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ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL MANUFACTURING AND QUALITY CONTROL: A COMPREHENSIVE REVIEW

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ABSTRACT

Artificial Intelligence (AI) is rapidly transforming pharmaceutical manufacturing and quality control by enhancing efficiency, accuracy, and regulatory compliance. The integration of AI technologies, including machine learning, deep learning, and data analytics, enables real-time monitoring, predictive maintenance, and optimization of manufacturing processes. This review provides a comprehensive analysis of the applications of AI in pharmaceutical production, focusing on process optimization, fault detection, and continuous manufacturing systems. Additionally, the role of AI in quality control is examined, particularly in areas such as automated inspection, anomaly detection, data integrity, and quality assurance. The implementation of AI-driven tools improves decision-making by analysing large datasets generated during drug development and production. Furthermore, AI facilitates adherence to regulatory frameworks such as Good Manufacturing Practices (GMP) by ensuring consistency and reducing human error. Despite these advantages, challenges including data security, lack of standardization, high implementation costs, and regulatory uncertainties remain significant barriers to widespread adoption. Recent advancements, including the integration of AI with Industry 4.0 technologies such as the Internet of Things (IoT) and digital twins, are also discussed to highlight future perspectives. Overall, AI holds immense potential to

revolutionize pharmaceutical manufacturing and quality control, offering improved productivity, product quality, and patient safety. Continued research and regulatory harmonization are essential to fully realize its benefits in the pharmaceutical industry.

KEYWORDS: Artificial intelligence, pharmaceutical manufacturing, machine learning, quality control, quality assurance, digital twins, smart manufacturing, process monitoring.

INTRODUCTION

Artificial intelligence is increasingly being recognized as a transformative technology in pharmaceutical manufacturing and quality control, with its role expanding from research and development into regulated production environment. In recent years, AI and machine learning are being applied to process monitoring, inspection, anomaly detection, predictive control, and quality assurance, supporting a shift from reactive testing toward more proactive and data-driven manufacturing strategies.[1]

Pharmaceutical manufacturing is a complex and highly regulated process that requires strict adherence to quality standards, process control, and regulatory compliance. Traditional manufacturing approaches often face limitations in terms of process variability, inefficiencies, and delayed decision-making. In this context, AI-based technologies such as machine learning, deep learning, and data analytics have been explored to overcome these challenges by enabling predictive modelling, real-time monitoring, and process optimization.[2]

The application of AI in pharmaceutical manufacturing extends to various domains, including process analytical technology (PAT), quality by design (QbD), quality control (QC), and quality assurance (QA). These approaches support improved process understanding, enhanced product quality, and reduced risk of failure. Furthermore, the integration of AI with emerging concepts such as Industry 4.0, digital twins, and smart manufacturing has further accelerated the transformation of pharmaceutical production systems into more adaptive and efficient frameworks.[3]

Despite these advancements, the implementation of AI in pharmaceutical manufacturing is associated with several challenges, including data quality issues, regulatory constraints, validation requirements, and the need for skilled personnel. Addressing these challenges is essential to ensure the reliable and compliant use of AI technologies in pharmaceutical

processes.[4]

Therefore, the present review aims to provide a comprehensive overview of the role of artificial intelligence in pharmaceutical manufacturing and quality control. The article focuses on key applications, technological advancements, associated challenges, and future perspectives, with an emphasis on improving process efficiency, product quality, and regulatory compliance within the pharmaceutical industry. An overview of the integration of artificial intelligence in pharmaceutical manufacturing and quality control processes is presented in **Fig. 1.**

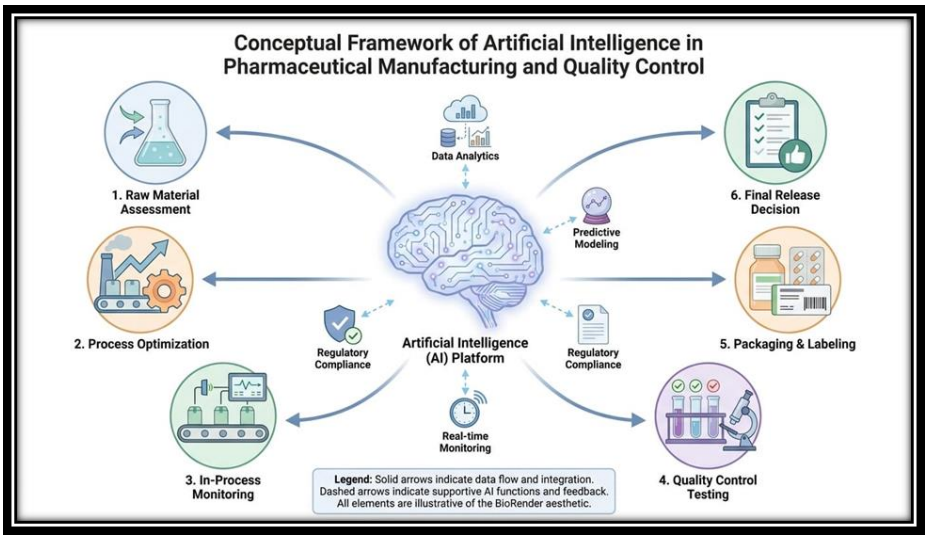

FIG. 1: Conceptual framework of artificial intelligence in pharmaceutical manufacturing and quality control. AI supports data analytics, predictive modelling, real-time monitoring, regulatory compliance, process optimization, quality control testing, packaging and labelling, and final release decision-making.

