INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Artificial Intelligence in Pharmaceutical Quality Assurance and Good Manufacturing Practice (GMP): Applications, Challenges and Future Perspectives

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ARTICLE INFO

Published: 7 July. 2026
Keywords:
Artificial Intelligence (AI), Pharmaceutical Quality Assurance, Good Manufacturing Practice (GMP), Machine Learning, Predictive Quality Control, Regulatory Compliance.
DOI:
10.5281/zenodo.21240194

ABSTRACT

Artificial intelligence (AI) is rapidly transforming the pharmaceutical industry, offering significant potential to enhance the development, manufacturing, and quality assurance of active pharmaceutical ingredients (APIs) and medicinal products. By enabling advanced data analysis, predictive modeling, real-time monitoring, and automation, AI supports improved efficiency, reduced human error, accelerated time-to-market, and stronger regulatory compliance. Key AI techniques—including machine learning, deep learning, artificial neural networks, natural language processing, and computer vision—are increasingly applied across drug discovery, formulation, chemical synthesis, manufacturing, quality control, and regulatory documentation. In particular, AI-driven solutions strengthen pharmaceutical quality assurance and Good Manufacturing Practice (GMP) compliance by enabling automated defect detection, predictive quality control, anomaly identification, and process optimization. While AI adoption presents opportunities for enhanced performance and patient safety, it also necessitates responsible implementation in line with evolving regulatory frameworks such as EU-GMP Annex 11. In regions like Sub-Saharan Africa, and specifically Kenya, AI offers strategic potential to overcome structural and regulatory challenges, improve

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

manufacturing standards, and align local production with global quality expectations. Also learn more about future opportunities, regulatory concerns and challenges of AI implementation. Overall, AI represents a central enabler of the fourth industrial revolution in pharma, driving data-driven insights, operational efficiency, and improved patient access to medicines.

INTRODUCTION

Artificial intelligence offers significant potential to transform and enhance the development and commercialisation of active pharmaceutical ingredients and medicinal products by improving efficiency and enabling deeper data-driven insights, ultimately accelerating patient access to medicines. To realise these benefits, the pharmaceutical industry must continue to use AI/ML responsibly, ensuring that systems remain trustworthy and compliant with both existing and emerging regulatory requirements in order to maintain its licence to operate. As the application of AI/ML across manufacturing and quality activities continues to evolve rapidly, uncertainty around its use has prompted calls for the introduction of additional regulations within GMP-regulated environments. However, EU-GMP Annex 11 on computerised system validation is currently under review by the EMA to incorporate considerations specific to AI/ML technologies. Industry stakeholders have provided input on proposed updates to the current framework, advocating for enhanced oversight while avoiding unnecessary additional regulatory burden.[1]

As a central driver of the fourth industrial revolution, artificial intelligence is significantly reshaping industrial operations, including pharmaceutical manufacturing. AI is a multidisciplinary field that enables machines to replicate aspects of human intelligence, allowing them to perform tasks that traditionally require cognitive capabilities such as learning, reasoning, and problem-solving. Within manufacturing, AI is transforming processes by enabling real-time analysis of production data, thereby supporting enhanced monitoring of critical quality attributes. AI-based automated visual inspection systems provide continuous, real-time oversight and can detect defects with greater accuracy than conventional visual inspection methods, which are often influenced by human and environmental variability. In addition, the application of predictive analytics allows AI systems to analyse historical datasets to anticipate potential quality risks, identify early warning signals, and detect process outliers. This capability supports the timely implementation of corrective and preventive actions to mitigate predicted quality deviations.[2]

