

Digital advancement and transformation in pharma sector - a review

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Abstract- The pharmaceutical industry is undergoing a transformative journey through the digitalization of its processes and operations. This review article explores the integration of cutting-edge technologies, including Internet of Things (IoT), Artificial Intelligence (AI), Cloud Computing, and Big Data Analytics, into the pharma sector. The objective is to elucidate the profound impact of this digital revolution on various aspects of pharmaceutical manufacturing, quality control, and product safety.

Digitalization, enabled by IoT, facilitates real-time monitoring and data collection, resulting in enhanced process control, reduced downtime, and proactive maintenance. AI applications, such as machine learning and predictive analytics, optimize research and development, drug discovery, and clinical trials, ultimately saving both time and money. Cloud computing solutions streamline data storage, accessibility, and further contributing to cost-efficiency.

Moreover, Big Data Analytics harnesses vast datasets to uncover valuable insights, leading to improved decision-making, better resource allocation, and product quality enhancement. The paramount focus on quality and safety is strengthened by digitalization through more precise quality control, traceability, and compliance management.

In conclusion, the digitalization of the pharma sector not only saves time and money but also elevates the overall quality and safety of pharmaceutical products. This review provides a comprehensive overview of these technological advancements, emphasizing their pivotal role in reshaping the pharmaceutical landscape.

Keywords: Digitalization of Pharma Sector, Internet of Things (IoT), Artificial Intelligence (AI), Cloud Computing, Big Data Analytics, Quality Assurance.

Introduction:

The advancement of the manufacturing industry heavily relies on digitalization as a pivotal step in enhancing production processes. This digitalization encompasses the greater utilization of robotics, automation solutions, and computerization. This, in turn, leads to cost reduction, enhanced efficiency and productivity, and increased adaptability to changes. Among the various sectors, the pharmaceutical industry (PI) stands out as one of the fastest-growing economic segments, boasting global sales surpassing \$1,228.45 billion in 2020. Over the period since 2017, the pharmaceutical market has displayed remarkable growth, experiencing an impressive annual rate of 5.8%. (1)

Pharmaceutical companies have the opportunity to adopt digitization as a strategic response to the anticipated increase in demand from international markets. This digital transformation can be leveraged for several purposes, including ensuring compliance with regulatory requirements, identifying manufacturing efficiencies to lower operational costs, and establishing faster and more efficient communication channels with suppliers and distributors through cloud-based information exchanges (2). The acknowledgment of digitalization as the prevailing technological trend is fundamentally transforming not only our society but also the very fabric of the business environment (3).

Embracing digitalization within the manufacturing sector is a crucial step forward in enhancing the intricacies of the production process. This transformative transition to digitalization involves the seamless integration of robotics, automated solutions, and computerized systems. This orchestration of technological advancements not only helps reduce operational expenses but also significantly boosts operational efficiency and productivity to unprecedented levels. Furthermore, the integration of digitalization into manufacturing bestows a heightened capacity to navigate the ever-evolving dynamics of the industrial landscape (4)

Digital transformation offers pharmaceutical companies the capability to collect data from diverse sources, standardize its format, and conduct comprehensive analysis to enhance quality assurance. Simultaneously, it enables continuous monitoring of various stages and production levels within manufacturing facilities, facilitating the identification and correction of quality issues while streamlining reporting processes. By leveraging digital innovations, organizations can significantly enhance their insight into supply chain operations, enabling quicker and more informed decision-making. The digitization process enables seamless integration of the entire supply chain, thereby improving operational effectiveness and efficiency, as well as increasing adaptability and responsiveness to changing circumstances

According to the International Trade Administration (ITA), the pharmaceutical industry primarily revolves around activities related to the research, development, production, and promotion of medications and biological products for both human and veterinary purposes. This sector plays a pivotal role in healthcare worldwide. To gain insights into consumer demand and enhance the effectiveness of supply chain operations, the pharmaceutical industry is increasingly embracing digitalization. This entails harnessing the power of shared information through systems integration, the utilization of connected devices, and various other

technological advancements. By leveraging these digital tools, the industry aims to better anticipate market trends and optimize the efficiency of its supply chain processes, ultimately ensuring the timely delivery of crucial medications to those in need (5). Consequently, this leads to enhancements in planning accuracy, productivity and efficiency in manufacturing processes, optimized inventory management, and elevated service standards (6). The advent of digital health technology tools presents a significant opportunity for the development of medical products that empower patients to take control of their treatment regimens. Moreover, these tools hold the potential to revolutionize the landscape of clinical trials. Digital health technology tools are invaluable in the realm of clinical trials. They enable the measurement of trial endpoints within the comfort of patients' homes, offering the prospect of enhanced external validity and greater sensitivity in assessing the effectiveness of medicinal products. This shift towards remote monitoring and data collection not only enhances patient engagement but also augments the reliability of clinical trial outcomes, potentially expediting the development and approval of new medical treatments (7).

