

Emerging Role of Artificial Intelligence in Pharmaceutical QC and QA and its Applications across the Industry

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ABSTRACT

Quality Control (QC) and Quality Assurance (QA) are key elements in the pharmaceutical sector. They help to ensure the safety, efficacy and consistency of medicines. This article discusses the purpose of QC and QA for pharmaceutical manufacturing in the modern era and outlines their development, principles and problems relating to the application of technology and universal quality standards. The article reaffirms the need for continuous and seamless improvement in the maintenance of quality system improvements that are responsible for global health standards and that can be applied to licensed drugs in a wide range of settings, ensuring the effectiveness of medicines delivered to patients in a sustainable manner. QC and QA are important components in pharmaceutical production. Their combined function is to ensure that all products are safe, efficient and reliable. As the industry evolves and moves toward digitalization, automation and data-centric systems, QC and QA evolve from reactive functions to predictive and preventive tools. Continuous improvements, regulatory compliance and the adoption of technology will shape the future of pharmaceutical quality. This paper also analyzes the beneficial use of Artificial Intelligence (AI) within the pharmaceutical sector throughout all phases, from drug discovery to drug development, as well as in various departments. Besides necessitating less human labor, it also improves the efficacy of clinical research and pharmaceutical output while diminishing the likelihood of mistake. The report examines the existing challenges in the implementation of AI within the pharmaceutical sector. Furthermore, it evaluates existing challenges and proposes remedies.

Keywords: Artificial intelligence, Pharmaceutical manufacturing, Predictive quality analytics, Quality assurance, Quality by design, Quality control, Regulatory compliance.

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INTRODUCTION

Quality is a top priority in pharmaceutical operations. The highest level of safety, effectiveness, and dependability in products is ensured by two interconnected but distinct components: Quality Control (QC) and Quality Assurance (QA). QC focuses on procedures that include testing, inspecting, and certifying raw materials, in-process samples, and finished goods to ensure they fulfill specified requirements (Mundari *et al.*, 2024). In contrast, QA focuses on prevention through the creation and application of actual structures, provisions, and documentation, ensuring that high-quality products are consistently produced (Khinvasara *et al.*, 2024). QC and QA work together to create a comprehensive Quality Management System that complies with international regulatory bodies like the Food and Drug Administration (FDA), the World Health Organization (Geneva), and the International Council for Harmonization (ICH). This methodical approach

lowers UN, fosters consumer confidence, and achieves regulatory compliance (Jain, 2024).

The application of Artificial Intelligence (AI) has expanded around the world in several industries. Its significant effects on the pharmaceutical industry are still being reviewed. AI is being used in many pharmaceutical disciplines, such as medication research and development, medicine repurposing, accelerating pharmaceutical manufacturing, and clinical studies, which reduces the amount of labor required from humans while also advancing goals more quickly (Baran and Henstock, 2022). The difficulty of gathering, analyzing, and applying that knowledge to difficult healthcare scenarios has increased with greater digitalization (Ramesh *et al.*, 2004). This article looks at the application of AI to several areas of the pharmaceutical industry, from drug discovery to medication development. It involves using AI to carry out clinical research, repurpose medications, boost pharmaceutical production, and more. The use of digitalization in the pharmaceutical sector has experienced considerable advancement. The necessity for scrutiny and reliable information to tackle problems. The acquisition and application in the field may pose one of the challenges that change invariably brings. These challenges necessitate the incorporation of AI, since it can efficiently handle large data sets with enhanced automation. A



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contemporary technology-driven system known as AI employs sophisticated tools, networking, and technologies to replicate human intelligence. It comprises hardware and software capable of deriving conclusions from the supplied data and operates autonomously. Computers are employed in artificial intelligence to replicate intelligent decision-making. The fundamental subset of AI known as Machine Learning (ML) is frequently conflated with AI itself. The phrase “machine learning” denotes the ability to autonomously analyze data statistically without explicit programming (Cisco, 2023).

The application of AI has the potential to substantially alter the velocity and breadth of contemporary drug discovery. The integration of AI in the pharmaceutical sector can yield improvements such as:

- AI-driven drug discovery does not depend on predefined objectives. Consequently, personal prejudices and prior experiences are disregarded during the pharmaceutical development process.
- AI formulates novel algorithms for drug development by integrating the latest advancements in biology and technology. Owing to the swift augmentation of processing capacity and the reduction in processing expenses, AI possesses the requisite capabilities to elevate the competitive landscape in pharmaceutical research. AI possesses an enhanced ability to delineate relevant interactions in pharmacological screenings. Consequently, the probability of false positives can be diminished by meticulously choosing the previously indicated test parameters (Larrañaga *et al.*, 2006).