Notwithstanding recent technological advances in pharmaceutical manufacturing, Sub-Saharan Africa continues to face substantial structural and regulatory challenges. Pharmaceutical production capacity remains concentrated in only 9 of the 46 countries in the region, with just 6 manufacturers attaining World Health Organization (WHO) prequalification. A persistent shortage of adequately trained regulatory professionals has contributed to the widespread presence of substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products. Kenya, in particular, hosts more than 35 licensed pharmaceutical manufacturers, positioning it as the largest producer within the Common Market for Eastern and Southern Africa (COMESA) region. Nevertheless, the majority of these manufacturers do not fully comply with WHO good manufacturing practice (GMP) requirements. The introduction of Kenya's National AI Strategy (2025–2030) elevates artificial intelligence to a national priority and offers a strategic opportunity for the pharmaceutical sector to strengthen GMP compliance. Consequently, it is critical that

Kenyan pharmaceutical manufacturers leverage AI-driven solutions, particularly to enhance quality assurance processes, to remain competitive and aligned with global standards.[3]

7. Concept of Quality Assurance (QA)

Quality assurance is a component of quality management focused on providing assurance that required quality standards are achieved. In the pharmaceutical industry, QA ensures that raw materials are obtained from approved suppliers, manufacturing data are properly documented and reviewed in accordance with cGMP, and suitable procedures exist for equipment operation and calibration. Pharmaceutical Quality Systems consist of eight key elements that work together with QA to ensure the consistent production of high-quality finished products. An effective PQS helps pharmaceutical companies maintain product quality, safeguard patient safety, and enhance their overall performance and reputation.[4]

7. Overview of Good Manufacturing Practices (GMP)

Good Manufacturing Practice (GMP) inspections are essential to the pharmaceutical industry, as they ensure that medicinal products meet established quality standards prior to market release. GMP requires manufacturers to systematically identify and rectify deficiencies within their quality management systems to protect patient safety and prevent regulatory sanctions. Regulatory agencies such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and the World Health Organization (WHO) issue guidelines to support GMP compliance and safeguard public health. Nevertheless, challenges often arise due to differences between regulatory expectations and their practical implementation by manufacturers.

The GMP inspection framework assesses five key elements premises, procedures, processes, personnel, and products. Premises encompass the physical manufacturing environment, while procedures consist of approved and documented methods of operation. Processes represent standardized, repeatable activities that ensure consistency, compliance, and product quality, and are governed by standard operating procedures. Personnel play a central role in executing, overseeing, and continuously improving GMP practices. Product evaluation involves the assessment of quality based on documented evidence. Deficiencies identified during inspections or failures in product quality may result in production interruptions, extensive root cause investigations, and regulatory actions, potentially leading to drug shortages, treatment delays, and economic losses. Moreover, the detection of quality issues after product distribution highlights the need for proactive and preventive quality strategies[5].

5Challenges faced in QA and GMP

- Manual documentation error.
- Human error
- Delayed detection of deviation
- Large data management difficulties

7. Need for AI in pharma

1. Enhanced Data Processing and Analysis
2. Predictive Quality Assurance
3. Automated Quality Control
4. Improved Decision Support
5. Compliance and Regulatory Support
6. Reduction in Human Error
7. Faster Time-to-Market
8. Cost Efficiency
9. Adaptive Learning and Continuous Improvement [6]

7. AI techniques used in pharma

1. Machine Learning (ML)

Artificial intelligence (AI) and machine learning (ML) have the potential to significantly transform the pharmaceutical industry. AI refers to the development of computer systems capable of performing tasks such as decision-making, problem-solving, and language processing, while ML, a subset of AI, enables systems to learn from data and improve performance without explicit programming. Growing interest and investment in AI and ML within the pharmaceutical sector are driven by their ability to analyze large datasets, identify patterns, and generate insights that support innovation and informed decision-making. These technologies are applied across various areas, including drug discovery and development, clinical trials, pharmacovigilance, and supply chain management. For example, ML models can analyze patient data to identify biomarkers and optimize therapies, while AI algorithms can predict drug efficacy and toxicity by evaluating molecular structures. AI-powered chatbots and virtual assistants are also being used to improve patient engagement and medication adherence. Despite their promise, challenges such as regulatory compliance, data privacy, security concerns, and the need for specialized expertise and infrastructure remain. Nevertheless, continued investment highlights the importance of AI and ML in advancing pharmaceutical research, healthcare delivery, and quality assurance, making it essential for pharmaceutical professionals to understand these technologies[7].