Following are the technologies help for the Digitalization of pharma sector

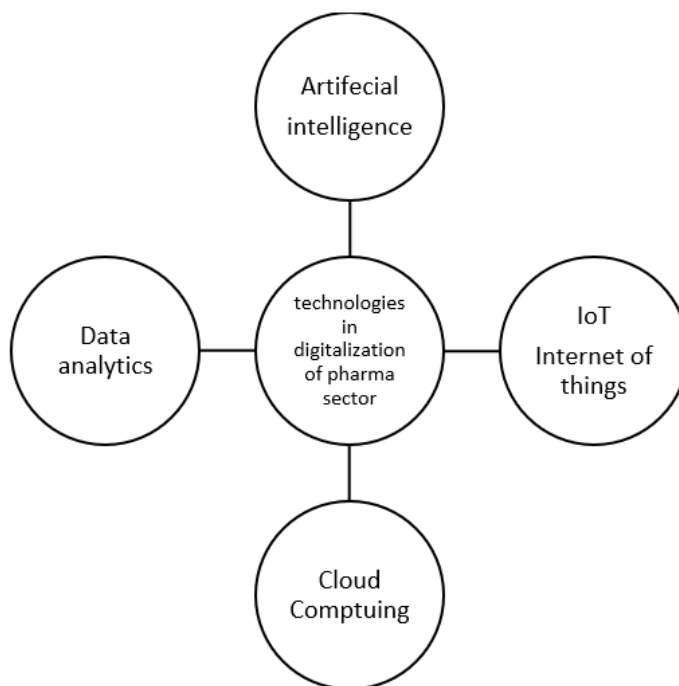


Fig 1. Technologies applicable in pharma sector

A) Artificial Intelligence:

Artificial intelligence (AI) refers to the emulation of human intelligence to perform tasks with minimal human intervention. Coined in 1956, the term AI originated alongside The Logic Theorist program, which aimed to simulate human problem-solving capabilities (8).

Artificial intelligence (AI) represents a convergence of diverse intelligent processes and behaviours, meticulously designed through sophisticated computational models, advanced algorithms, or comprehensive rule sets. This remarkable amalgamation empowers machines to emulate and replicate a wide array of cognitive functions inherent in humans, including but not limited to learning, problem-solving, reasoning, perception, language understanding, and decision-making. Through these intricate mechanisms, AI systems aim to comprehend and interact with the world, adapt to novel scenarios, and continually improve their performance, bridging the gap between human-like intelligence and the capabilities of machines (9).

1) AI in research and development:

AI offers a significant advantage in automating the collection and analysis of data, particularly in pharmaceutical research and development (R&D). It enables the integration of diverse data sources, such as electronic health records, administrative records, and health surveys, resulting in a more comprehensive and precise data collection and management process. Consequently, this enhanced data handling capability leads to more reliable and robust trial results (10).

2) AI in drug Development:

AI is revolutionizing drug discovery through its diverse applications. It can analyze extensive data sets, generate hypotheses, and produce novel insights to drive the development of new medicines. By leveraging AI, researchers can identify potential drug candidates more efficiently. Moreover, AI enables the analysis of patient samples from healthy and diseased states, leading to the discovery of innovative biomarkers and therapeutic targets. Predicting the binding affinity and pharmacological properties of molecules allows for faster and more targeted drug development. AI also streamlines the process by filtering for drug-like properties of molecules, making it easier to identify promising candidates. Additionally, AI's involvement in protein design helps reduce

complexity, opening up new possibilities for drug development. In essence, AI's applications in drug discovery hold tremendous promise for accelerating the development of life-saving medications and improving healthcare outcomes (11).

3) AI in Pharmaceutical manufacturing:

Process design and scale-up: Utilizing AI models, specifically machine learning, based on process development data can expedite the identification of ideal processing parameters and facilitate the scale-up of processes. This approach holds the potential to significantly reduce development time and minimize wastage during the process design and optimization stages.

Advanced Process Control (APC): It enables real-time dynamic control of manufacturing processes to attain desired outputs. The integration of AI methods with real-time sensor data allows the development of process controls that can anticipate the progression of the manufacturing process. By combining AI techniques with a profound comprehension of the chemical, physical, and biological transformations occurring during manufacturing, APC approaches are projected to gain widespread acceptance and have already been implemented by various pharmaceutical manufacturers (12)

4) Process Monitoring and Fault Detection:

AI methods offer the capability to monitor equipment and identify deviations from normal performance, prompting timely maintenance actions and minimizing process downtime. Additionally, AI can be employed to monitor product quality, encompassing aspects like packaging quality. By utilizing vision-based quality control, where AI-based software analyzes images of packaging, labels, or glass vials, any deviations from the specified quality attributes of a product can be swiftly detected and addressed (13)

5) AI in clinical trials:

The drug discovery process involves time-consuming testing of chemicals against samples of sick cells. To identify physiologically active compounds deserving further study, additional investigation is needed. At Novartis, research teams employ machine learning algorithms to analyze images and predict which untested chemicals hold potential for further investigation. Leveraging this technology enables the rapid discovery of new data sets compared to traditional human analysis and laboratory experimentation. Consequently, it expedites the availability of novel and effective medications while also reducing operational costs associated with manual investigation of each substance (14)