Literature Search and Selection Methodology: A comprehensive literature review was conducted to identify relevant studies on the application of artificial intelligence (AI) in pharmaceutical manufacturing and quality control. Systematic searches were performed using electronic databases including PubMed, Scopus, Web of Science, and Google Scholar.

The search strategy employed combinations of keywords such as “artificial intelligence,” “machine learning,” “pharmaceutical manufacturing,” “quality control,” “process analytical technology (PAT),” “automation,” and “Pharma 4.0,” using Boolean operators (AND, OR) to refine the results.

The literature search focused on articles published between 2010 and 2025 to capture recent

advancements in AI technologies within the pharmaceutical sector. Only publications in the English language were considered.

Inclusion and Exclusion Criteria

Studies were included if they

- Focused on AI, machine learning, or data-driven approaches in pharmaceutical manufacturing or quality control
- Reported applications, case studies, or technological advancements
- Were original research articles, review articles, or systematic studies

Studies were excluded if they

- Where not directly related to pharmaceutical applications of AI
- Lacked sufficient methodological detail
- Were conference abstracts, editorials, or non-peer-reviewed sources

SCREENING AND DATA EXTRACTION: Initially, titles and abstracts were screened to identify relevant articles. Full-text screening was subsequently performed to confirm eligibility based on the inclusion criteria. Relevant data were extracted and categorized according to application areas, including process optimization, quality control, predictive maintenance, and regulatory compliance.

Data Synthesis: The selected studies were analysed and synthesized qualitatively to identify key trends, technological advancements, benefits, and challenges associated with AI implementation in pharmaceutical manufacturing and quality control. A descriptive and comparative approach was used to summarize findings and highlight future research directions.

OVERVIEW OF PHARMACEUTICAL MANUFACTURING: Pharmaceutical manufacturing is a highly regulated and complex process that involves the transformation of raw materials into finished pharmaceutical products while ensuring consistent quality, safety, and efficacy. The manufacturing process is governed by stringent regulatory frameworks such as Good Manufacturing Practices (GMP), which ensure that products are produced under controlled conditions and meet predefined quality standards.[5]

Modern pharmaceutical manufacturing systems incorporate advanced quality frameworks

such as Quality by Design (QbD) and Process Analytical Technology (PAT). These approaches emphasize process understanding, risk management, and real-time monitoring to ensure product quality throughout the manufacturing lifecycle. Despite these advancements, conventional manufacturing processes often face challenges including process variability, equipment inefficiencies, limited real-time monitoring, and delayed decision-making.

These limitations highlight the need for advanced technologies capable of enhancing process control, improving efficiency, and reducing variability. In this context, artificial intelligence (AI) has emerged as a promising tool for enabling predictive analytics, real-time monitoring, and intelligent decision-making in pharmaceutical manufacturing. The integration of AI with Industry 4.0 technologies is further transforming traditional manufacturing systems into smart, automated, and data-driven production environments.[6]

Key Stages in Pharmaceutical Manufacturing: Pharmaceutical manufacturing consists of several sequential stages, which may vary depending on the type of dosage form being produced. These stages typically include raw material handling, formulation development, granulation, drying, blending, compression, coating, and packaging.

Raw material handling involves the identification, testing, and storage of active pharmaceutical ingredients (APIs) and excipients under controlled conditions. Formulation development ensures that the appropriate composition and processing parameters are selected to achieve the desired product characteristics. Granulation and drying are critical steps that influence the physical properties of the material, such as flowability and compressibility.

Subsequent stages such as blending and compression are essential for achieving uniformity and consistency in dosage units, while coating enhances product stability, appearance, and release characteristics. Finally, packaging ensures product protection, labelling, and compliance with regulatory requirements.[7]

Each of these stages involves critical process parameters that must be carefully monitored and controlled to ensure product quality. However, traditional monitoring methods may not always provide real-time insights or predictive capabilities. The integration of AI technologies at these stages offers significant potential for improving process efficiency, minimizing variability, and enabling proactive quality control.

An overview of the pharmaceutical manufacturing process, including its key stages and

control points, is illustrated in Fig. 2.

In addition to these conventional stages, modern pharmaceutical manufacturing increasingly incorporates advanced technologies to enhance process understanding and control. Tools such as Process Analytical Technology (PAT), real-time monitoring systems, and data-driven models enable continuous assessment of critical quality attributes (CQAs) throughout the production cycle.

Overall, a well-structured manufacturing process combined with advanced analytical tools plays a crucial role in ensuring the safety, efficacy, and quality of pharmaceutical products.[8]