Historical Background

The need for standardization brought about by industrialization led to the development of the concepts of QC and QA. Following past cases of contaminated and ineffective medications, quality became a significant concern in the pharmaceutical industry. Regulatory bodies like the United States. The S. Good manufacturing practices and guidelines from the ICH were established because of strict quality standards set by the FDA and the World Health Organization. These efforts created the first quality systems, which are still developing today (Hamden, 2024).

Function of Quality Control

Quality Control guarantees the integrity of medicinal products adhere to established criteria of quality and purity effectiveness (“Revolutionizing automation testing with AI: A New Era of intelligent quality assurance.”, 2024). The process entails the methodical evaluation of raw materials, intermediate samples, and final products to ensure adherence to specifications.

Key Factors of quality control includes (Kothamali *et al.*, 2024):

- Raw Material Testing: ensures the purity and compatibility of incoming resources.

- In-Process Control: monitors parameters during manufacturing to prevent deviations.
- Finished product testing: ensures compliance with regulatory criteria.

Analytic method validation: ensures accurate and repeatable findings.

Modern QC uses advanced analytic techniques such as HPLC, UV spectroscopy, gas chromatography, and microbiological testing to ensure product consistency.

Function of Quality Assurance

Quality assurance is a discipline centered on processes and the verification of each component. Production adheres to the requirements established by regulations and internal quality protocols. Quality assurance aims to eradicate flaws rather than only identifying them postoccurrence (Cherekar, 2024).

The essential elements of quality assurance comprise (Bhadurgatte and R, 2024; Makki *et al.*, 2025):

- Administration of documentation and standard operating procedures.
- Verification and qualification of equipment and processes.
- Ensuring training and proficiency.
- Executing internal and external audits.
- Execution of corrective and preventive measures.
- Corrective and preventive action.
- Quality assurance ensures compliance with the principles of good manufacturing practice and promotes a culture of continuous improvement.

The Interconnection Between Quality Control and Quality Assurance

Quality Control and Quality Assurance are two interrelated entities. In summary, QC is tasked with detecting quality deviations through testing, whereas QA concentrates on establishing systems and processes to prevent such deviations from arising initially (Feng and Yang, 2020). QC supplies data and outcomes that are utilized by QA in their assessments, whereas QA frameworks ensure that QC operations are standardized and compliant.

Raw materials → quality control → manufacturing → quality assurance → product launch
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Current Scenario

In the current landscape, the pharmaceutical industry’s QC and QA functions are shaped by regulatory requirements centered

on risk-based methodologies, data integrity, and comprehensive life cycle management (Pysmennyi *et al.*, 2025). Contemporary quality systems are significantly shaped by digital technology, including Laboratory Information Management Systems, electronic batch records, and real-time monitoring (Klock and Monostori, 2020). Automation and robots have enhanced accuracy, efficiency, and traceability in quality control testing methods. Global harmonization has been accomplished via ICH norms, and the ISO 9001 initiative has enhanced the international quality framework (Chiu and Tsai, 2021).

FUTURE PROSPECTS

The future of QA and QC relies on technology transformation. The primary trends are:

- **AI AND ML:** for real-time predictive analytics and anomaly detection.
- **Quality by design:** Incorporates quality into the product from the design phase.
- **Process analytic technology:** Enables real-time quality monitoring.
- **Digital twins:** Virtual representations of a manufacturing system utilized for simulation and process management.
- **Blockchain:** To enhance traceability and authenticity inside the supply chain. These tools will provide a more proactive, data-driven, and efficient approach to quality management.

Obstacles and Prospects

The pharmaceutical quality system continues to encounter several challenges despite progress.

1. Violations of data integrity and regulatory compliance.
2. Substantial expenses for implementing technology.
3. Insufficient trained personnel.
4. Global regulatory discrepancies (Sinha and Jana, 2025).
5. Can recognize opportunities for ongoing enhancement, skill development, and technological progress. Coordination among regulators, academics, and industry will be essential for developing quality systems that are prepared for the future (Lee *et al.*, 2015).

Current Function of AI in Quality Control

Automated visual examination

AI-powered computer vision systems utilize cameras and deep learning algorithms to evaluate items with safety, precision, and immediacy. They possess the ability to identify nuanced surface imperfections, dimensions discrepancies, and color inconsistencies with far more precision than a human inspection.