AI has emerged as a game-changer in the realm of clinical trials, presenting a range of applications that revolutionize medical research and patient care. One of the key contributions is the ability to transform diverse biomedical and healthcare data into computer models that accurately represent individual patients. This breakthrough allows for the delivery of personalized medicine on a large scale, revealing optimal health interventions tailored to each patient's unique needs. Additionally, AI is instrumental in analyzing medical records, streamlining the process of finding suitable patients for clinical trials. It further automates the matching of cancer patients to relevant trials by leveraging personal medical histories and genetic analysis, increasing the efficiency and success rates of these studies. Moreover, AI aids in improving pathology analysis, leading to more accurate diagnoses and treatment decisions. Finally, AI's ability to identify patients who would benefit from novel therapies holds immense potential for advancing medical research and fostering better patient outcomes. Overall, AI's integration into clinical trials promises to usher in a new era of precision medicine and healthcare innovation (15)

Tencent Holdings, in collaboration with Medopad, has created AI algorithms designed to assist patients with Parkinson's disease. Using the smartphone's camera, the AI system observes the patients' movements and accurately assesses the severity of their symptoms. Moreover, it enables doctors to remotely monitor patients, make necessary adjustments to medication dosages, and schedule appointments conveniently (16)

6) AI in data management:

In the realm of Data Management, the effective handling of medical records plays a crucial role. Advanced technologies, such as Ai Cure's sensor or mobile application, have revolutionized medication monitoring by utilizing AI to track patients' drug usage in real-time. This innovative approach proves particularly advantageous for individuals facing adherence challenges and for enhancing the efficiency of clinical trials (16)

Table.1 AI Companies and technology used by them in pharma Sector (15)

Company	computational techniques used	Tech abstracts
Berg	<ul style="list-style-type: none"> Machine learning (ML) Deep learning Bioinformatics 	The analysis of patient samples in both healthy and diseased states aims to identify new biomarkers and therapeutic targets. This approach enables researchers to generate unbiased therapeutic targets from biological data and implement personalized medicine on a large scale.

Benchsci	<ul style="list-style-type: none"> • NLP (Natural Language Processing) • (DL) Deep Learning • Machine Learning 	Analyzing open and closed-access data on reagents, such as antibodies, and presenting actionable insights from published figures enables researchers to save time, money, and reduce uncertainty in experiment planning.
Bioz	<ul style="list-style-type: none"> • NLP • DL • ML 	Bioz has created a search engine for the Life Sciences community that utilizes natural language processing and machine learning to scan vast amounts of complex and unstructured scientific papers online. The technology then converts this information into a user-friendly and visualized format for easy consumption.
Exscientia	<ul style="list-style-type: none"> • ML • DL • Bioinformatics • Cheminformatics 	Predicting the ADME (Absorption, Distribution, Metabolism, and Excretion), novelty, synthetic accessibility, and pharmacological properties of molecules, including both single and multi-target predictions.
Medchemia	<ul style="list-style-type: none"> • ML • Cheminformatics 	Molecular design and analysis
NuMedii	<ul style="list-style-type: none"> • Big data analytics • Machine learning 	Researchers can explore intricate relationships between drugs and diseases on a vast scale by analyzing an extensive dataset comprising human, biological, pharmacological, and clinical information, comprising hundreds of millions of raw data points. This analysis facilitates the identification of potential drug candidates and biomarkers that can predict the effectiveness of treatments for various diseases.
Nuritas	<ul style="list-style-type: none"> • Deep learning • Bioinformatics 	By predicting the therapeutic potential of bioactive peptides derived from food, researchers can efficiently develop precisely targeted treatments for specific diseases using natural food sources. This approach enables cost-effective exploration of these bioactive compounds for potential therapeutic applications.
Berkeley lights	<ul style="list-style-type: none"> • ML • Bioinformatics 	With automation, researchers can choose, handle, and study cells more easily. This speeds up the process of creating cell lines and automates the production of cellular therapies, making it faster and more efficient.
Kyndi	<ul style="list-style-type: none"> • NLP • Deep learning • Machine learning 	Explainable A

Phenomic AI	<ul style="list-style-type: none"> • Deep learning • Reinforcement 	Phenomic uses AI to figure out which cells can withstand chemotherapy and finds special substances that can specifically target these tough cells. After identifying these substances, Phenomic will develop them further and make them available for use. The AI part comes in when using advanced cell imaging technology to make these predictions.
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Ongoing challenges in adopting AI:

