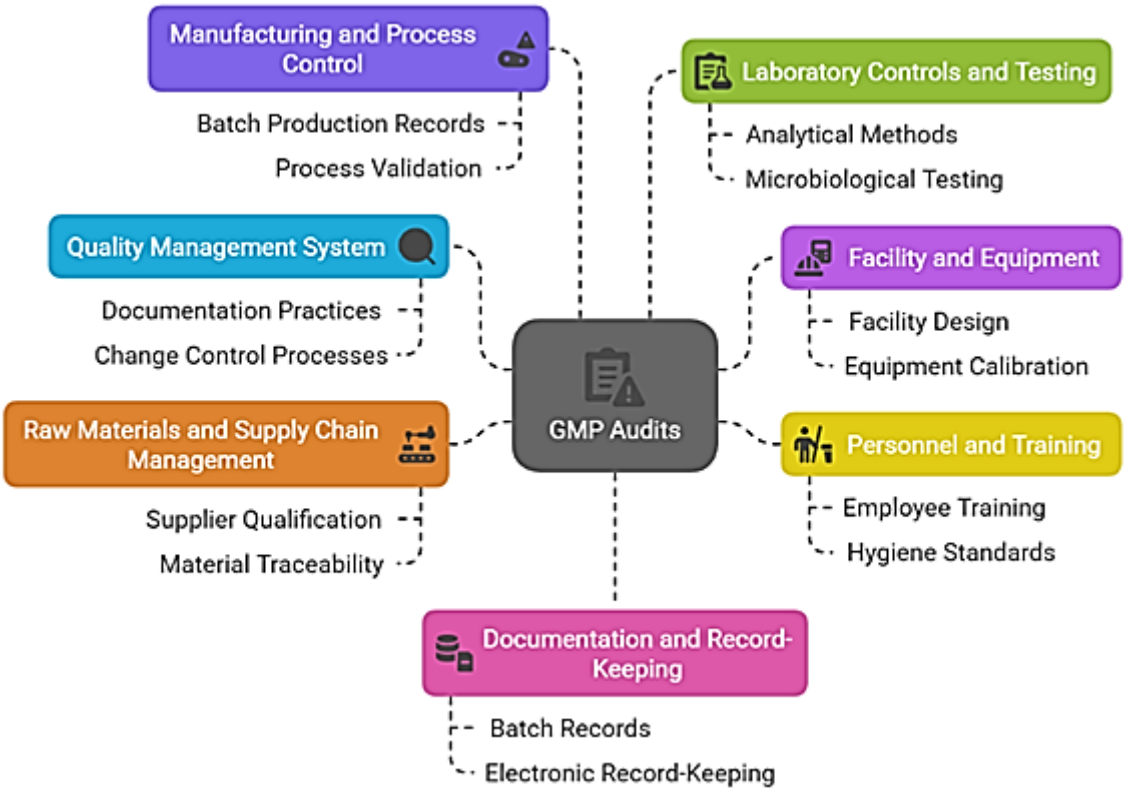

Figure 2: Key Components of GMP Audits.

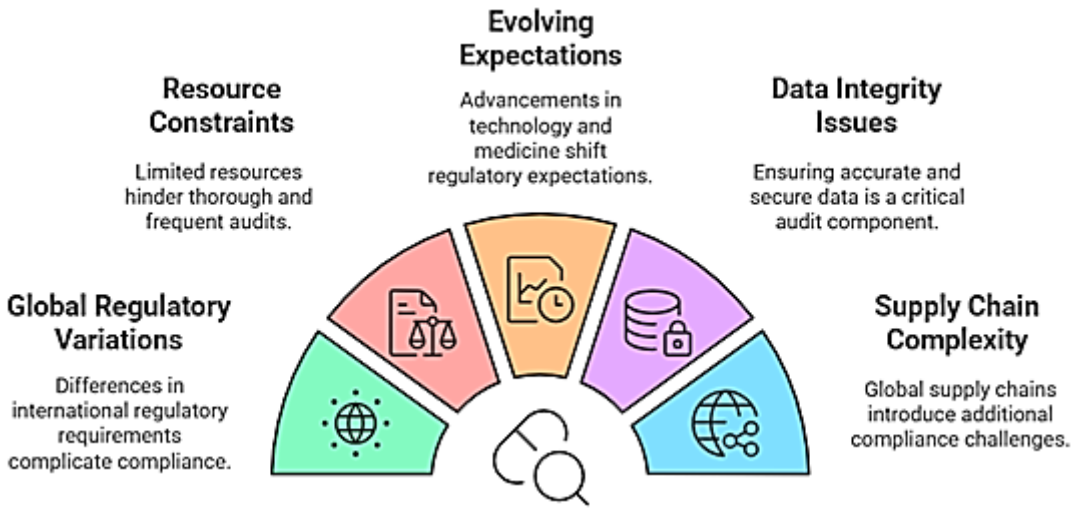

Figure 3: Navigation Complexities and Challenges in GMP Audits.

trying to overcome the barriers, still there are significant differences between the likes of the U.S. FDA, EMA, WHO, and CDSCO (India). Thus, companies with products for several markets cannot avoid complying with several sets of GMP standards, which can thus become unwieldy and at times conflicting. The variation causes wide audits, hence increasing compliance costs and obligating the manufacturers to maintain a stock of knowledge regarding the different regulatory expectations. Jurisdictional variations of regulatory interpreters may also lead to a disparity in audit findings, making it a challenge for a manufacturer to standardize its QMS across the globe (United Nations Office on Drugs and Crime [UNODC], 2023).

