*DOI: 10.55522/jmpas.V13I5.6689* **ISSN NO. 2320 – 7418**

International peer reviewed open access journal

**Journal of Medical Pharmaceutical and Allied Sciences**

Journal homepage: www.jmpas.com CODEN: JMPACO

Case study

# Application of artificial intelligence (AI) as a process analytical technology (PAT) tool in healthcare industry

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**Received** - 09-09-2024**, Revised** - 27-09-2024, **Accepted** - 21-10-2024 **(DD-MM-YYYY)**

**Refer This Article**

Aarti Shastri, Saurabh Kasar, Namita Veer, Anjali Adsul, Arti Swami, 2024. Application of artificial intelligence (AI) as a process analytical technology (PAT) tool in healthcare industry. Journal of medical pharmaceutical and allied sciences, V 13 - I 5, Pages - 6795 – 6801. Doi: https://doi.org/10.55522/jmpas.V13I5.6689.

## ABSTRACT

Process Analytical Technology (PAT) has revolutionized manufacturing by providing real-time insights into process parameters. This guide delves into the synergistic potential of AI and PAT, offering a comprehensive overview of their integration. It explores the way AI algorithms can enhance data analysis, prediction, and control complex manufacturing processes. The document provides a fundamental understanding of AI concepts relevant to PAT, including machine learning, deep learning, and computer vision. Real-world case studies help to illustrate the practical application of AI in diverse industries, such as pharmaceuticals, chemicals, and food processing. By highlighting the benefits of AI-driven PAT, such as improved product quality, increased efficiency, and reduced costs, this guide empowers readers to harness the power of AI for process optimization and innovation. The objective of this review is to provide a base for establishing the regulatory guidelines and adaptation of PAT controlled applications in the regulations.

**Keywords:** Process Analytical Technology, AI, machine learning, Deep learning, Computer vision, Case studies, Manufacturing, Process optimization**.**

## INTRODUCTION

The modeling of human behavior in connection to the intellectual process involved in problem solving is known as “Artificial intelligence” (AI). The core of artificial intelligence is a machine’s ability to learn as well as skillfully apply knowledge across various real-world situations using current data. Process Analytical Technology (PAT) serves as an essential system in the pharmaceutical and chemical sectors, aimed at guaranteeing superior product quality via real-time monitoring and regulation of manufacturing processes. With the rising need for enhanced efficiency, cost reduction, and strict adherence to regulatory standards, incorporating advanced technologies into PAT has become crucial. Notably, Artificial Intelligence (AI) has surfaced as a game-changing asset, providing exceptional abilities in data analysis, predictive modeling, and process optimization.

AI includes various technologies such as machine learning (ML), deep learning, and natural language processing, capable of processing and analyzing extensive data beyond human capability. Utilizing these AI technologies, PAT systems can greatly improve their capacity to predict, monitor, and control manufacturing processes in real-time. This results in better product consistency, less waste, and quicker responses to process deviations [1].

Integrating AI into PAT provides numerous significant benefits. Firstly, AI-powered PAT systems can handle and analyze extensive datasets produced during manufacturing. It can assist detecting patterns and correlations that might be invisible to human analysts. This ability facilitates more precise and prompt predictions of process outcomes, allowing for proactive adjustments to maintain ideal conditions. Secondly.

AI enhances the robustness and dependability of PAT systems through continuous learning and adaptation. ML algorithms can evolve and improve over time, increasing their predictive accuracy and resistance to process variations.

Additionally, integrating AI into PAT aligns with the broader Industry 4.0 movement, which focuses on the digital transformation of manufacturing through cyber-physical systems, IoT (Internet of Things), and advanced analytics. By including AI, PAT systems can reach higher levels of automation, connectivity, and intelligence, propelling the next generation of smart manufacturing and analysis.

This review article investigates the applications of AI in PAT by examining current trends, technological advancements, and practical implementations across various industries. We discuss the advantages and challenges of AI integration, and highlight case studies demonstrating the real-world impact of AI-enhanced PAT systems. Through this exploration, we aim to provide a comprehensive understanding of how AI is transforming PAT leading to more efficient, reliable, and innovative manufacturing practices [2].

**History of AI in Healthcare**

The artificial intelligence term was used in the year 1956, and the concept was used from the year 1950, under the topics of problem solving and symbolic methods [3]. The sequence of the events in the development of AI was shown as in Table 1.

Neural networks (1950- 1970's) ⇨ ML (1980-2010's) ⇨ Deep learning.