The efficacy of AI is intrinsically linked to the presence of substantial datasets, as these serve as the bedrock for subsequent system training. Acquiring data from diverse database providers can impose supplementary financial burdens on companies, with the added prerequisite that the data maintain both reliability and high quality to uphold precise outcome prognostication. However, several impediments hinder the comprehensive integration of AI within the pharmaceutical sector. These include a scarcity of proficient personnel capable of navigating AI-driven platforms, budgetary constraints primarily afflicting smaller entities, reservations surrounding human workforce displacement, wariness concerning AI-generated data authenticity, and the enigma encapsulated within the "black box" phenomenon—elucidating the inner workings of AI-derived conclusions (11)

B) Internet of things IoT:

The Internet of Things (IoT) represents a powerful convergence of diverse technologies that has the potential to revolutionize the capabilities of the current internet. IoT operates through the integration of various enabling and emerging technologies, including wireless sensor networks (WSNs), sensor technologies, machine learning, artificial intelligence (AI), big data, and advanced analytics. Central to IoT's functionality are WSNs, which comprise sensors strategically placed in designated areas to continuously monitor specific phenomena, such as environmental conditions, and gather valuable data. The synergy of these technologies in IoT holds immense promise for transforming industries, improving efficiency, enhancing decision-making, and creating new possibilities for a connected and data-driven world. With IoT's continued growth and advancements, we can expect to witness unprecedented innovations and improvements across various sectors, ushering in a new era of smart and interconnected devices and systems (17)

The concept of the 'Internet of Things' (IoT) or 'Internet of Objects' refers to a vast array of electrical or electronic devices, varying in sizes and functionalities, all interconnected through the Internet. These devices, collectively known as IoT devices, encompass a wide spectrum of capabilities and are continuously expanding their reach beyond traditional machine-to-machine communication (M2M). As IoT technology evolves, it incorporates an extensive range of networking protocols, applications, and network domains, enabling seamless connectivity and communication among these devices. This interconnectedness not only revolutionizes the way machines interact but also introduces a transformative shift in how humans interact with the digital world around them. The expanding scope of IoT applications encompasses everything from smart home devices, wearables, and industrial sensors to sophisticated healthcare equipment, autonomous vehicles, and environmental monitoring systems. As the IoT landscape continues to grow and diversify, it is poised to reshape industries, improve operational efficiency, enhance decision-making processes, and create innovative solutions that drive progress and connectivity in the ever-evolving digital era (18)

IoT in Pharma industry:

The pharmaceutical industry has been witnessing significant advancements with the implementation of the Internet of Things (IoT) in its manufacturing and supply chain processes, primarily driven by the integration of Radio Frequency Identification (RFID) technology. Unlike conventional bar codes, IoT devices utilizing RFID technology do not require manual scanning; instead, they seamlessly transmit real-time information to other interconnected devices via the Internet. This has led to improved efficiency and accuracy in tracking pharmaceutical products and managing inventory throughout the entire lifecycle. Beyond its impact on manufacturing and supply chain optimization, IoT has also found a crucial role in providing medical services within the pharmaceutical sector. By incorporating IoT devices into various applications, including production, distribution, patient monitoring, and personalized health solutions, a comprehensive and interconnected ecosystem has been established. This interconnectedness facilitates streamlined management of services, offering greater control and monitoring capabilities across all stages of pharmaceutical processes. The utilization of IoT-driven RFID tags in manufacturing has revolutionized inventory management, reduced errors, and optimizing production workflows by providing real-time data on product locations, stock levels, and expiration dates. This automation empowers manufacturers to maintain optimal stock levels, prevent shortages, and eliminate the distribution of expired medications. In the supply chain, IoT has introduced increased transparency and efficiency, as RFID-enabled devices enable real-time tracking and monitoring of pharmaceutical shipments, mitigating product losses, theft, and counterfeiting. Moreover, IoT's integration into medical services has resulted in patient-centric healthcare, as smart devices such as IoT-enabled pill dispensers and wearable health monitors empower patients to actively manage their medications, while allowing healthcare providers to remotely monitor patient health. This convergence of IoT and pharmaceuticals has triggered a paradigm shift in the industry, driving it toward greater digitization, automation, and interconnectedness, ultimately enhancing the overall quality of services provided in the pharmaceutical sector (19)

Applications of IoT in pharma:

The pharmaceutical industry is gradually adopting IoT, utilizing smart devices and machine-to-machine communication to digitize processes and data. This disruptive technology is revolutionizing conventional practices in drug manufacturing and distribution, despite the industry's stringent regulations. Pharmaceutical companies are becoming more open to exploring IoT applications to improve quality, productivity, reduce errors in production, and meet stakeholders' expectations regarding drug efficacy. By implementing IoT in pharmaceutical manufacturing, supply chain management, clinical development, and patient engagement, companies can reduce time to market for drugs and identify errors in real-time, leading to enhanced regulatory compliance. Investment in IoT is common in various industries, and in the pharmaceutical sector, several standard applications are well-suited, such as connected equipment, materials, workforce, smart packaging, cold chain monitoring, and sample lifecycle management. In pharmaceutical manufacturing, where operations are typically batch-based and equipment is self-contained, executives often lack sufficient information to make informed decisions regarding overall equipment effectiveness (OEE), scheduling, and maintenance. Despite established industrial automation and control technologies, IoT solutions enable companies to connect and gain visibility into shop floor activities, significantly improving production efficiency and complying with Good Manufacturing Practice (GMP) guidelines (20)