They are extensively utilized in the automotive, electronics, and pharmaceutical sectors (Jardine *et al.*, 2006).

Predictive quality surveillance

Predictive Quality Monitoring is a novel approach that utilizes data analytics, AI, and ML to anticipate quality problems in manufacturing or production settings. Predictive Quality Monitoring continually gathers data from sensors, equipment, and process parameters to identify early signs of deviations, rather than detecting faults postproduction (Khan and Yairi, 2018).

Statistical process control utilizing artificial intelligence

Artificial intelligence improves statistical process control by perpetually learning from data trends. It autonomously detects process deviations and underlying reasons, resulting in expedited remedial measures (Zhang *et al.*, 2019).

Quality Documentation and Adherence

Effective excellent Management Systems (QMS) depend on excellent documentation and compliance as essential elements. Quality documentation entails the systematic recording of methods, standards, and records to guarantee that goods and processes adhere to defined quality criteria. Examples of quality documentation encompass quality manuals, standard operating procedures, job instructions, and quality records. These records provide transparency, traceability, and uniformity across all activities (Wei *et al.*, 2019).

The Function of Artificial Intelligence in Quality Assurance

Intellectual assessment and verification

In software quality assurance, artificial-intelligence systems may autonomously develop test cases, anticipate probable defects, and prioritize high-risk domains (Chen *et al.*, 2021). In pharmaceuticals, AI facilitates the validation of analytic procedures and the assessment of batch consistency.

Risk evaluation and decision assistance

Risk assessment and decision support are essential components of modern industrial and quality management systems. Risk assessment is the methodical procedure of discovering, examining, and evaluating the risks linked to processes, goods, or activities (Ghosh *et al.*, 2022). Through risk assessment, organizations may ascertain the probability and importance of prospective hazards, enabling them to choose which risks to proactively manage while balancing their emphasis on quality and safety (Sandanyaka *et al.*, 2023).

Continuous process enhancement

Machine-learning algorithms evaluate historical data to recommend process optimization. Facilitates sustained

enhancement of the quality assurance framework (Duan *et al.*, 2023).

The importance of artificial intelligence in QC and QA

- **Enhanced precision:** It minimizes human mistake in quality inspections and paperwork.
- **Velocity and efficacy:** The capacity to deliver real-time analysis reduces inspection duration.
- **Decreased Expenditure:** Identify failures promptly to reduce waste and rework.
- **Predictive Maintenance:** Failures can be detected before occurrence, hence enhancing process dependability.
- **Data-Driven Decisions:** AI can transform raw data into useful insights for quality improvement.

Obstacles In Execution

- **Significant Initial Expenditures:** Investment in training and artificial-intelligence infrastructure.
- **Issues of Quality:** Poor data quality or restricted data diminishes performance.
- **Insufficient skilled workforce:** Expertise in artificial intelligence is required.
- **Challenges in integration:** Difficulty in assimilating AI with legacy systems.
- **Regulatory Concerns:** Pertaining to privacy and transparency.

Future Prospects of AI in QC and QA

Autonomous Quality Management Systems

Autonomous Quality Management Systems provide a novel approach to quality assessment in manufacturing, integrating AI, ML, and the Internet of Things (IoT) to facilitate self-learning and self-correcting quality processes (Huang *et al.*, 2021). These systems actively analyze production data in real time, identify deviations, anticipate possible quality issues, and autonomously remediate the issues without human intervention.

Integration of AI and IoT

Integration of AI and the IoT The integration of AI with the IoT is revolutionizing global businesses by creating intelligent, interconnected systems capable of real-time data collection, analysis, and action. IoT devices generate substantial data from sensors and networks, while AI offers systems to analyze this data by identifying patterns and autonomously making judgments (Qin *et al.*, 2023). This will provide predictive maintenance, advanced manufacturing, healthcare surveillance, energy optimization, and intelligent transportation systems. AI-integrated IoT solutions will augment industrial productivity, minimize downtime, and

elevate user experiences associated with IoT implementation. The amalgamation of AI and IoT is expected to propel the emergence of fully automated smart environments in the future, enhancing industries' adaptability, sustainability, and data-driven capabilities (Ren *et al.*, 2024).