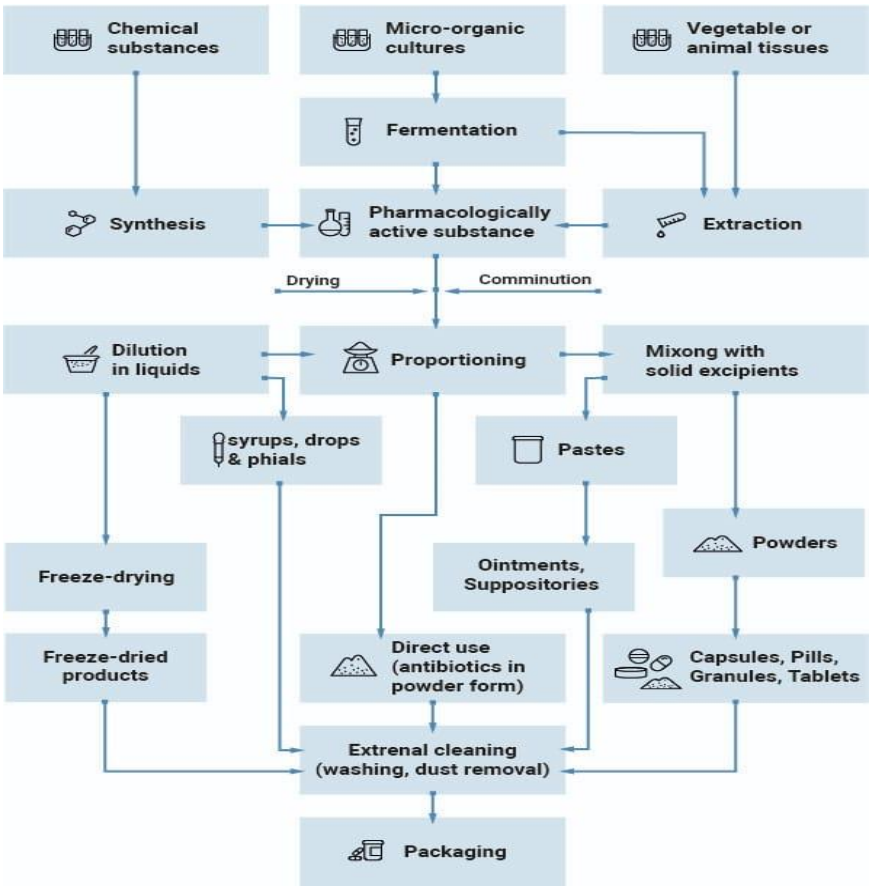

Fig. 2: Presents The Conventional Pharmaceutical Workflow, Showing The Sequence of Operation From Raw Material Handaling To Final Product Release (Adapted From.[12]).

Traditional manufacturing challenges: Traditional pharmaceutical manufacturing continues to face challenges related to variability, process complexity, scale-up, and efficiency. Older systems often depend on fixed procedures and retrospective quality checks, which means that problems may only be detected after production is complete. As a result,

product loss, batch failure, and delayed corrective action can occur.

Scale-up is another major challenge. Processes that work well at laboratory or pilot scale may behave differently at commercial scale because of changes in material flow, mixing, heat transfer, and process dynamics. Reviews on modernization and continuous manufacturing also show that the industry must deal with quality assurance, process stability, and the limitations of conventional batch systems.[9]

Table 1: Comparison Between Traditional Pharmaceutical Manufacturing and Industry 4.0-Based Manufacturing.

Dimension	Traditional manufacturing	Industry 4.0
Work Execution	Manual, paper based	Mobile-first' digital workflows
Asset monitoring	Periodic and manual	Continuous IoT
Maintenance strategy	Reactive and time-based	Predictive and data driven
Workforce tools	SOP manuals, tribal knowledge	Guided apps, AI support, AR assist
Date & Decision making	Gut feel, delayed reporting	Real-time, analytics-driven insights
Cost saving	Can achieve cost Savings of 10-20%	Higher costs due to inefficiencies and manual processes
Efficiency	Optimizes production Processes and workflows	Manual processes and limited automation
Traditional vs Industry 4.0		

Need for smart manufacturing (INDUSTRY 4.0): The shift toward smart manufacturing has emerged as a direct response to the limitations of conventional pharmaceutical production. Industry 4.0 technologies such as automation, data-driven modelling, digital connectivity, and continuous monitoring are increasingly being seen as essential for modern

pharmaceutical manufacturing. These systems are expected to improve flexibility, responsiveness, and quality management while also supporting sustainability and operational resilience.[10]

Industry 4.0 is also important because it creates a more integrated manufacturing model in which data, process design, and quality control work together. This approach can help companies address workforce challenges, safety concerns, and sustainability goals while also improving competitiveness. For these reasons, smart manufacturing is increasingly seen as the future of pharmaceutical production rather than just an optional improvement.[11] The key components of industry 4.0 and their role in enabling smart pharmaceutical manufacturing are illustrated in **Fig. 3.**

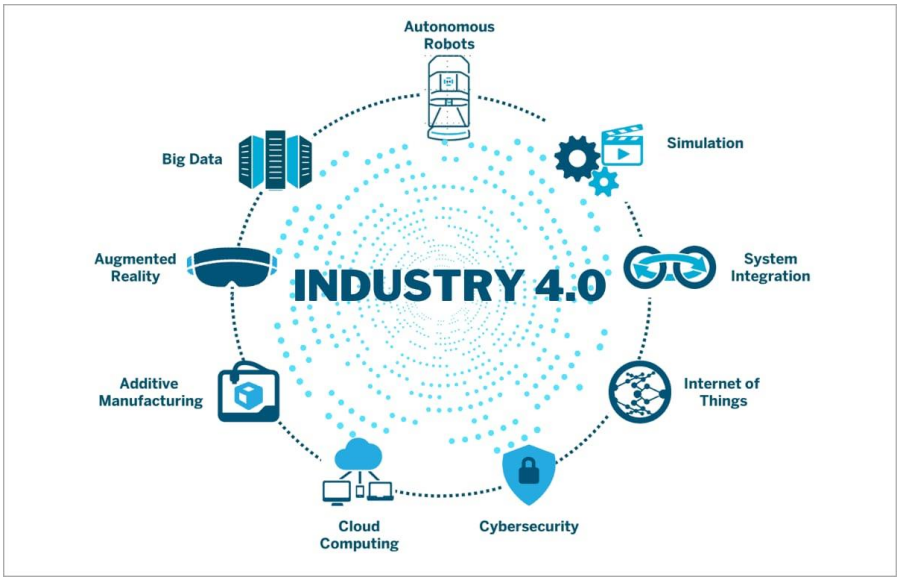

Fig. 3: Industry 4.0 Framework in Pharmaceutical Manufacturing Showing Integration Of Iot, Big Data, Cloud Computing, and Intelligent Automation (adapted from[25]).