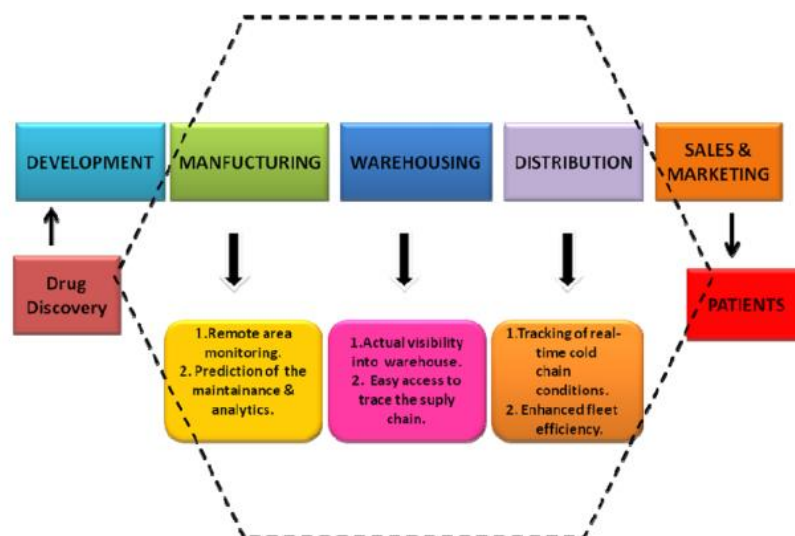


Fig.2 Application of IoT in pharma sector (20)

1) Drug discovery and development :

The drug discovery process typically takes 12-14 years and involves significant investments. However, automation through artificial intelligence (AI) has reduced costs by up to 70%. London-based company Benevolent utilized AI to identify potential drug targets for Alzheimer's disease, attracting pharmaceutical companies' interest in these methods. Another firm, Exscientia, employs AI for drug design and screening, speeding up the discovery process.

The rapid growth of data processing has facilitated drug discovery through machine learning, IoT, cloud computing, and other technologies. Large datasets are collected from equipment, clinical trials, and patients, processed through AI algorithms, and stored in the cloud. This approach has revolutionized drug discovery by moving from traditional trial and error to patient-driven biology and predictive hypotheses.

IoT-based data analysis in drug discovery enhances repeatability, reduces human involvement and errors, and improves product quality. It allows researchers to identify potential issues early in the development process, saving time and costs. While IoT has immense potential in life sciences, some scientists are yet to fully embrace its benefits in their research work. Nonetheless, the convergence of IoT and other technologies holds promise for the future of drug discovery (17)

2) Supply Chain Visibility and Control :

Internet of Things (IoT) devices play a crucial role in revolutionizing inventory management for businesses. By leveraging interconnected sensors and seamless communication, these devices offer real-time tracking of material availability, leading to significant cost reductions and operational efficiency improvements. A paramount aspect of utilizing IoT in inventory management is the ability to trace the source of supplies. This feature becomes indispensable in ensuring the quality of products, maintaining the speed of production, and mitigating potential risks like ingredient substitution. In industries such as pharmaceuticals, where counterfeit medicines or drug theft pose severe threats, IoT-enabled solutions can provide a robust security framework to safeguard the company's interests and protect public health. Overall, the integration of IoT devices in inventory management empowers businesses with enhanced visibility, agility, and security, leading to streamlined operations, cost savings, and a competitive edge in the market (21)

3) IoT in manufacturing in pharma sector :

The pharmaceutical industry has been implementing batch production for several years, but the integration of automated processing systems goes beyond just regulating equipment and materials. It also brings about significant improvements in drug production efficiency and related activities. IoT-enabled devices facilitate seamless communication of operational data to other devices or manufacturing engineers, thereby enhancing productivity rates and streamlining the industry. The pharmaceutical manufacturing

process comprises various stages, including processing, manufacturing, extraction, purification, and packaging of drug products. These operations are divided into two main stages: the production of the active drug ingredient and the transformation of the active pharmaceutical ingredient into the final pharmaceutical drug product. Throughout the process, from granulation and milling to coating and packaging, IoT-based applications play a critical role in ensuring efficient and quality-conscious manufacturing. By utilizing IoT control systems, the entire production chain, from assembly lines to finished goods packaging, is closely monitored. This continuous surveillance allows the system to adapt, eliminate inefficiencies, and optimize workflows. Sensors are vital components of these devices, providing real-time process information and enabling intelligent decision-making to maintain product quality. Environmental conditions significantly impact pharmaceutical drug production. Hence, IoT implementation is employed to monitor and regulate parameters such as humidity, light, temperature, and radiation exposure. Real-time sensors detect these environmental factors, and intelligent devices can respond by issuing alerts to prevent any loss in product quality. Throughout the product development cycle, IoT sensors gather crucial information, including raw material usage, temperature variations, disposals, and transportation details. This real-time monitoring is essential in confirming the quality of the product and maintaining high standards of pharmaceutical manufacturing. By employing IoT-based pharmaceutical applications, the industry ensures transparent drug processing, seamless quality control, and adherence to regulatory standards. Overall, IoT plays a pivotal role in revolutionizing the pharmaceutical industry by optimizing processes, reducing risks, and enhancing product quality (22).