Digital Twins for Quality Forecasting

Digital twins are virtual representations of physical systems that employ real-time data and artificial intelligence to predict and improve product quality. By integrating sensors, the IoT, and machine learning, digital twins enhance the production process and detect anomalies that impact quality. Digital twins will allow enterprises to identify product problems beforehand and to modify production settings in real-time based on variables impacting quality. This is especially beneficial in the automotive and pharmaceutical sectors for predictive quality control applications aimed at minimizing faults and waste while ensuring consistent quality. Digital twins signify a transition from inspection to proactive surveillance. Digital twins utilize real-time data and machine learning to oversee product quality and facilitate data-driven decision-making processes. Future advancements will rapidly increase and expand the possibilities of digital twins inside intelligent, self-optimizing manufacturing environments, prioritizing continual improvement in product quality (Raj *et al.*, 2022).

The Role of Artificial Intelligence in Regulatory Compliance

Because it automates hard operations, improves accuracy, and reduces risks, AI is revolutionizing regulatory compliance across all sectors of the economy. The conformity with external rules, regulations, and guidelines that drive corporate operations is referred to as regulatory compliance. This is especially important in areas such as the pharmaceutical industry, the financial industry, the healthcare industry, and the manufacturing industry.

Collaboration between Humans and Artificial Intelligence

The collaboration between human beings and AI in the quality space QC and QA is transforming the way in which businesses operate. This is accomplished by combining human intelligence with AI to improve accuracy, efficiency, and reliability. Artificial-intelligence systems are able to collect and analyze production data in a short amount of time, allowing them to discover errors through picture recognition and predict quality defects before they occur. In addition, humans carry with them the ability to perceive context, to think ethically, and to make decisions (Schwartz *et al.*, 2023).

Applications of Artificial Intelligence in the Pharmaceutical Industry

Artificial intelligence in drug discovery

Drug development and research is an endeavor that is both expensive and arduous. It requires balancing multiple properties of molecules to attain clinical efficacy and safety that is wanted. Among these qualities, the drugs' performance mostly rely on their Pharmacokinetics /Pharmacodynamics (PK/PD) characteristics, nonclinical safety profiles, and Absorption, Distribution, Metabolism, and Elimination (ADME) characteristics. It is possible that current developments in artificial intelligence and machine learning techniques might be beneficial to the process of drug discovery and development. These innovations have the potential to boost the chance of success and speed up decision-making. Huge datasets that contain information on chemical structures and the related experimental readouts are utilised to train the AI/ML system, which then clarifies the underlying ideas, biological processes, and interactions between chemical structures. These datasets are used to train the system. The artificial intelligence and machine learning models may then be utilised to make predictions regarding the predicted biological reactions of a molecule that has not yet been tested and, in certain instances, has not even been synthesized all based on the chemical structure of the molecule. These artificial intelligence and machine learning algorithms are utilised by discovery scientists working in the ADME industry in order to choose ultra-small compounds that have the highest potential ADME profiles for synthesis, testing, and process development. The selection of these compounds was made from among the hundreds of thousands of alternatives that are theoretically possible (Morgan Stanley, 2022).

The application of artificial intelligence in the process of drug development may be broken down into the following categories:

Validation and selection of the target

Determining the function of prospective therapeutic targets, which are genes or proteins of a small molecule, and the significance of these molecules in the treatment of sickness needs an understanding of how these molecules function. When selecting and validating methodologies, it is necessary to consider functional genomics, structural genomics, proteomics, *in vitro* cell-based assays, and *in vivo* animal research assays. The medication Information Bank is evaluated by artificial intelligence to determine the positive effects of medication candidates, genetic expressions, interactions between proteins, and clinical data records from a public library. To determine the effectiveness target of a medicine, it is necessary to have an understanding of the function of various molecular targets and the importance of these targets in the context of sickness.

Compound screening and lead optimization

Compound screening and lead optimization processes combine virtual screening, high-throughput screening, and combinatorial chemistry to identify potential candidates for drug development. For the purpose of constructing the chemical database for artificial intelligence-based virtual screening, considerable quantities of compounds are acquired from chemo genomics libraries that are freely accessible.

These libraries contain millions of compounds together with structural information.

Research that is not yet clinical

In the laboratory, preclinical investigations, which are also frequently referred to as nonclinical studies, are tests that are carried out *in vitro* and *in vivo* on new medicinal compounds to determine the characteristics of their safety and effectiveness. Clustering-based machine learning approaches take RNA sequencing technologies into consideration

In order to uncover a molecular mechanism of action. This allows for the rapid collection of relevant and enormous volumes of biological data. In addition to this, it reveals a number of previously undiscovered connections between various stimuli and the cytokines that they influence.