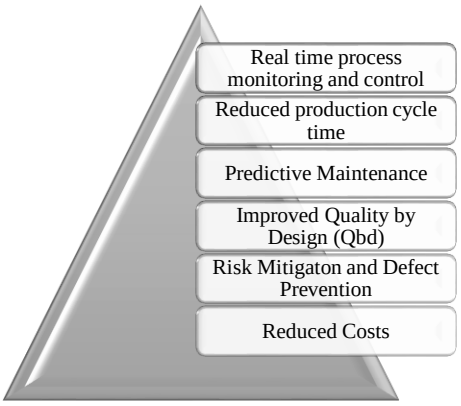
**Table 1:** Mile stones in the artificial intelligence process

| Year | Milestone |
|---|---|
| 1950 | Alan Turing develops the "Turing Test" |
| 1952 | Machine learning |
| 1956 | John McCarthy coins the term "AI" |
| 1961 | Unimate, the first industrial robot, joins the assembly line at GM |
| 1964 | First chatbot: Eliza |
| 1974 | This period known as the "First AI Winter" |
| 1986 | Back propagation algorithm design was developed by Georey Hinton which is widely using in deep learning nowadays |
| 1987 | This phase is called as "Second AI winter" |
| 2000 | Deep learning |
| 2007 | IBM began development of Deep QA technology (Watson) |
| 2017 | Arterys: First FDA approved cloud based DL application in healthcare |
| 2018-2020 | AI trials in Gastroenterology |

**Objectives in development of AI and its applications as a PAT tool**

The objectives in development of AI as a PAT tool [4], [5], [6] are as summarized in Figure 1.

**Figure 1:** Objective of AI in healthcare industry




**What is PAT?**

PAT According to the FDA "It is a system for planning, assessing, and controlling the manufacturing process by quickly examining the critical performance and quality attributes of raw materials, materials in process, and procedures." This framework encourages the pharmaceutical industry to modernize manufacturing through enhancements in process control. PAT measurements can be used qualitatively to construct process signatures or trajectories that identify deviations in process behaviors, which can be utilized to characterize process variability. Although performance traits or important in-process quality control attributes are not always directly associated with models, the PAT framework aims to create and implement well-defined processes that consistently ensure a specified quality standard at the conclusion of the manufacturing process [7].

PAT is available for use online, at-line, in-line and offline [8].

**At line**

Once the sample is removed, separated, and inspected, a measurement is made near the process stream.

**Online**

Measures that involve removing the sample from the manufacturing process and reintroducing it into the process flow.

**Inline**

Measurements that are either invasive or noninvasive and do not remove the sample from the process stream.

**Offline**

A measurement that involves taking a sample out of the process and testing it in a lab.

**Regulatory Framework**

The FDA's "Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century-A Risk Based Approach" initiative, which aims to modernize and improve pharmaceutical manufacturing processes, heavily relies on PAT. This PAT initiative was first proposed by the FDA's Center for Drug Evaluation and Research (CDER) with the intention of bringing substantial financial and health benefits to pharmaceutical production by integrating contemporary process management techniques and

testing. The FDA Science Board then approved the formation of a PAT subcommittee of the Advisory Committee for Pharmaceutical Science (ACPS) in November 2001. The four working groups that comprised this subcommittee were led by academic specialists, business executives, and representatives of the FDA.

PAT initiative resulted in the formation of the following four working groups:

PAT application group.

PAT product and process development group.

Analytical validation and the PAT process group.

PAT chemometrics group.

The FDA released a draft PAT guidance for the industry in September 2003, titled "A framework for Innovative Pharmaceutical Manufacturing and Quality Assurance." The Office Regulatory Affairs (ORS) and the Center for Veterinary Medicine (CVM) worked together to produce the final version, which was released in September 2004. This guidance was the result of collaboration between several FDA offices, including CDER, CVM, and ORA [9]. The primary objective was to boost pharmaceutical manufacturing efficiency through innovations, basic scientific and engineering knowledge, and quality management concepts. The International Conference on Harmonization (ICH) guidelines, the Japanese Ministry of Health, Labor, and Welfare (MHFW) and the European Medicines Agency (EMA) have all endorsed the PAT initiative.

The PAT concepts are also in-line with the recently introduced initiative known as "Quality by Design" (QbD). According to the ICH Q8 guideline (QbD) is "a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management [10]."The process entails multiple steps to guarantee consistent process performance throughout the product's life cycle: determining the features that are critical to safety and efficacy, creating the procedure to attain these features, keeping in place a strong control strategy to guarantee ongoing process performance, and verifying and documenting the procedure to show how well the control strategy works then keeping an eye on the procedure after that maintaining processes and developing a strong strategy for process control both require PAT.