In the realm of pharmaceutical manufacturing, IoT plays two crucial roles. Firstly, it facilitates seamless connections among various components, such as machines and equipment, optimizing the efficiency of manufacturing processes. Sensors and analog-to-digital converters (ADCs) are often utilized to achieve this objective, albeit with some limitations. Secondly, IoT enables the collection and utilization of data generated or induced by the products themselves, transforming them into intelligent entities. This smart functionality empowers businesses to leverage the gathered data to benefit customers and enhance overall operations. By implementing IoT-based technologies, pharmaceutical companies can effectively connect and control their equipment, networks, and systems, leading to improved supervision, data acquisition, and process standardization (23)

4) IoT in Warehousing :

Pharmaceutical industries rely on in-house warehousing facilities to ensure a constant and timely flow of their products. Warehousing constitutes a significant portion of logistics costs for pharmaceutical companies, making it an expensive aspect of their operations. Implementing Internet of Things (IoT) technology in warehouses can enhance effectiveness and accuracy in various processes such as stock-taking, product sorting, inbound, and outbound activities. Several IoT technologies like RFID (Radio Frequency Identification), WSN (Wireless sensor network), and wireless video monitoring systems are used to optimize warehouse operations. RFID technology, when used in inbound and outbound activities, increases product identification rates and automates monitoring and control. AGV positioning with RFID technology minimizes errors during product handling. Combining RFID with automotive vision systems improves the productivity of inbound and outbound activities. IoT provides several benefits for warehouse operations, including real-time inventory tracking, vision picking with smart glasses, data analytics for improved decision-making, and automated tasking using drones and robotics. Smart warehouses with IoT technology offer increased efficiency and visibility by providing real-time information to warehouse technicians and managers. Sensors installed in storage areas and stock items help interpret vital information, allowing for better management of pharmaceutical products, including sensitive medicines, and resource allocation for problem areas (13).

5) IoT in Packaging :

Packaging performance and cost effectiveness can be improved by integrating IoT devices into both packaging materials and specific products. Through efficient tracking systems, IoT integration enables the handling of several clients at once. This technology enables early detection of any quality decline and provides insightful information about how environmental conditions and transportation networks affect product quality. IoT consequently makes a big contribution to several elements of packaging. The packaging of pharmaceutical products is the final stage of the production process and is crucial to the pharmaceutical industry's marketing strategy. The packing option used depends on the particular product type, which affects how the market perceives the product's quality in the long run (24)

6) IoT in Monitoring of production flow :

In the realm of product manufacturing, an IoT-based monitoring system plays a pivotal role in scrutinizing the entire production process, from the assembly lines to the final product packaging. This system meticulously observes the operations being executed and compiles a real-time database that offers opportunities for enhancement. This vigilant monitoring empowers the system to make improvements, eliminate bottlenecks, and streamline unnecessary tasks. Monitoring the manufacturing process is of paramount importance when it comes to ensuring product quality and maintaining the integrity of the pharmaceutical system. At the heart of monitoring any system are sensors, which serve as the foundation for acquiring genuine insights into the ongoing processes. These sensors transmit real-time data to a central system, enabling informed decision-making and facilitating the seamless maintenance of product quality. Every phase of the manufacturing process, including milling, coating, granulation, and packaging, undergoes continuous scrutiny during the monitoring process. Additionally, stringent control over environmental conditions throughout the pharmaceutical manufacturing process is imperative to uphold product quality. Achieving this level of control is made possible through diligent monitoring. IoT technology assumes a critical role in remotely monitoring the production system using smart devices and sensors, ensuring the real-time assessment of production quality from a distance. To assess the quality of production and the overall system performance, the monitoring phase is indispensable (18)

7) IoT in Preventing Theft Of Drugs During Transportation :

During the transportation process, the pharmaceutical industry faces significant losses due to drug theft. This illicit activity not only impacts the industry's revenue but also disrupts the timely supply of drugs to stakeholders. Leveraging IoT technology, specifically GPS for vehicle tracking and RFID tags for monitoring product status, can enhance the security of the entire shipment. This technology enables the logistics team to access real-time shipment information from anywhere, thus reducing the risk of drug

theft. The process begins with a customer requesting a quotation from the company. Subsequently, the company utilizes RFID tags when delivering the package to the customer, effectively safeguarding it against theft. Drug theft during transportation poses a substantial financial setback for pharmaceutical companies, but this issue can be mitigated by integrating shipment packages into an IoT-based network. Through this network, vehicle locations during transportation can be tracked, and the current status of the consignment can be monitored using IoT-enabled smart devices (18)

C) Cloud Computing:

NIST (2014) provides a definition for cloud computing, describing it as a framework that allows widespread and easy network access to a shared collection of adaptable computing resources (such as networks, servers, storage, applications, and services). These resources can be swiftly allocated and de-allocated with little need for extensive management or direct involvement with service providers.