2. Deep Learning (DL)

Deep learning (DL) has been applied to several pharmaceutically relevant problems and often performs as well as or better than traditional machine-learning methods. Early successes include predicting aqueous solubility, sites of metabolism, drug repurposing from gene expression data, drug release from formulations, and QSAR modelling, with DL frequently outperforming SVMs, random forests, and standard neural networks in cross-validation and time-split tests. While DL has shown comparable performance to other methods in challenging areas like drug-induced liver injury, its overall use in pharmaceutical modelling remains limited. Given its strong performance across diverse datasets, many existing pharmaceutical prediction tasks could likely benefit from wider adoption of DL[8].

3. Artificial Neural Networks (ANNs)

Pharmaceutical technology improves drug substances with suboptimal properties by transforming them into effective dosage forms, a process that requires deep understanding of physicochemical properties and formulation variables. Machine learning (ML) and especially deep learning/ANNs support this by modeling complex, nonlinear relationships among formulation components and process parameters without predefined assumptions. Unlike traditional ML, deep learning adapts to complex systems where explicit rules (e.g., distinguishing amorphous vs crystalline forms) are difficult to define. Within the Quality by Design (QbD) framework, ANNs can link critical quality attributes (CQAs) with critical material attributes (CMAs) and critical process parameters (CPPs), enabling predictive modeling, sensitivity analysis, and optimization of formulations and processes. ANNs are valuable for simulating unit operations, optimizing tablet properties, and developing multi-drug or controlled-release formulations. Emerging applications include designing advanced nanocarriers such as cerasomes, where ANNs can optimize composition and process conditions to

achieve desired size, stability, and targeting efficiency[9].

4. Natural Language Processing (NLP)

The MEDIQA challenge focused on improving medical-domain natural language interfaces, recognizing question entailment (RQE), and question answering. Results showed that ensemble methods and transfer learning with multitask language models outperformed traditional deep learning approaches for RQE. The best-performing systems fine-tuned pretrained models such as BERT and further improved results through transfer learning from NLI tasks, while multitask learning and ensemble strategies also proved effective. RQE is closely related to semantic textual similarity (STS), but is more directly connected to question answering and information retrieval in the medical domain[10]

5. Computer Vision

Computer vision is a field of artificial intelligence that enables computers to interpret and analyse images and videos, allowing machines to perform visual tasks that normally require human vision.

In quality assurance, computer vision can be used in multiple applications to automatically inspect, monitor, and evaluate products or processes.

- Defect Detection
- Measurement and Inspection
- Sorting and Classification
- Monitoring Production Processes[11].

Application of AI in pharmaceutical quality assurance

- **AI in quality control testing**

Analytical testing plays a critical role in pharmaceutical quality control and assurance by confirming that raw materials, in-process samples, and finished products comply with established quality standards. Conventional testing methods rely heavily on manual procedures, which can be time-consuming and prone to human error and variability. In contrast, automated analytical testing integrates technologies such as robotics, artificial intelligence, machine learning, and computerized systems to reduce human involvement, thereby enhancing testing accuracy, efficiency, consistency, and regulatory compliance[12].

- **Application of AI improve QC**

1. **Visual Inspection and Defect Detection:** AI-driven computer vision systems automatically examine pharmaceutical products, packaging, and labels to detect defects, inconsistencies, or impurities, ensuring that only high-quality products proceed in the production process. This is achieved using image recognition, machine learning, and computer vision technologies.
2. **Predictive Quality Control:** AI analyses historical data to forecast whether a batch will meet quality standards, reduce manual testing and speed up batch release.
3. **Real-time Monitoring:** AI combined with IoT sensors continuously tracks critical process parameters, triggering alerts for deviations to enable immediate corrective actions and prevent defective products.
4. **Anomaly Detection:** AI uses advanced algorithms to identify deviations or unusual patterns in manufacturing processes, enabling early intervention to prevent defects and maintain product quality[13].