AI TECHNOLOGY IN PHARMA: Artificial intelligence is playing an increasingly important role in pharmaceutical manufacturing because it can process large datasets, recognize patterns, and support more informed decision-making across production and quality systems.[13] AI is described as a key enabler of modern pharmaceutical innovation, especially where manufacturing efficiency, process consistency, and quality assurance are concerned. Rather than functioning as a single technology, AI in pharma includes several complementary methods, each contributing to a different part of the manufacturing and quality-control process.[14]

- ❖ Machine Learning

- Deep Learning
- Computer Vision
- Natural Language Processing

Machine Learning: Machine learning is one of the most widely applied AI approaches in pharmaceutical manufacturing because it can learn from historical data and use those patterns to support prediction and optimization. In the literature, ML has been linked to process analytical technology, real-time monitoring, and automated quality assurance, particularly for solid dosage manufacturing.[15] The widespread adoption of machine learning across industries, particularly in manufacturing and healthcare sectors relevant to pharmaceutical applications, is illustrated in **Fig.4**. This makes it especially valuable in production environments where many interacting variables influence output quality.

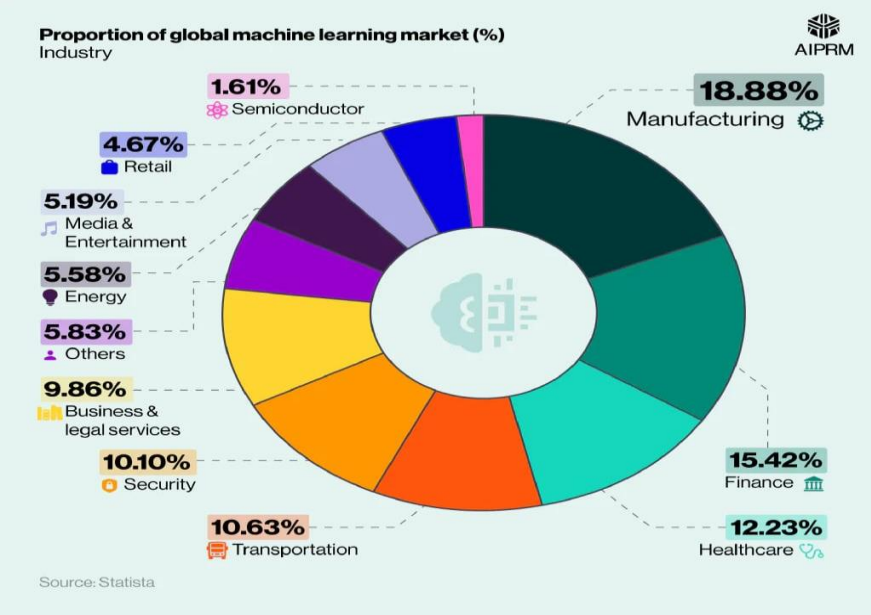

Fig. 4: Proportion of global machine learning market across different industries, highlighting significant contributions from manufacturing, finance, and healthcare sectors (Adapted from[26]).

Deep Learning: Deep learning has gained attention because of its ability to handle more complex datasets and extract useful features without requiring extensive manual feature design. In pharmaceutical manufacturing, deep learning is often discussed alongside machine learning as part of the broader digital transformation of production and quality systems. Its strength lies in recognizing patterns from images, signals, and other high-dimensional data that may be difficult to analyse using conventional methods.

In a manufacturing setting, deep learning can support tasks such as automated inspection, prediction, and advanced process analysis. It is especially relevant where continuous monitoring and rapid interpretation of data are needed to maintain product consistency and quality. As pharmaceutical manufacturing becomes more connected and data-rich, deep learning is likely to become even more important in intelligent control and quality-related applications.[16]

Computer Vision: Computer vision is closely tied to visual inspection, which is a major part of pharmaceutical quality control. This technology allows computers to analyse images and detect defects, irregularities, or appearance-related issues that may affect product acceptability. In pharmaceutical manufacturing, this is particularly useful for tasks such as package inspection, defect detection, and automated visual quality assessment.

One of the main advantages of computer vision is that it can improve consistency and reduce dependence on manual inspection, which may be affected by fatigue or human error. It also supports faster decision-making in production lines where visual checks must be performed repeatedly and reliably. For this reason, computer vision is becoming an important tool in modern inspection systems and a practical example of AI-driven quality control.[17]

Natural Language Processing: Natural language processing is the AI method used to work with written text, reports, and documents, making it highly relevant in a regulated industry such as pharmaceuticals. In the broader pharmaceutical literature, NLP is often associated with literature mining, documentation support, and the management of large amounts of scientific and regulatory text.[18] This is useful because pharmaceutical manufacturing depends heavily on recordkeeping, traceability, and knowledge management.

NLP can help organize technical information, extract useful content from documents, and support faster access to relevant knowledge. Although it is less directly visible than machine learning or computer vision in the manufacturing line, it still contributes to digital transformation by improving how information is handled across the pharmaceutical workflow. As the industry continues to expand digital documentation and AI-supported decision systems, NLP is likely to become more important in future pharmaceutical operations.[19]

APPLICATION OF AI IN PHARMACEUTICAL MANUFACTURING AND

QUALITY CONTROL: Artificial intelligence is applied to pharmaceutical manufacturing and quality control, enabling better monitoring, inspection, prediction, and decision-support, particularly at runtime, and thus facilitating more intelligent processes. There are multiple works utilize AI and ML for advanced process control, monitoring, and supervision, as well as for developing soft sensors, detection tools, and inspection systems, and realizing more efficient, data-driven practices.