The cloud computing paradigm encompasses five fundamental attributes: extensive network reach, swift scalability, resource consolidation, self-initiated provisioning, and usage-based measurement. It comprises three service configurations: software as a service (SaaS), platform as a service (PaaS), and infrastructure as a service (IaaS). Additionally, it involves four deployment options: public cloud, private cloud, hybrid cloud, and community cloud. Cloud computing offers numerous benefits, including simplified administration, cost efficiency, uninterrupted service delivery, disaster recovery capabilities, and environmentally conscious computing (NIST, 2014) (25).

Cloud computing in pharma:

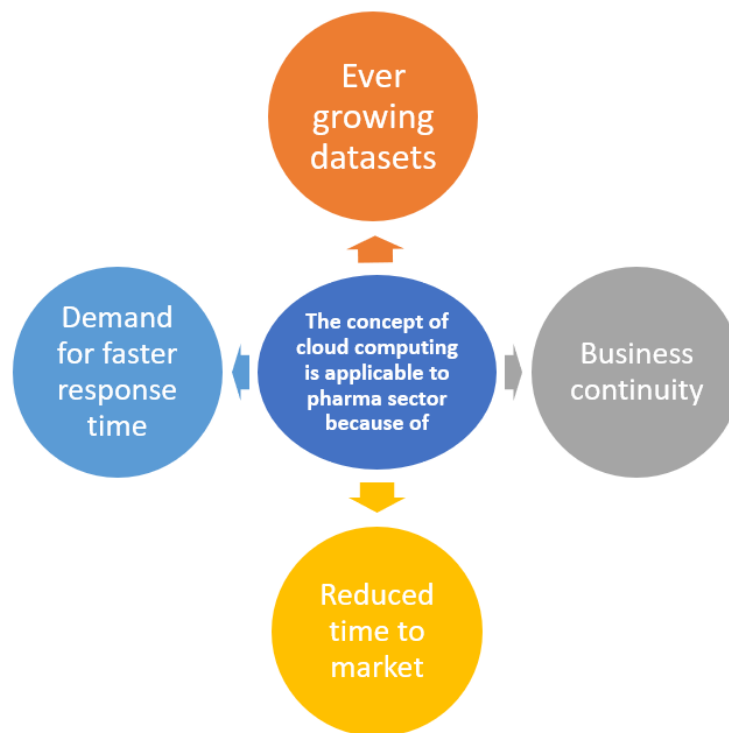


Fig.3 The concepts of Cloud Computing are applicable to pharma industry.

Table.2 Advantages of utilizing cloud computing in the pharmaceutical industry (27)

Advantages of Cloud Computing in Pharma industry	Description
1. Cost Savings	Lower upfront investment compared to traditional IT models. Immediate savings by using cloud service provider resources.
2. Data Protection	Securely store and access complex sales process data from anywhere in the world.
3. On-Demand Access	Continuous and responsive access to data from any device with a web browser.
4. Scalability	Easily adjust data storage needs based on pharma operations' scaling requirements.
5. Enhanced Collaboration	Facilitates real-time data sharing and communication among various teams and reps.
6. Automatic Updates	Cloud system updates automatically, keeping the technology up-to-date.

Cloud computing in clinical trials and design (27)

Cloud computing offers valuable advantages in the design and management of clinical trials, particularly in the efficient recruitment of patients for various trial sites. Instead of storing data across multiple organizations, the cloud provides a centralized hosting solution. Here are some additional user-friendly ways in which cloud computing aids clinical trials:

- 1) Easy Control: Clinical trial managers can independently control site enrollment and manage access permissions, granting flexibility and control over the process.
- 2) Real-Time Data: With data available in real-time, there's no need to wait for delayed transfers or rely on supplementary reports, ensuring up-to-date information at all times.
- 3) Anytime, Anywhere Access: As long as there's reliable internet access, all trial data can be accessed from any device, wherever and whenever it's needed.
- 4) Cost Savings: Cloud technology eliminates the need to invest in physical storage space for data, resulting in reduced IT expenses.
- 5) Hassle-Free Setup: The cloud eliminates the requirement to install licensed software, simplifying the process with a straightforward login, allowing you to start the trial smoothly.