7 AI in data analysis

Big Data in Pharmaceutical QA: Big data platforms like Hadoop and Apache Spark enable integration of diverse datasets from sensors,

LIMS, and ERP systems. This supports real-time monitoring and predictive quality assurance models, improving scalability and adaptability in large-scale pharmaceutical operations[14].

AI in Documentation for QA: AI streamlines quality assurance documentation by automatically generating, organizing, and validating records. It reduces human errors, ensures compliance with regulatory standards, and enables faster retrieval and auditing of QA data[15].

AI in Risk Assessment for QA: AI analyses historical and real-time data to identify potential risks in pharmaceutical processes. It helps predict quality issues, prioritize interventions, and supports proactive decision-making to enhance product safety and compliance[16].

7 Applications of AI in GMP Operations

Traditional GMP operations often depend on manual monitoring, documentation, and human decision-making, which may lead to errors, delays, and inconsistencies. Artificial Intelligence (AI) helps overcome these limitations by introducing automation, real-time monitoring, predictive analysis, and smart decision systems. AI improves efficiency, accuracy, and regulatory compliance in pharmaceutical manufacturing[17].

7.1 Smart Manufacturing and Automation: AI-driven automation systems manage and oversee production processes with minimal human involvement.
Applications:

- Automated filling and packaging operations
- Robotic handling of materials
- Intelligent mixing and blending systems
- Continuous production processes[18]

7.2 Process Monitoring and Control (PAT – Process Analytical Technology): AI evaluates real-time process data to maintain manufacturing parameters within specified limits.

- Applications:
- Monitoring temperature
- Controlling pressure
- Tracking humidity
- Ensuring blend uniformity
- Measuring tablet hardness[19]

7.3 Predictive Maintenance of Equipment

AI uses historical and real-time data to predict equipment failures before they occur. It helps monitor machine performance, analyse vibrations, detect wear, and schedule maintenance in advance to reduce downtime and costs[20].

7.4 Automated Documentation and Data Integrity

Good Manufacturing Practice (GMP) requires detailed documentation, and AI helps streamline and automate these records. It supports Electronic Batch Records (EBR), generates reports automatically, verifies data accuracy, and monitors audit trails to ensure compliance and data integrity[21].

7.5 Quality Control and Inspection

AI-powered computer vision systems identify defects during the manufacturing process. They are used for inspecting tablets and capsules, verifying labels, checking packaging accuracy, and detecting leaks to ensure product quality[22].

7.6 Deviation and Risk Management

AI analyzes data to detect patterns and anticipate possible deviations. It assists with root cause analysis, predicts failures, assigns risk scores, and supports Corrective and Preventive Actions (CAPA).[23]

7.7 Environmental Monitoring

AI systems continuously track cleanroom conditions to ensure compliance and safety. They monitor particle levels, regulate temperature and humidity, and detect potential microbial contamination[24].(Ashour, M. S. E. D., Mansy, M. S., & Eissa, M. E. (2011). Microbiological environmental monitoring in pharmaceutical facility. *Egyptian Academic Journal of Biological Sciences, G. Microbiology*, *3*(1), 63-74.)

7.8 Supply Chain and Inventory Management

AI improves the management of raw materials and product distribution. It supports demand forecasting, optimizes inventory levels, assists in vendor qualification, and enhances warehouse automation for greater efficiency.[25]

7.9 AI in Training and Compliance

AI-powered tools support employee training and help maintain GMP compliance. They provide virtual training modules, track adherence to Standard Operating Procedures (SOPs), and monitor employee performance to ensure regulatory standards are meet.[26]

8. AI in pharmaceutical manufacturing

8.1 AI in Drug Discovery:

Pharmaceutical companies invest heavily in drug development, but many compounds fail during clinical trials, making the process costly and time-consuming. AI helps reduce these risks by using big data to improve target identification, optimize drug design, and speed up clinical trials. This lowers costs, reduces failure rates, and accelerates overall drug development[27].