Application in Manufacturing: In manufacturing, AI is primarily utilized for supporting process control, optimization, and supervision practices. Specifically, the spotlights studies on multivariate statistical process control, potency soft sensors, hybrid near-infrared (NIR) soft-sensor in-process control, and interpretable model predictive control, which are all related to better understanding and increased awareness of manufacturing processes. Notably, AI and ML are leveraged to develop advanced control and supervision systems that are capable of learning and adapting their behaviours based on collected data, thus facilitating better performance compared to conventional static systems. For instance, machine learning is used in upstream and downstream bioprocessing for neural network-based optimization and detection of chromatography anomalies. The application in pharmaceutical manufacturing is particularly relevant due to the complexity of the process and the numerous variables that impact it.[48]

Application in Quality Control: Quality control is one of the most prominent applications of AI in pharmaceuticals, with the reviewed works demonstrating its use for enabling better inspection practices. AI has been utilized for automated defect detection and inspection in tablet manufacturing and related processes, enabling more efficient inspection of products with critical quality attributes. Similarly, the more recent works included in the highlight of the application of AI for realizing monitoring, inspection, prediction, and maintenance practices in quality control. The utilization of AI is particularly beneficial in quality control due to the potential of traditional inspection practices to be time-consuming and limited in their ability to detect subtle flaws. By applying AI to inspection, pharmaceutical manufacturers can benefit from increased efficiency and accuracy in finding problematic patterns and performing the required adjustments.

Application in Quality Assurance: Similar to quality control, quality assurance is paramount in pharmaceutical manufacturing, as it is critical to ensure that all processes are validated and documented in accordance with GMP regulations and other requirements. AI is

leveraged for quality assurance to facilitate better inspection, monitoring, control, and supervision practices as well as support the required documentation processes.

The importance of AI for realizing compliance-by-design and improving quality frameworks, which implies that quality assurance is benefited by the implementation of AI in multiple stages and areas, thus supporting a broader transformation. In other words, the design of quality management processes can benefit from the inclusion of AI, enabling such processes as inspection, monitoring, and control while also supporting decision-making in accordance with the requirements.

Cross Functional Role of AI in Processes: Across multiple works, the essential role of AI in enabling both manufacturing and quality processes is demonstrated, with the two areas being connected as interrelated and complementary functions. Specifically, the importance of linking and tying together manufacturing and quality control processes, for instance, through AI-based process monitoring and inspection practices. By doing so, pharmaceutical manufacturers can create a more integrated environment in which quality data can be utilized for informing control and other process optimization decisions, thus facilitating a better and more efficient manufacturing environment.[49]

AI IN PROCESS MONITORING AND CONTROL: In pharmaceutical manufacturing, process monitoring and control are essential for maintaining product quality, process stability, and regulatory compliance.[20] Traditional monitoring systems are important, but they may not always capture the full complexity of modern pharmaceutical processes, especially when many variables change at the same time. AI is increasingly being used to address this limitation by improving the way process data are interpreted, quality attributes are tracked, and control decisions are made.[21]

AI in Process Monitoring: Process monitoring is the first step in keeping a manufacturing process under control. Process Analytical Technology uses real-time sensors and analytical tools to monitor production conditions, but AI adds another layer by helping interpret the large volume of data generated during manufacturing. This is especially useful in complex processes where minor raw material or process variations can quickly influence product quality.[22]

AI-enhanced monitoring can support early anomaly detection, continuous quality assessment,

and estimation of quality attributes that are difficult to measure directly. In practice, this means that problems can be identified earlier, before they lead to batch failure or unnecessary downtime. The combination of AI and PAT therefore creates a more responsive monitoring environment than conventional sensor-based systems alone.[23]

AI in Process Control: Once a process is being monitored, the next step is control. Model predictive control is one of the most important control strategies for continuous pharmaceutical manufacturing because it can use process models to predict future behaviour and adjust operating conditions accordingly.[24] This is valuable when the process is dynamic and when quality attributes must remain within tight limits.[25]

AI strengthens process control by making the models more flexible and data-driven. For example, recurrent neural networks have been used to support system identification and closed-loop control in continuous pharmaceutical systems. This is important because physics-based models are not always easy to develop or maintain, especially for complex or changing processes. Data-driven AI models can therefore provide a practical alternative for stabilizing operations and improving control performance.[26]

PAT, Soft Sensors, and Early Detection: A major strength of AI in pharmaceutical monitoring is its ability to work with PAT data more effectively. PAT systems generate information from spectroscopy, sensors, and other inline measurements, but AI helps transform that information into useful process knowledge. This is where soft sensors become especially valuable, because they can estimate unmeasured variables and support decisions when direct measurement is difficult or impossible.[27]

AI also helps with early detection of abnormal trends or process drift. Instead of waiting until final testing, manufacturers can use AI-supported monitoring to recognize quality problems during production. This approach reduces waste, lowers the risk of batch rejection, and improves overall process reliability.[28]