**PAT Tools**

For ensuring the quality of a single unit operation or the entire manufacturing process suitable combination of various PAT tools may be used. Following are the various tools employed:

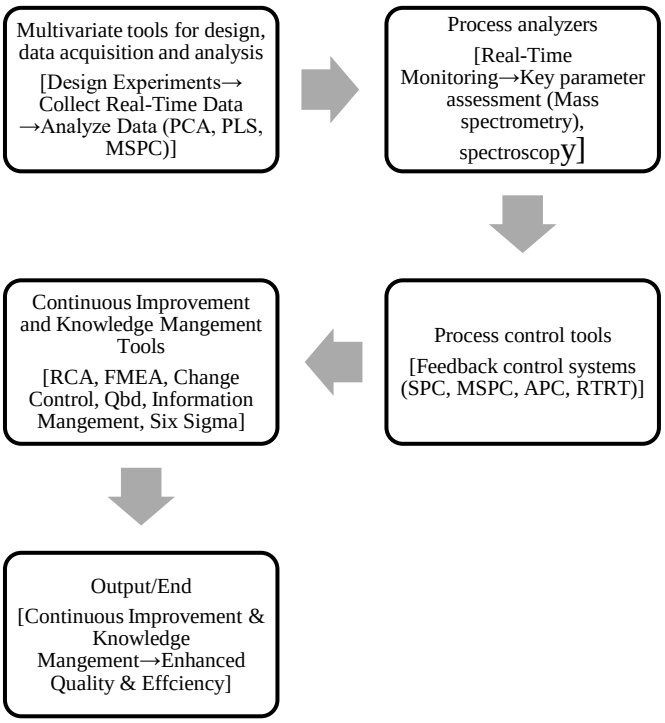
Multivariate tools for design, data acquisition and analysis

Process Analyzers

Process control tools

Continuous improvement and knowledge management tools Pharmaceutical companies can save manufacturing costs, enhance product quality, optimize processes, and more successfully assure regulatory compliance by utilizing various multivariate technologies like Principal Component analytic (PCA), Partial Least Squares (PLS), and Multivariate Statistical Process Control (MSPC), Statistical Process Control (SPC), Advanced Process Control (APC), Real-time Release Testing (RTRT), Root Cause Analysis (RCA), Failure Mode and Effects Analysis (FMEA), Quality by Design (QbD), etc. as depicted in Figure 2.

**Figure 2:** PAT Tools




**Advantages of AI in PAT**

Reduced Process Costs: AI-powered PAT devices optimize processes, reducing costs and boosting productivity.

Improved Product Quality: AI algorithms evaluate process data, ensuring quality by identifying deviations and enabling prompt corrective actions.

Drug Repurposing: AI identifies existing drugs for new therapeutic uses, saving time and money compared to traditional drug development methods.

Regulatory Compliance: AI-based PAT solutions provide reliable data for meeting industry standards and regulatory submissions [12], [13], [14].

**Disadvantages of AI in PAT**

Complexity and Integration Challenges: Integrating AI-powered PAT tools into existing pharmaceutical manufacturing can be difficult and time-consuming, especially with older equipment,

requiring additional resources for customization.

Regulatory Difficulties: Rapid AI advancements may outpace regulatory frameworks, leading to unclear requirements for AI-driven pharmaceutical products and processes, potentially delaying industry adoption.

Lack of Experience: AI-powered robots cannot improve through experience like humans, making it difficult to distinguish between diligent and less industrious workers.

High Initial Investment Costs: The substantial upfront investment in AI-powered PAT systems, including software, infrastructure, and training, can be a barrier for smaller pharmaceutical companies [12, 13, 14, 15].

**AI Application in the Pharmaceutical Industry**

**Drug Discovery Procedure and Design**

AI is used in the pharmaceutical industry to accelerate drug design and development. It plays a crucial role in identifying and validating therapeutic targets, from creating small compounds to discovering new biological targets. AI enhances the identification of biomarkers and facilitates multi-target drug creation, significantly reducing the time needed for drug development. This efficiency benefits drug makers by speeding up clinical trials and bringing new products to market faster. AI-driven processes also enable the development of innovative drugs with fewer side effects, improving patient care. AI can analyze data from Electronic Medical Records (EMR) and other omic data to identify and validate novel cancer treatments, using ML to design effective medications for tumor treatment [16].