8.2 AI in Drug Repurposing:

Drug repurposing finds new uses for existing approved drugs, reducing development time, cost, and risk. AI and machine learning speed up this process by analyzing large datasets and predicting potential drug-target matches, using methods like molecular docking, genetic associations, and clinical data analysis[28]

8.3 AI in Drug Screening:

AI analyzes a drug's molecular structure to predict its bioactivity, toxicity, and pharmacokinetic properties, helping to identify promising candidates efficiently[29]

8.4 AI in Chemical Synthesis

AI and robotics are transforming chemical synthesis by automating reaction design, execution, and analysis. Machine learning and deep learning predict reaction outcomes, conditions, and optimize processes, while tools like IBM's RoboRXN combine software and robotics to perform and plan chemical syntheses efficiently[30]

8.5 AI in Research and Development

AI and machine learning enhance pharmaceutical R&D by improving drug design, predicting molecular properties, optimizing formulations, and reducing costs and trial-and-error experiments. Companies use AI-driven tools and computational methods like QSAR, QSPR, and pharmacokinetic models to innovate efficiently and solve complex drug development challenges[31]

8.6 AI in Product Development

AI including neural networks and machine learning, is used to optimize pharmaceutical formulations by predicting chemical reactions and process outcomes. It enhances understanding of critical process parameters, improves product quality, and supports approaches like Quality by

Design (QbD) for more efficient and effective product development[32]

8.7 AI in Manufacturing Process

AI enhances pharmaceutical manufacturing by monitoring processes in real time, predicting equipment maintenance, reducing waste, and optimizing production. Integrated with Industry 4.0 technologies—like IoT, robotics, cloud computing, and big data—AI improves efficiency, ensures product quality, accelerates production, and supports predictive decision-making across manufacturing, supply chain, and delivery[33].

8.8 AI in Quality Assurance and Control

AI improves pharmaceutical quality assurance and control by enhancing product quality, reducing errors and waste, and optimizing lab processes. It accelerates inspections, detects deviations in real time, supports multivariate modelling through approaches like QbD, and uses tools such as neural networks and deep learning to ensure consistent, high-quality products while saving time and costs[34]

CONCLUSION:

Artificial intelligence (AI) is rapidly transforming the pharmaceutical industry by enhancing efficiency, accuracy, and decision-making across all stages of drug development, manufacturing, and quality assurance. From drug discovery and repurposing to chemical synthesis, product development, and manufacturing processes, AI technologies—including machine learning, deep learning, neural networks, natural language processing, and computer vision—enable faster, safer, and more cost-effective operations. In quality assurance and control, AI ensures compliance with GMP standards, reduces human error, predicts risks, and maintains consistent product quality.

The integration of AI with Industry 4.0 technologies, big data, and automated systems empowers pharmaceutical companies to optimize production, supply chains, and regulatory adherence, ultimately accelerating patient access to medicines. While challenges such as regulatory compliance, data security, and workforce readiness remain, responsible and strategic adoption of AI offers the potential to revolutionize pharmaceutical research, manufacturing, and quality management, positioning the industry for improved innovation, competitiveness, and global healthcare impact

REFERENCES

1. Niazi, S. K. (2025). Regulatory Perspectives for AI/ML Implementation in Pharmaceutical GMP Environments. Pharmaceuticals, 18(6), 901.
2. Inshutiyimana, S., Rana, K. R., Abdullahi, F. A., & Aleu, M. M. (2025). Artificial Intelligence for Pharmaceutical Quality Assurance in Kenya. IET Collaborative Intelligent Manufacturing, 7(1), e70033.
3. Saha, G. C., Eni, L. N., Saha, H., Parida, P. K., Rathinavelu, R., Jain, S. K., & Haldar, B. (2023). Artificial intelligence in pharmaceutical Manufacturing: Enhancing quality control and decision making. Rivista Italiana di Filosofia Analitica Junior, 14(2), 2023.
4. Mishra, A. K., Singh, R., Chaurasia, D. K., & Shukla, D. T. P. (2023). A review: quality assurance and quality control. Int J Res Appl Sci Eng Technol (IJRASET), 11, 45.
5. Al Azawei, A., Loughrey, K., Surim, K., Connolly, M. E., & Naughton, B. D. (2025). The management of good manufacturing practice (GMP) inspections: a scoping review

of the evidence. Frontiers in Medicine, 12, 1687864.)