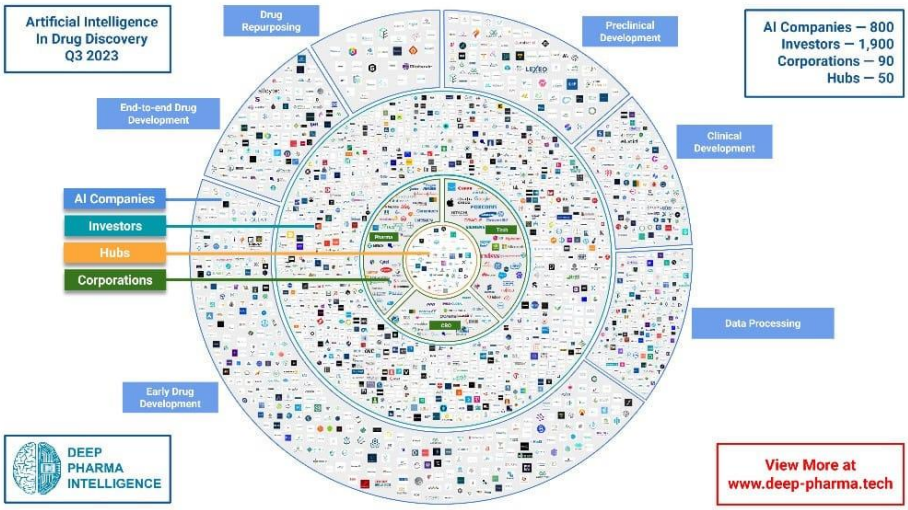

Fig. 5: Overview of Ai Application Across Pharmaceutical Process Monitoring, Control, And Drug Development, Highlighting Data-Driven Decision-Making, Predictive Analytics, And Integration Across The Manufacturing Lifecycle (Adapted From Deep Pharma Intelligence[32]).

AI IN QUALITY CONTROL AND QUALITY ASSURANCE: Artificial intelligence appears in the quality control and assurance field as a decision-supporting tool, as a way to ensure ongoing compliance, and to optimize the processes involved in such a way to manage the quality-related data better. AI is discussed in relation to Quality Control (QC), Quality Assurance (QA), process optimization, regulatory affairs, and decision-supporting in the context of the pharmaceutical industry in particular and the manufacturing industry in general. In other words, there is a growing tendency to view artificial intelligence as a critical success factor for improving both product and process quality.[31]

AI in Quality Control: Quality control is a set of measures taken to ascertain whether products or processes conform to a given standard. AI is actively discussed in relation to quality control in the pharmaceutical industry. In particular, the topics of Artificial Intelligence in Pharmaceutical Manufacturing: Enhancing Quality Control and Decision Making and AI-driven pharmaceutical manufacturing: Revolutionizing quality control and process optimization imply that AI is instrumental in terms of inspection, monitoring, and making decisions about the ongoing processes.[32]

Practically speaking, when it comes to quality control, AI assists in detecting patterns and anomalies and helps make accurate decisions faster. It can be applied in complex settings where traditional methods are insufficient or when ongoing monitoring is required as opposed

to taking action at specific stages. In this respect, AI helps transform inspection-focused QC practices into something broader and more integrated.

AI in Quality Assurance: While quality control is but a part of the broader concept of quality assurance, which also involves managing the supporting processes and documentation. Thus, AI is discussed in relation to quality assurance, design quality by design, regulatory affairs, and pharmaceutical quality management in general. In other words, there is a growing recognition of the role that AI can play in ensuring that everything is done right, not just inspecting and making decisions about individual products or processes.

Quality assurance benefits from AI in terms of managing diverse sets of information about product and process quality, making decisions, and ensuring that all relevant regulations are followed. In fact, AI is considered a critical component of modern pharmaceutical quality management systems, which also involve quality by design principles. In other words, AI helps make the entire system better as opposed to focusing on individual aspects such as inspection or testing.[33]

AI for Decision Making and Process Optimization: Apart from QC and QA, AI is discussed in relation to decision-making and process optimization. Artificial intelligence plays a significant role in process optimization and decision-making in the context of pharmaceutical manufacturing in particular and industrial manufacturing in general. In the context of quality control, such a meaning implies the ability to analyse and assess various quality factors and take action in due time.

Thus, AI-driven decision making supports the creation of higher-quality products by preventing defects and taking corrective action in a timely manner. In this respect, the discussed article suggests that when it comes to quality control and assurance, AI can be a tool for optimizing manufacturing processes both in terms of quality management and product quality.[34]

AI, Regulation, and GMP: Finally, AI is actively considered in the context of regulatory affairs and good manufacturing practices (GMP). There is an awareness that AI integration may have a disruptive impact on the pharmaceutical manufacturing industry and that regulatory frameworks need to be created or adjusted to make sure that AI applications comply with existing requirements or help shape new regulations. After all, GMP and related

regulations are all about ensuring that the processes involved meet high-quality standards and that the products are consistently conforming to the established quality requirements.