**Research and Development (R & D)**

Global pharmaceutical companies are using AI and advanced ML techniques to validate and identify possible therapeutic targets, which speeds up the drug discovery process. Because these sophisticated techniques are made to recognize intricate patterns in large datasets, they are useful in addressing problems related to complex biological networks. The capacity to analyze disease patterns and ascertain the best drug compositions for treating particular disease characteristics is a highly advantageous skill [17].

**Next-Level Diagnosis**

The FDA has approved Gl Genius, a medical device that uses ML and AI algorithms to detect early signs of colon cancer during colonoscopies. This technology helps medical professionals easily identify potentially diseased areas in the colon. ML algorithms can also provide real-time diagnostic predictions and therapy recommendations based on data from electronic medical records (EMRs). Additionally, healthcare professionals worldwide are using cloud or centralized storage systems to securely store sensitive patient data, which can be accessed by physicians as needed. AI has become particularly important in the treatment of memory-related diseases and cancer, where deep learning and advanced computational techniques are leveraged to manage and analyze large volumes of data, improving diagnosis and treatment [18].

**AI in Clinical Trials**

Clinical trial failures are often due to inefficient patient recruitment and selection, with many trials failing to meet enrollment goals. AI tools can address these challenges by enhancing recruitment and selection processes. AI-powered platforms enable continuous data collection and analysis from multiple trial sites, allowing for more comprehensive patient characterization. Researchers can also use AI to develop AI-assisted randomization schemes and predict trial outcomes earlier, reducing the risk of participant harm. Overall, AI has the potential to improve patient care and accelerate medical advancements by making clinical trials more efficient and effective [19], [20].

**AI in vaccine development**

AI significantly benefits drug research by identifying optimal chemical components for potential medicines, performing rapid simulation testing, and discovering novel drug targets. e.g., Alpha Fold, a deep-learning system developed by Google Deep Mind, can predict the structures of unknown proteins, including those related to COVID-19. This capability accelerates the analysis of viruses and aids in vaccine development by helping scientists design vaccines that can trigger an immune response. Alpha Fold's predictions are now available to the global scientific community, enhancing collaborative research efforts [21].

**Case Studies of AI**

**Pfizer Case Study**

Pfizer, a leading pharmaceutical company, has integrated AI across various aspects of its operations. In its supply chains, AI optimizes inventory management, predicts demand, and ensures timely delivery, reducing costs and enhancing efficiency. In sales and marketing, AI personalizes campaigns and improves sales force operations by analyzing customer data and market trends. AI also accelerates drug discovery, optimizes clinical trials, and supports personalized medicine by analyzing patient data. Additionally, AI tools help Pfizer monitor drug safety and enhance Pharmacovigilance, ensuring product safety throughout their lifecycle [22].

**Alto Neuroscience Case Study**

Alto Neuroscience, a clinical-stage biopharmaceutical company founded in 2019, leverages AI to measure brain biomarkers, including EEG patterns, behavior, wearable data, and genetics. The company aims to develop targeted drugs for mental health conditions like major depressive disorder (MDD) and post-traumatic stress disorder (PTSD). Their clinical pipeline includes drugs such as ALTO-100, ALTO-202, and ALTO-300, which are in Phase II trials for MDD and PTSD. ALTO-100 has shown promising results in reducing depression severity in biomarker-identified patients during its Phase II a trial. The company uses biomarkers to assess patient outcomes,

focusing on those most likely to benefit from specific treatments. Future Phase IIb studies will further validate the effectiveness and safety of these drugs, with recent funding supporting ongoing drug development and new treatment explorations for mental health disorders [23].