Resource Constraints

Completing an in-depth GMP audit demands substantial resources, including finances, manpower, and IT. Many companies in the pharmaceutical arena, especially SMEs, contract-manufacturing companies, and startup companies, face challenges related to heavy costs in assuring compliance with well-established GMPs. Costs associated with improving infrastructure, undertaking validation studies, training employees, and corrective actions following the audit could mount up. Regulatory authorities could be on limited resources and staffing shortages themselves, which would cause inspections to be delayed and increase the GMP certification backlog. In some instances, limited resources could lead to gaps in self-inspection, where manufacturers do not conduct internal audits at prescribed frequencies, and consequently, that could be considered a violation of compliance (Piccirillo and Zhang, 2022).

Evolving Regulatory Expectations and Emerging Technologies

GMP regulations and expectations are undergoing constant change, driven by advances in biopharmaceuticals, personalized medicine, and digital transformations. This is creating a plethora of issues relative to GMP audits concerning, among other things, data integrity, continuous manufacturing, and advanced medicinal therapeutic products (ATMPs). Any company would have to stay abreast of these changes to ensure compliance, which warrants continuous investment into regulatory intelligence and training of staff. Regulators, on the other hand, would also want more intense focus on risk-based auditing approaches wishing for much stronger risk management frameworks to be instituted at manufacturing facilities (International Council for Harmonisation [ICH], 2022).

Data Integrity and Compliance Issues

The major concern of GMP audits nowadays is data integrity, which compels regulatory agencies to impose stringent policies to prevent falsification, manipulation, or unauthorized modification of data. It is expected that all records, whether paper or electronic, should comply with the ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available). Data integrity violation is one of the most common findings during regulatory audits. Issues involved with improper data integrity include backdated records and missing raw data, means of unauthorized access to the electronic systems, and lack of audit trails, all of which contributed to a lot of warning letters and import bans. The way to conquer this challenge entails appropriate data governance, secured electronic Quality Management Systems (eQMS), and regular audits for data integrity (GXP Compliance Institute, 2023).

Supply Chain Complexity and Third-Party Audits

Globalization of the pharmaceutical supply chain engenders major challenges to GMP compliance. Many pharmaceutical companies depend on third-party suppliers, contract manufacturers, and raw material providers located across several countries, thereby making the regulation and enforcement of GMP on these external

Figure 4: Future Perspectives of GMP Audits.

entities burdensome from a logistical and fiscal standpoint. Non-compliance situations impinge on drug quality generated by supply chain vulnerabilities like counterfeiting, contamination risks, and conditions of poor storage. Particularly weak areas during the COVID-19 pandemic in auditing the supply chain were due to travel restrictions, which limited both the ability of regulatory agencies and companies to conduct in-person supplier inspections. While remote audits and digital supply chain tracking technologies are implemented, other challenges exist to verify the real-time compliance of suppliers (European Federation of Pharmaceutical Industries and Associations [EFPIA], 2022).

FUTURE PERSPECTIVES

As technology advances, regulatory bodies work more closely together, and the application of risk-based thinking improves, the GMP audit landscape is rapidly evolving. As manufacturing grows more complex with time, GMP audits are likely to rely increasingly on automation, Artificial Intelligence (AI), digitization for compliance purposes, and real-time systems for monitoring to improve efficiency and continue assuring at the same time the quality of products (Srinivasan and Patel, 2023). One of the major factors that will change the future of GMP audits is the incorporation of AI and ML into quality assurance operations. AI-based analytics will unveil hidden patterns within manufacturing data and will be able to detect abnormalities and predict possible impending compliance risks before these manifests through product recalls or regulatory deviations (United States Pharmacopeia [USP], 2023). Instead, by using big data analytics, companies are moving towards predictive compliance models in which their GMP audits have proactive risk mitigation rather than simply addressing issues reactively. Another technological application into practice is that of blockchain technology, which gives strong testimony for data integrity, secure recording, and clear supply chain management, thereby reducing the chances of counterfeit drugs getting into the market (World Bank, 2022). Although traditional onsite inspections will always remain, a new paradigm in GMP auditing is the growing acceptance of remote and hybrid audit models. Regulatory authorities are now increasingly applying virtual audits, digital document reviews, and live-streamed facility walkthroughs in addition to physical inspections to meet efficiency and compliance requirements of a long-term goal of continuous GMP compliance rather than limited periodic auditing. However, the issue of cybersecurity and data privacy-related issues, which are compounded by the lack of a robust digital infrastructure, has yet to be addressed for the credibility and reliability of any one such virtual inspection undertaking (GSK, 2022).