6. Inamdar, S., Kedar, T., Gujar, H., Tanpure, P., & Sapkal, S. (2024). Harnessing AI And Machine Learning in Pharmaceutical Quality Assurance. Int J Sci R Tech, 1(11).
7. Singh, S. (2024). Leveraging AI and Machine Learning in Six‐Sigma Documentation for Pharmaceutical Quality Assurance. Chinese Journal of Applied Physiology, 40, e20240005.
8. Ekins, S. (2016). The next era: deep learning in pharmaceutical research. Pharmaceutical research, 33(11), 2594.
9. Teja, T. B., Sekar, M., Pallavi, T., Mettu, S., Murthy, T. E., Mat Rani, N. N. I., ... & Bonam, S. R. (2022). Role of Artificial Neural Networks in Pharmaceutical Sciences. Journal of Young Pharmacists, 14(1).)
10. Saraswat, N., Li, C., & Jiang, M. (2023). Identifying the Question Similarity of Regulatory Documents in the Pharmaceutical Industry by Using the Recognizing Question Entailment System: Evaluation Study. JMIR AI, 2(1), e43483.
11. Owen, A., & Hannah, J. (2021). Automated Quality Assurance Using AI and Computer Vision.
12. Coito, T., Martins, M. S., Firme, B., Figueiredo, J., Vieira, S. M., & Sousa, J. M. (2022). Assessing the impact of automation in pharmaceutical quality control labs using a digital twin. Journal of Manufacturing Systems, 62, 270-285.
13. Saha, G. C., Eni, L. N., Saha, H., Parida, P. K., Rathinavelu, R., Jain, S. K., & Haldar, B. (2023). Artificial intelligence in pharmaceutical Manufacturing: Enhancing quality control and decision making. Rivista Italiana di Filosofia Analitica Junior, 14(2), 2023.
14. ISLAM, R. (2025). AI and big data for predictive analytics in pharmaceutical quality assurance. Available at SSRN 5564319.
15. Bracken, A., Reilly, C., Feeley, A., Sheehan, E., Merghani, K., & Feeley, I. (2025). Artificial Intelligence (AI)–Powered Documentation Systems in Healthcare: A Systematic Review. Journal of Medical Systems, 49(1), 28.
16. Sonawane, S. S., & Baviskar, M. D. (2025). Risk-Based Validation of Software, Automation and Artificial intelligence in Pharmaceuticals. Biosciences Biotechnology Research Asia, 22(4), 1279-1293.)
17. Karmacharya, J. B. (2014). Good manufacturing practices (GMP) for medicinal products. Promising Pharmaceuticals, 101.)
18. Arden, N. S., Fisher, A. C., Tyner, K., Yu, L. X., Lee, S. L., & Kopcha, M. (2021). Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. International journal of pharmaceutics, 602, 120554.
19. Simon, L. L., Pataki, H., Marosi, G., Meemken, F., Hungerbühler, K., Baiker, A., ... & Chiu, M. S. (2015). Assessment of recent process analytical technology (PAT) trends: a multiauthor review. Organic Process Research & Development, 19(1), 3-62.
20. Ben-Bouazza, F. E., Manchadi, O., Dehbi, Z. E. O., Rhalem, W., & Ghazal, H. (2022, May). Machine learning based predictive maintenance of pharmaceutical industry equipment. In International Conference on Advanced Intelligent Systems for Sustainable Development (pp. 497-514). Cham: Springer Nature Switzerland.
21. Kulkarni, P., & Kothari, C. (2024). Documentation and data integrity in pharmaceutical industry. In Modern Aspects of Pharmaceutical Quality Assurance: Developing & Proposing Application models,

SOPs, practical audit systems for Pharma Industry (pp. 381-403). Singapore: Springer Nature Singapore.