**Table 2:** AI Collaboration with Pharmaceutical Industry

| Pharmaceutical company | AI used |
|---|---|
| Sanofi | Sanofi collaborated with Aily Labs in 2018 to create an AI platform named "plai" aimed at leveraging artificial intelligence for various aspects of clinical trials, drug discovery and manufacturing. This platform integrates Sanofi's internal data to enhance decision-making throughout the drug development cycle. Additionally, Sanofi has teamed up with Hillo to apply AI technology to connected insulin pens, enhancing their commitment to utilizing AI in both drug development and healthcare devices [26]. |
| AstraZeneca | In 2021, AstraZeneca teamed up with Benevolent AI to identify targets and Oncoshot to use AI for patient-trial matching; however, the precise timeline and results of these projects remain undisclosed. Because of the success of its collaboration with Benevolent AI, AstraZeneca chose five targets for its portfolio, with two focusing on chronic kidney disease (CKD) and three on idiopathic pulmonary fibrosis (IPF). Research on heart failure and systemic lupus erythematosus has since been added to the partnership's scope [26]. |
| Bristol Myers Squibb | Bristol Myers Squibb has teamed up with Exscientia to employ AI in the discovery of small molecule drugs. This partnership involves leveraging Exscientia's AI platforms to expedite the discovery of potential small molecule drug candidates across various disease fields such as oncology and immunology. By merging Exscientia's AI capabilities with BMS's extensive drug development experience, the collaboration aims to accelerate the initial phases of the drug development pipeline [26]. |
| Exscientia | Exscientia reported at the begin of 2020 that the first drug candidate developed with AI is ready for clinical testing. This UK-based company was the initial to use AI to small-molecule drugs. Design and has recently developed its AI platform to utilize generative AI to produce innovative therapeutic antibodies. Exscientia is collaborating on drug research projects with Sanofi, GSK, and Path AI in addition to Bristol-Myers Squibb on several therapeutic candidates intended for clinical trials. Furthermore, the company and MD Anderson are working together to develop novel small-molecule cancer treatments [27]. |
| Recursion Pharmaceuticals | Recursion Pharmaceuticals, a Salt Lake City-based biotech beginning in the clinical stage, uses its own Recursion Operating System to specialize in machine learning-based drug development. The business focuses on illnesses associated with DNA mutations and contains one of the biggest biological and chemical datasets in the world. It has several compounds in Phase 1and 2 trials, including treatments for neurofibromatosis type 2 and cavernous cerebral malformation. Recursion performs millions of experiments every week using robotic lab automation, machine learning, and supercomputers. The business went public in 2021, demonstrating how artificial intelligence (AI) can expedite drug discovery, increase the efficacy of clinical trials, and create new treatments [28]. |
| Pfizer | Since 2020, Pfizer has advanced drug development through the use of IBM's supercomputing and artificial intelligence capabilities, specifically for PAXLOVID, an oral COVID-19 therapy that was approved in 2022.They report a significant 80-90% reduction in computational time, attributing the technology to enabling the drug's design within a swift four-month timeframe. Additionally, Pfizer has entered into an agreement with CytoReason, which has developed an AI representation of the immuno system [26]. |
| Novartis | Novartis is integrating AI to enhance drug discovery and operational efficiency, with over 150 active projects leveraging AI across its operations. Collaborating with Microsoft and NVIDIA, Novartis plans to expand AI deployment over the next decade, aiming to enhance accessibility, reduce costs, and potentially improve health outcomes, though the current impact remains uncertain [26]. |
| Bayer | To examine the application of AI in small molecule drug discovery, Bayer has partnered with Exscientia. Exscientia and Bayer will work together on three projects, with the former focusing on cardiovascular illness and the latter on cancer treatments targets. The agreement includes potential payments totaling up to €240 million, covering upfront research funding, clinical milestones, and near-term achievements. This partnership seeks to integrate Exscientia's AI platform with Bayer's drug development proficiency to accelerate the identification of new small molecule drug candidates in critical disease areas targeted by Bayer [26]. |
| GlaxoSmithKline (GSK) | GSK has collaborated with Cloud Pharmaceuticals and Insilico Medicine to employ their AI platforms for identifying targets, designing drugs, and generating leads. Additionally, GSK has initiated an Advantage AI program to explore further partnerships in AI [26]. |
| Merck | Merck has collaborated with BenchSci, Atomwise, C4 Therapeutics, and ACMED on various initiatives leveraging AI for drug discovery and development [26]. |
| Roche | Roche joined forces with Recursion Pharmaceuticals to leverage their AI platforms for drug discovery as well as development. Following the announcement of over 25 AI collaborations, Roche established an AI hub [26]. |
| Lilly | Lilly, a large pharmaceutical firm with a $420 billion market valuation, disclosed to Insider that it intends to use over 100 AI initiatives to increase its "digital workforce equivalent" to 2.4 million hours by the end of the year, or 274 years of human labor. CEO David Ricks addressed how AI may improve worker productivity, automate regulatory processes, and enable novel approaches to drug development that are beyond the abilities of chemists working alone. According to Ricks, AI will greatly increase workplace productivity and free up people's time for other worthwhile activities [26]. |
| Janssen | Janssen is actively investigating AI applications across drug discovery, clinical trials, disease diagnosis, and manufacturing, as highlighted by Drug Discovery & Development. There are Trials360.ai platform is enhancing trial design to improve patient care and outcomes. With a portfolio exceeding 100 AI initiatives, Janssen is implementing a scalable strategy to test and implement AI technologies effectively [26]. |
| Genesis Therapeutics, Genentech | Genesis Therapeutics along with Genentech agreed into a multi-target drug research agreement in October 2020. They made use of Genesis' ability in graph ML to find possible medication candidates to treat a variety of diseases [28]. |
| Roivant, Silicon Therapeutics | In February 2021, Roivant acquired Silicon Therapeutics for $450 million. This acquisition encompassed Silicon's platform, which utilizes physics-based methods for in silico design of small-molecule drugs. Roivant intends to integrate this platform with its own ML methodologies [28]. |