Clinical research

A new generation of artificial intelligence tools for clinical trials would function exceptionally well in terms of identifying patient conditions, locating gene targets, predicting the result of a newly developed medicine, and identifying on and off-targets. Compared to traditional direct observation therapy, one artificial intelligence mobile application increased medication adherence by 25 % in clinical investigations that were conducted during Phase ("How artificial intelligence is revolutionizing drug discovery", 2023).

Applying artificial intelligence to drug screening

In the process of drug screening, artificial intelligence is utilised for a variety of purposes, including but not limited to target identification, molecular simulations, drug property predictions, de novo drug production, synthesis of route generation, and candidate drug prioritization (Chen *et al.*, 2023).

AI-based tools and resources for the development of new drugs

One of the most essential aspects of applying artificial intelligence for drug discovery and assessment is the utilization of data resources. Examples of the following: ChEMBL, ChemDB, COCONUT, DGIdb, DrugBank, DTC, INPUT, PubChem, and SIDER or STITCH are some of the other data repositories that are available. Methods such as Delta Vina, neural graph fingerprint, alpha fold, and computer are examples of common artificial

intelligence approaches. Other techniques include clustering, classification, and regression analysis techniques (Ramesh *et al.*, 2004; Sima, n.d.).

AI in medicinal molecules design

Traditionally, the process of creating a therapeutic molecule requires a significant amount of effort and involves a number of unsuccessful efforts. An example of this would be a synthesis plan that may consist of hundreds of individual processes, many of which would result in undesirable by-products or side effects, or they would simply fail to function when implemented. By contrast, artificial intelligence is currently beginning to improve the effectiveness of design and synthesis, therefore accelerating, simplifying, and cutting the cost of firm operations while simultaneously reducing the amount of chemical waste (Venkatraman and Miah, 2022). Over the course of the past several years, AI research and theoretical studies have given way to practical implementations. AI and ML techniques, such as deep learning, have advanced to the point that robots can now simulate the intellect of humans by learning from data. As a consequence of this, molecular design may undergo a revolution because of the use of AI and ML techniques. Before the advent of artificial intelligence, the organization of experiments, as well as the characterization, evaluation, and analysis of the results of such investigations, were virtually entirely the duty of professionals working in experimental laboratories that investigated and created novel substances. Because of this bottleneck, the production of new materials has slowed down, which may have implications for a number of industries, including the technological sector, the pharmaceutical industry, and the energy storage industry. There are a great number of tools accessible to users because of developments in the field of computer science and the use of machine-learning technologies. The introduction of machine-learning techniques in quantum chemistry simulation demonstrates the potential of far fewer simulations that need a significant amount of computer power while yet providing acceptable precision for chemical applications. Examples of applications for machine learning include the calculation of stable structural conformations and the production of coarse-grained models for simulations of molecular dynamics. Using machine learning to make predictions about molecular features has produced some very encouraging research outcomes. It is currently common practice to utilize machine-learning algorithms to make predictions about characteristics of proteins, such as their reactivity, toxicity, and capacity to bind to receptors, based on the electrical structure and amino acid backbone of the protein.

It is possible to use this method to the field of chemistry in order to simulate the process of creating unique synthetic structures. The development of synthetic molecular design with the assistance of this technology has the potential to significantly

enhance chemical research ("Artificial Intelligence in molecular design", 2023).

With the use of artificial intelligence, new pharmaceutical items are being developed, including the following:

European Commission (2024)

- The identification and diagnosis of diseases.
- Individualized therapy via the use of digital treatments and techniques for behavioural modification.
- Chemical research and manufacturing of drugs.
- Forecasting, or prognostication.
- Laboratory examinations.

Artificial Intelligence for the production of pharmaceutical products

Manufacturing complexity has risen compared to previous years due to current advancements in pharmaceutical technology and unique innovations. For the complicated process, a product that has been tested and shown to be good and useful is also needed. Modern pharmaceutical production systems are trying to combine human skill with machines to make the manufacturing process better. Using AI in the production process might help the pharmaceutical sector grow. AI technologies will help automate a lot of pharmaceutical tasks. This may help with difficulties that can come up throughout the manufacturing process and also help with numerical stimulation (Mak and Pichika, 2019). AI can be used in the production of drugs to get the proper amount of results by using other cutting-edge manufacturing technologies.