This is why the role of AI in pharmaceutical QC and QA has to be understood within the context of regulatory affairs and process optimization. In other words, while AI appears to be a very promising technology for pharmaceutical manufacturing, its implementation has to follow established regulations and quality management principles.[35]

AI-ENABLED QUALITY-BY-DESIGN AND SMART MANUFACTURING: Artificial intelligence is increasingly recognized as playing a crucial role in Quality-by-Design and smart manufacturing, as it enables pharmaceutical companies to transition from reactive quality control to more predictive and integrated approaches to process management. A substantial body of research exploring the intersection of AI, QbD, PAT, and digital twins in pharmaceutical and biopharmaceutical manufacturing, illustrating the domain's recognition of AI as a viable tool for advancing process understanding, quality assurance, and manufacturing flexibility.[37]

AI and Quality-by-Design: Quality-by-Design aims to ensure quality of the final product through process understanding rather than relying solely on end-product testing. The results demonstrate this by including the title Artificial intelligence algorithm qualification: a quality by design approach to apply artificial intelligence in pharma. This highlights the consideration of AI as integral to QbD processes. This is further illustrated by the phrase 'a quality by design approach to apply artificial intelligence,' which implies that QbD principles go beyond product design to include process design and the qualification of supporting tools such as AI.[38]

Moreover, the illustrate the emphasis on the role of modelling and process understanding in QbD. In the context of pharmaceutical manufacturing, this implies the utilization of AI for design space exploration, robustness assessment, and control of critical quality attributes to meet QbD requirements. By doing so, AI contributes to the realization of the QbD philosophy of building quality into the process through enhanced process understanding and predictability.[39]

Digital Twins in Smart Manufacturing: Digital twins represent a paradigm of smart manufacturing, and their prevalence in pharmaceutical manufacturing. This is demonstrated

by the title Digital twins in pharmaceutical and biopharmaceutical manufacturing: a literature review and related work on process design and batch-versus-continuous manufacturing. Moreover, the phrase 'digital twins in pharmaceutical and biopharmaceutical manufacturing' illustrates the extent to which the concept is utilized in the context of smart manufacturing and AI-enabled process management.

The presence of the phrase 'Industry 4.0 and smart manufacturing' further demonstrates the connection between digital twins and smart manufacturing. Overall, the connection between digital twins and smart manufacturing is grounded in their ability to enable integrated, data-informed process management through the utilization of modelling and data analytics.[40]

AI for Process Understanding and Control: The role of AI in process understanding and control is further highlighting the use of AI to enable smart manufacturing and advanced process control within the framework of QbD. The presence of the title A framework for AI-driven operating model redesign in the pharmaceutical industry further illustrates the potential role of AI in transforming pharmaceutical manufacturing. In particular, suggests that AI can enable smart manufacturing at multiple levels, from basic process informatics to strategic process redesign.[41]

CHALLENGES AND LIMITATIONS: Although the application of artificial intelligence in pharmaceutical manufacturing leads to multiple opportunities, that demonstrates that this emerging technology encounters several challenges and limitations. Those include the quality of data and its integration, validation and regulation issues, a lack of relevant expertise, and the complexity of the system, among others. Since the pharmaceutical industry is a strictly regulated environment, these factors can significantly impact the manufacturing process.[42]

Data Quality and Integration: The most apparent limitation of implementing AI in pharmaceutical manufacturing is the issue of data, namely, its quality, availability, and structure. The integration of data resources, their structure, and quality is one of the main challenges in adopting digital twins' technology in pharmaceutical manufacturing. Poor data management leads to the appearance of errors and biases that can impact the performance of machine learning models.[43]

Validation and Regulation: It highlights the fact that validation is one of the main challenges in pharmaceutical manufacturing when using AI systems. The researchers state

that AI and ML systems require additional regulatory considerations when applied in the GMP environment, which makes them harder to implement in the pharmaceutical manufacturing process. The problem stems from the need to validate those systems in terms of specific contexts in which they will operate, their traceability, performance, and compliance with regulations.[44]

Human and Organizational Barriers: One of the challenges of implementing smart pharmaceutical manufacturing is the necessity to ensure that there are appropriate people within the organization who can use these technologies. In other words, AI systems require specialists who understand their principles and possess the relevant skills and competencies. Those people should also have an adequate awareness of the system, including its capabilities, limitations, and ways of applying the technology in specific contexts.[45]

Digital Twin Limitations: Since the application of AI in pharmaceutical manufacturing is dominated by studies referring to digital twins, it is possible to conclude that they are considered a significant step towards the development of the industry.[46] However, one of the main challenges of implementing such systems is the necessity to ensure appropriate process modelling and data exchange rates. It states that those factors, along with the ability to introduce and integrate such AI-driven systems in the manufacturing process, appear to be major limitations of digital twins in pharmaceutical manufacturing.[47]

FUTURE PERSPECTIVE: The future perspective implies the development of AI in pharmaceutical production and documentation, quality control, regulatory affairs, and related areas. The tendency shows that the application of AI in the pharmaceutical industry may go further and contribute to the creation of more integrated and optimized production and control systems that are based on data science and advanced decision support technologies, and in this way, change the status quo.[50]

More Integrated Production: There is a tendency for integrated digitalization, data analytics, and AI in the pharmaceutical industry. It implies that the pharmaceutical production in the future will be characterized by more integrated processes and include more automated and optimized control systems based on models and data analytics.

More Emphasis on Quality and Regulatory Affairs: The future perspective implies that there will be more emphasis on quality control, quality assurance, and regulatory affairs. AI

will be used to optimize and improve the pharmaceutical production in terms of quality, control, documentation, and decision-making.

More Attention to Multivariate Control and Monitoring: Another future tendency is more attention to multivariate control and monitoring. there is a tendency for AI application in the context of multivariate control, which implies a more integrated and sophisticated approach to monitoring and managing the processes.