22. Hassen, A. A., & Kirka, M. M. (2018). Additive Manufacturing: The rise of a technology and the need for quality control and inspection techniques. Materials Evaluation, 76(4).
23. Boltic, Z., Ruzic, N., Jovanovic, M., & Petrovic, S. (2010). Measuring the performance of quality assurance processes: pharmaceutical industry deviation management case study. Accreditation and quality assurance, 15(11), 629-636.
24. Ashour, M. S. E. D., Mansy, M. S., & Eissa, M. E. (2011). Microbiological environmental monitoring in pharmaceutical facility. Egyptian Academic Journal of Biological Sciences, G. Microbiology, 3(1), 63-74.
25. Uthayakumar, R., & Priyan, S. (2013). Pharmaceutical supply chain and inventory management strategies: Optimization for a pharmaceutical company and a hospital. Operations Research for Health Care, 2(3), 52-64.
26. Mohammed, Z. A., Mohammed, M., Mohammed, S., Syed, M., & Syed, F. A. (2024, December). AI in Regulatory Compliance for Pharmaceuticals. In International Conference on Data Science and Management (pp. 185-195). Singapore: Springer Nature Singapore.
27. Kiani, M., & Nasir, F. (2024). AI in drug discovery: Accelerating pharmaceutical research. International Journal of Advanced Engineering Technologies and Innovations, 1(1), 80-98.
28. Wan, Z., Sun, X., Li, Y., Chu, T., Hao, X., Cao, Y., & Zhang, P. (2025). Applications of Artificial Intelligence in Drug Repurposing. Advanced Science, 12(14), 2411325.
29. Blanco-Gonzalez, A., Cabezon, A., Seco-Gonzalez, A., Conde-Torres, D., Antelo-Riveiro, P., Pineiro, A., & Garcia-Fandino, R. (2023). The role of AI in drug discovery: challenges, opportunities, and strategies. Pharmaceuticals, 16(6), 891.
30. Ruiz-Gonzalez, A. (2025). AI-Driven Chemical Design: Transforming the Sustainability of the Pharmaceutical Industry. Future Pharmacology, 5(2), 24.
31. Mak, K. K., & Pichika, M. R. (2019). Artificial intelligence in drug development: present status and future prospects. Drug discovery today, 24(3), 773-780.
32. Suriyaamporn, P., Pamornpathomkul, B., Patrojanasophon, P., Ngawhirunpat, T., Rojanarata, T., & Opanasopit, P. (2024). The artificial intelligence-powered new era in pharmaceutical research and development: A review. Aaps Pharmscitech, 25(6), 188.
33. Mehta, A. K., Lanjewar, P., Murthy, D. S., Ghildiyal, P., & Faldu, R. (2023, December). AI & Lean Management Principles Based Pharmaceutical Manufacturing Processes. In 2023 10th IEEE Uttar Pradesh Section International Conference on Electrical, Electronics and Computer Engineering (UPCON) (Vol. 10, pp. 1599-1604). IEEE.
34. Bachhav, J. B., Sonawane, G. B., Gunjal, P. A., & Aher, S. N. PROCESS AUTOMATION IN PHARMA QUALITY ASSURANCE. Pharmaceutical Research, 14(23), 38-60.

HOW TO CITE: Manashri Mokal*, Pranali Sawant, Teena Dubey, Swati Burungale, Rajendra Patil, Artificial Intelligence in Pharmaceutical Quality Assurance and Good Manufacturing Practice (GMP): Applications, Challenges and Future Perspectives, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 7, 1364-1373. https://doi.org/10.5281/zenodo.21240194