The United States. FDA produced a discussion paper that said that AI may be used in the following ways in the manufacturing of drugs:

- **Process design and scalability:** AI can quickly figure out the processing parameters, which cuts down on waste and development time.
- **Advance Process Control (ACP):** AI can help make process controls easier to make when combined with real-time sensor data. This lets you understand how a process will change over time. AI tools can tell the difference between different ways of maintaining things and making changes to equipment. This cuts down on downtime.
- **Finding trends:** AI may look at changes in consumer feedback and complaints ("Using artificial intelligence and machine learning in the development of drug and biological products", 2023).

AI in pharmaceutical production may make processes faster and more efficient, but it's also vital to think about how it will affect the equipment and infrastructure that are in place.

Artificial intelligence for quality assurance and control

The implementation of AI technology is anticipated to enhance pharmaceutical quality assurance and control systems. Bands are commonly employed in the pharmaceutical business to guarantee compliance with product quality standards, however they may not always exhibit the desired precision. AI applications in the pharmaceutical business can forecast minor deviations that may affect product operation and safety. The application of AI in pharmaceutical quality control and assurance can enhance product quality and process precision. Nevertheless, the products must undergo manual quality control inspections to ensure consistency between batches. The integration of AI is currently not a viable method. The Electronic Lab Notebook, a platform for automated data entry, along with advanced AI algorithms, can ensure product quality. Adopting new technology for intelligent quality control is achievable through the use of overall quality management expert systems, data mining, and other knowledge discovery methodologies (Mak and Pichika, 2019).

Artificial Intelligence used in the design of Clinical Trials

Clinical trials are conducted to assess the effectiveness and safety of pharmaceutical agents in people for a specific condition state. The completion of this arduous procedure may involve 6-7 years or more, along with a substantial financial investment. Moreover, the success rates are unacceptably low, imposing a considerable strain on the sector. Failures may stem from an inadequate patient selection approach, deficient infrastructure, or insufficient technological requirements. The integration of AI can mitigate these problems (*Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products*). AI is capable of executing all phases of clinical trial design, encompassing study planning and implementation. This might enhance trial success rates while alleviating the burden of pharmaceutical research and development. The use of AI in clinical trials necessitates prior evaluation to achieve ethical and benchmarked outcomes. An effective plan can decrease trial expenses and failure rates while concurrently accelerating the process. Artificial Intelligence can assist in the identification of populations with particular medical disorders for Phase II and Phase III trials through the study of patient-specific genomic and exposomic profiles (Henstock, 2019).

CONCLUSION

Artificial intelligence is progressively immersing itself into our everyday routines and enhancing its intelligence with each day that passes. This guarantees its presence in all facets of our lives. The use of AI in the pharmaceutical sector has the capacity to transform the industry; yet, its present developmental stage requires enhancement. Quality Control (QC) and Quality Assurance

(QA) are essential elements in pharmaceutical production. Their collective purpose is ensuring that each product is secure, efficient, and reliable. The pharmaceutical industry stands to benefit from AI, since it may expedite and reduce the costs associated with drug discovery while enhancing clinical and pharmacological data through advanced technologies. Artificial intelligence will advantage future generations, and the pharmaceutical industry will likewise derive benefits from it. Numerous barriers and problems are associated with this technology; hence, no medications developed using AI methodologies are yet available on the market. Notwithstanding this, AI is expected to become an essential instrument for the pharmaceutical business in the near future. As the industry progresses towards digitalisation, automation, and data-centric systems, quality control and quality assurance will transition from reactive activities to predictive and preventative instruments. Ongoing enhancement, adherence to regulations, and technological acceptance will determine the future of quality in medicines.

ABBREVIATIONS

AI: Artificial Intelligence; **ML:** Machine Learning; **QC:** Quality Control; **QA:** Quality Assurance; **QMS:** Quality Management System; **FDA:** Food and Drug Administration; **WHO:** World Health Organization; **ICH:** International Council for Harmonisation; **GMP:** Good Manufacturing Practice; **LIMS:** Laboratory Information Management System; **QbD:** Quality by Design; **PAT:** Process Analytical Technology; **CAPA:** Corrective and Preventive Action; **IoT:** Internet of Things; **ADME:** Absorption, Distribution, Metabolism, and Elimination; **PK/PD:** Pharmacokinetics/Pharmacodynamics; **HPLC:** High-Performance Liquid Chromatography; **UV:** Ultraviolet; **ACP:** Advanced Process Control; **SOP:** Standard Operating Procedure; **ISO:** International Organization for Standardization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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