**Merck Case Study**

The case study focuses on the intermediate 2′-C-methyluridine (MU) used in a research molecule by Merck & Co., Inc.

When crystallized from water, MU forms a dihydrate (DH) solid, which contains 12.2% water. For further synthesis, DH must be fully dried, as it's water-sensitive. A distillation drying method was developed, where DH converts to either a hemihydrate (HH) or the desired anhydrous (AH) form, depending on the drying conditions.

The study explored the thermodynamic stabilities of these solid forms based on water activity and temperature. Since AH is unstable under ambient conditions, it can rehydrate before analysis. In-line analytics, including Fourier-transform infrared (FT-IR) spectroscopy and Raman spectroscopy, were used to study form conversion kinetics and quantify water content. Ternary diagrams (TDs) were utilized to clarify the relationships between the various solid phases and to define the process operating space. This understanding is crucial for controlling the manufacturing process and ensuring the consistent production of the desired solid form [24].

**Elunic Software Case Study**

Elunic, a 4.0 software company, provides AI tools for the pharmaceutical industry, supporting Industry 4.0. One of their key offerings, AISEETM, is an AI-driven visual quality control and defect detection system for manufacturers. It consists of two main modules: AISEE Core which manages and analyzes data, and AISEE Line Inspector, which uses smart cameras and AI to assess photos directly on the production line. This system combines artificial neural networks with advanced image processing to ensure accurate detection of errors and defects in real-time. By continuously monitoring the inspection line, AISEETM enables prompt issue identification and resolution, enhancing overall production quality [25].

**Pharmaceutical Market of AI**

From 2023, AI was used by pharmaceutical businesses for marketing purposes. The pharmaceutical business may benefit from additional advantages from using AI systems, such as enhanced value propositions, efficient resource allocation leads to increased market share gains, growth maximization scope, and access to specialized marketing and sales data and channels. AI along with various computer software can be used in drug discovery. The pharmaceutical business invests a significant amount of money yearly in the creation of new compounds and given the significant risk of failure in clinical trials, the challenge lies in screening around 10,000 molecules to find one successful molecule. Businesses usually spend $2.6 billion developing one pharmaceutical chemical. Pharmaceutical companies are designing clinical trials to address these problems, reduce failure rates, and save R&D costs by utilizing big knowledge and AI. It is expected that the artificial intelligence market would develop rapidly, increasing $5 billion by 2024 at a 40% compound annual growth rate.

**The Future of AI in the Pharmacutical Industry**

The pharmaceutical business has started developing with use of AI technologies and there are no signs that this usage is going to decrease. ML has the ability to completely transform the industry, helping with drug development as well as automating healthcare procedures. Al should be used by more companies to improve R&D processes and patient care. Pharmaceutical companies can develop new drugs with the aid of AI capable computers like IBM Watson, which can interpret millions of pages of clinical trial data and scientific literature. These computers can uncover connections between diseases that were previously unknown and provide an assessment in a matter of minutes. Pfizer Inc. and IBM Watson Health officially declared their collaboration.

## CONCLUSION

AI has demonstrated significant potential to enhance various aspects of pharmaceutical production in the pharmaceutical industry, particularly when employed as a PAT tool. AI-based solutions could ensure regulatory compliance, expedite clinical trials, improve product quality, and streamline industrial processes. Pharmaceutical companies can gain favorable outcomes such as lower expenses, better product quality, customized treatment, and increased regulatory approval by utilizing AI technologies like machine learning, deep learning, and natural language processing.

With the cutting-edge advantages, it still possesses few limitations such as challenges integrating AI-powered tools, complex regulations, the potential for employment displacement, a dearth of experience-based development, and expensive upfront investment costs. However, the pharmaceutical industry can overcome these challenges and further transform medicine with careful application and ongoing advancements in AI.

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