In Figure 4, shows the future prospective of GMP Audits, Including Global harmonisation, Regulatory Divergence, cybersecurity risks and Technology use. Regulatory harmonization is expected to greatly determine the future of GMP audits. The International Council for Harmonisation (ICH), the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and the World Health Organization (WHO) are actively undertaking the alignment of GMP standards across various territories (Novartis, 2023). Mutual Recognition Agreements (MRAs) between regulatory agencies lessen the compliance burden on pharmaceutical companies by doing away with redundant inspections, thus simplifying global trade. In the future, it is possible that globally there may be a common GMP audit framework under which companies will be subjected to a single, comprehensive audit that will be recognized by many regulators (Pfizer, 2023). Besides technology, the future of GMP audits will be characterized by enhanced supply chain transparency and resilience. Disruptions in global pharmaceutical supply chains during the COVID-19 pandemic highlighted the need for real-time tracking, digital quality assurance systems, and more stringent audits of third-party suppliers (McKinsey and Company, 2022). This realization has led manufacturers to

adopt end-to-end digital supply-chain-monitoring systems with real-time insights regarding the sourcing of raw materials, storage conditions, and transportation, thus ensuring compliance at all stages of the supply chain. In addition to the changes mentioned above, environmental and sustainability considerations will also become part of GMP compliance in the future. Such regulatory agencies will likely tighten restrictions on green manufacturing practices, solid waste disposal, and energy-efficient production. Firms whose practices promote pollution prevention, such as utilizing eco-friendly manufacturing technologies, principles of green chemistry, and having a sustainable supply chain, will not only meet the regulatory requirements but will position themselves favorably in an environmentally conscious market few others can service (IBM Blockchain Research, 2022).

CONCLUSION

GMP audits ultimately ensure the maintenance of high-quality, safety, and efficacy pharmaceutical products through much stricter compliance with regulatory requirements. Audits are initial steps to identify manufacturing deficiencies, prevent contamination threats, and maintain quality standards in the drug manufacturing process. There are several regulatory agencies, such as FDA, EMA, WHO, and PIC/S, to oversee GMP compliance in assuring that the production of pharmaceutical products conforms to internationally recognized best practices. GMP audits, however, face many challenges in technical diversity in regulations, limited human and capital resources, lack of data integrity, and complicated supply chain management. Digitization efforts with AI in quality monitoring and blockchain in records are to further revolutionize auditing in terms of compliance efficiency and proactivity. The future of GMP compliance would further lessen the hassle of frequent manual inspection by focusing on audit automation along the lines of remote audits, real-time monitoring, and predictive analytics. Whereas the future of GMP audits appears to be the harmonization of global regulatory standards, embedding digital tools of compliance, and sustainability-led manufacturing, this is all on theory. Conversely, it is also famous for helping improve the efficiencies of pharmaceutical operations while de-risking those operations from the regulatory perspective and ensuring consistent access for patients to high-quality medicines. In the end, GMP audits are not merely a regulatory requirement. Rather, they are effective tools in public health protection. Innovation, cooperation, and continuous improvement will thus always dictate an appropriate installation of GMP compliance in the ever-changing pharmaceutical industry.

ABBREVIATIONS

GMP: Good Manufacturing Practice; **PIC/S:** Pharmaceutical Inspection Co-operation Scheme; **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals; **CGMP:** Current Good Manufacturing Practice; **QMS:** Quality Management System; **AI:** Artificial Intelligence; **PMDA:** Pharmaceuticals and Medical Devices Agency, Japan; **CDSCO:** Central Drugs Standard Control Organization, India; **NMPA:** National Medical Products Administration, China; **IoT:** Internet of Things.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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AUTHORS CONTRIBUTIONS

Mayur R. Dandekar conceptualised and finalised the review, supervised the literature analysis and acted as the corresponding author. Isha A. Mirzapure and Yash M. Salve conducted literature searches, analyzed the data, and drafted key sections of the manuscript. Dr. Deepak Khobragade contributed to the methodology, validated the data, and drafted the technical sections, ensuring scientific accuracy.

ETHICAL STATEMENTS

It is a literature review entirely on the analysis and synthesis of past, and usually released, regulatory documents. There have been no new experiments conducted with human participants or animals, nor has there been any collection or use of patient data or personal information during the preparation of this manuscript. The authors declare that the 'work is consistent with the ethical standards of academic integrity and in accordance with guidelines set forth for scholarly publishing'. All information sources, data, and references have been properly cited in order to recognize the contributions of other researchers and institutions. No conflict of interest is declared by the authors, nor is there any involvement in financial or commercial terms that might be construed as affecting the contents of this paper.

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