More Focus on Regulatory and Human Factors: Finaly, there is a tendency for more focus on regulatory and human factors in the context of AI application in the pharmaceutical industry. It implies that the future use of AI in pharmaceutical production will involve more attention to regulatory affairs, documentation, control, and other factors that are critical for the pharma production.[51]

The projected growth of the Pharma 4.0 market, as illustrated in Fig. 7, highlights the increasing adoption of advanced digital technologies in pharmaceutical manufacturing. The market is expected to expand significantly from approximately USD 11.9 billion in 2023 to USD 67.2 billion by 2033, with a compound annual growth rate (CAGR) of 18.9%. This growth is driven by the rising integration of artificial intelligence (AI) and machine learning, cloud computing, Internet of Things (IoT), data analytics, and blockchain technologies. Among these, AI and data analytics are expected to play a dominant role in enabling predictive manufacturing, real-time monitoring, and data-driven decision-making. The continuous expansion of these technologies indicates a future where pharmaceutical processes become increasingly automated, interconnected, and efficient, supporting the transition toward smart and sustainable manufacturing systems.[52]

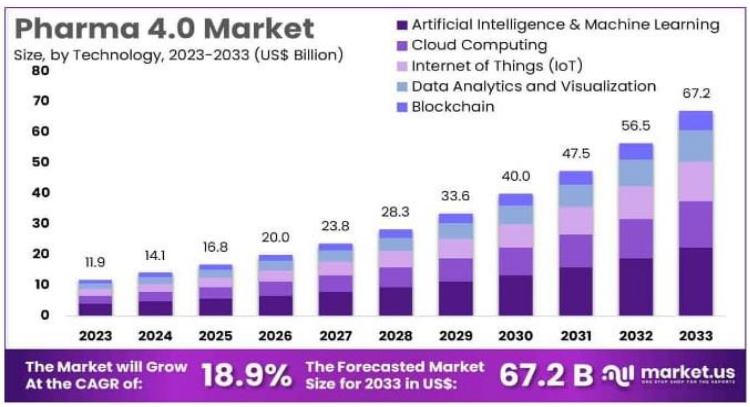

FIG. 6: Projected Growth of The Pharma 4.0 Marketed By Technology From 2023 To

2033 (Usd Billion), Showing Incresing Contributions From Artificial Intelligence, Cloud Computing, Iot, Data Analytics, And Blockchain. (Adapted from Market.US[36]).

CRITICAL ANALYSIS: The integration of artificial intelligence (AI) in pharmaceutical manufacturing and quality control has demonstrated significant potential in improving efficiency, accuracy, and process optimization. AI-driven techniques such as machine learning and predictive analytics enable real-time monitoring, fault detection, and data-driven decision-making, thereby enhancing product quality and reducing human error.

However, despite these advancements, several limitations hinder the widespread implementation of AI in the pharmaceutical industry. One major challenge is the lack of high-quality, standardized datasets required for training robust AI models. Many pharmaceutical processes generate heterogeneous and complex data, making integration and interpretation difficult. Additionally, regulatory uncertainty remains a critical barrier, as existing guidelines are not fully adapted to AI-based systems.

Another limitation is the high cost and technical complexity associated with implementing AI technologies, particularly for small and medium-sized pharmaceutical companies. The need for skilled professionals and infrastructure further restricts adoption. Moreover, issues related to data security, model transparency, and explainability raise concerns in regulatory compliance and decision validation.

Although current studies highlight the benefits of AI in process analytical technology (PAT), quality assurance, and predictive maintenance, most applications remain at the experimental or pilot stage. There is still a gap between research findings and large-scale industrial implementation.

Therefore, while AI holds transformative potential for pharmaceutical manufacturing and quality control, its practical adoption requires overcoming technical, regulatory, and operational challenges.

RESEARCH GAPS: Despite the growing body of research on artificial intelligence in pharmaceutical manufacturing, several research gaps remain that need to be addressed for effective implementation.

First, there is a lack of standardized frameworks for integrating AI into existing

pharmaceutical manufacturing systems. Most studies focus on isolated applications rather than end-to-end system integration.

Second, limited availability of high-quality, labelled datasets restricts the development of reliable and generalizable AI models. Data sharing across organizations is also constrained due to confidentiality and regulatory concerns.

Third, there is insufficient research on the regulatory acceptance of AI-based systems. Clear guidelines and validation protocols for AI-driven decision-making in pharmaceutical processes are still under development.

Additionally, the issue of model interpretability remains largely unexplored. Many AI models, particularly deep learning approaches, operate as "black boxes," which is not ideal for highly regulated industries like pharmaceuticals.

Another gap lies in the scalability of AI solutions. While many studies demonstrate successful small-scale implementations, there is limited evidence on their performance in large-scale industrial environments.

Finally, there is a need for more interdisciplinary research combining pharmaceutical sciences, data science, and regulatory expertise to develop practical and compliant AI solutions.

Addressing these gaps will be essential for advancing the adoption of AI in pharmaceutical manufacturing and ensuring its successful integration into quality control systems.

CONCLUSION

Today, artificial intelligence impacts the pharmaceutical industry by making drug manufacturing more predictive, connected, and data-driven. In all the reviewed articles, AI was considered an essential component of process monitoring and control, process analytical technology, quality by design, quality control, and assurance, as well as smart manufacturing and digitalization capable of improving processes and making them more efficient and reliable. In the literature, particular emphasis was placed on data quality, validation, and regulatory science as critical success factors for implementing AI in the pharmaceutical manufacturing process.

Thus, in most of the readings, the pharmaceutical manufacturing process is presented as an intelligent information-intensive system in which AI, digital twins, and analytics play a pivotal role in driving continuous improvement and adding value to pharmaceutical products through enhanced performance and quality. However, it should be noted that for AI to realize its potential in pharmaceutical manufacturing, its application must be transparent and fit for purpose, guided by regulatory science and human expertise. Therefore, it can be concluded that AI is considered a key enabler of modern pharmaceutical production that should be embraced to optimize processes and contribute to better-quality products.

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