Table 3: Top 5 cloud computing startup impacting pharma companies (28)

Startup	POC Pharma	Curavit	Empiric Logic	ClinicaRx	Thrivor
Founding Year	2019	2019	2018	2016	2016
Services	Pharma Customer Engagement	Decentralized Clinical Trials	Cloud-based Phenotypic Analysis	Digital Health Services	Clinical Trial Management
Platform	SaaS Customer Engagement	DCT (Decentralized Clinical Trials)	AI-enabled Cloud-based Bioinformatics	AI-enabled Cloud-based Bioinformatics	Cloud-based Platform and Mobile Application
Industry	Pharmaceutical Sales Channel Management	Virtual Clinical Trials	Partner for Genomic Data Interpretation	Personalized Pharmaceutical Services	Participant Management
Advantages	Improved customer engagement	Access clinical trial data remotely	Centralized healthcare data platform	Access to primary medical services	Better clinical trial management, recruitment

D) Big Data analytics:

cutting-edge analytical methods to extract knowledge from enormous and varied datasets. These datasets range in size from terabytes to zettabytes and frequently include organized, semi-structured, and unstructured data from multiple sources. The core of big data is found in data sets that are larger than what can be stored in traditional relational databases, necessitating the use of novel techniques for quickly Big data analytics: Big data analytics is at the forefront of contemporary data processing, using collecting, organizing, and analysing data. Big data's origins are becoming more complex as a result of the effect of artificial intelligence (AI), mobile devices, social media, and the Internet of Things (IoT), which are characterized by their great volume, quick velocity, and wide variety. This complex data environment is influenced by a variety of sources, including sensors, devices, video/audio sources, networks, log files, transactional applications, and web and social media platforms. Much of this data is generated in real time and on a massive scale. Adopting big data analytics provides the path for sophisticated predictive modelling, improved business intelligence, and informed decision-making. Using open-source programs like Apache Hadoop, Apache Spark, and the larger Hadoop ecosystem to build solid big data solution shows promise as a cost-effective and flexible method for handling and storing the massive amounts of data that the modern world creates (29)

Big Data analytics in Pharma industry:

The gathering of substantial data from various sources serves the primary objective of using this extensive information to improve patient care and advance treatment paradigms in the pharmaceutical and healthcare industries. The traditional manual data maintenance method, which involved physical records and reports, is no longer relevant. It is essential to embrace digitization in the form of big data in the current environment, which is characterized by a surge in daily data generation. This change enables the pharmaceutical and healthcare sectors to develop a thorough understanding of public health. Big data, according to a 2012 report given to the US Congress, is "expansive quantities of data characterized by rapid generation, intricacy, and variability, necessitating advanced techniques and technologies to facilitate the capture, storage, dissemination, management, and analysis of this information." (30)

1) Data analytics in Research & development:

Various aspects of the healthcare and pharmaceutical industries are being revolutionized using creative methods. Predictive modelling is one such strategy that is crucial in reducing attrition rates. Companies are able to streamline their research and development pipelines for drugs and medical devices by utilizing these models, resulting in a more effective and targeted procedure. Advanced algorithms and statistical tools are also being used to improve clinical trial design. As a result, there are fewer unsuccessful clinical trials because researchers are better able to precisely match treatments to specific patients. As a result of the process becoming more precise and agile, this approach hastens the release of new treatments onto the market. In order to gain

deeper insights, analysis of clinical trials and patient records is also being used. Researchers can locate potential follow-on indications for current products by carefully examining these records. Additionally, this analysis helps in the proactive detection of negative effects prior to product introduction. This proactive approach ensures the security and effectiveness of drugs and medical equipment, enhancing general public health (30)

2) Data analytics in drug discovery:

The crucial role of big data analytics is significantly influencing the field of medical advancements and vaccine advancement. In this environment, the combination of data analytics and predictive modelling represents a game-changing force in the development of new drugs. The traditional strategy, which required researchers to manually test a variety of compound samples in search of novel drugs, has been replaced by this dynamic shift. This old-fashioned approach required a lot of time and effort in addition to high costs. Predictive modeling's introduction has ushered in a new era in which drug discovery is accelerated through an informed and data-driven approach. Researchers can decipher complex drug-drug interactions and pinpoint potentially toxic effects by utilizing the power of predictive algorithms. This not only quickens the drug discovery process but also acts as a preventative measure to guarantee security and effectiveness. In essence, the marriage of predictive modelling and data analytics has revolutionized medicine discovery and vaccine development. It has democratized access to insights that hold the potential to reshape healthcare landscapes, yielding innovative solutions while optimizing the allocation of valuable resources. (31) Computers with specialised software prove very useful in data analysis. (32)

3) Big data analytics in sales and marketing:

Utilizing big data analytics to analyze information extracted from real-world sources like electronic health records, social media platforms, and medical records holds significant potential for pharmaceutical companies. This approach empowers these companies to delve into untapped markets and devise innovative strategies for enhancing their sales and marketing endeavours. By harnessing the power of big data analytics within the pharmaceutical sector, companies can revolutionize the way they provide treatments, leading to more targeted and efficacious therapeutic interventions (31)

Conclusion:

The digitalization of the pharmaceutical sector represents a transformative shift that holds immense promise for the industry's future. This review article has examined the integration of advanced technologies, including the Internet of Things (IoT), Artificial Intelligence (AI), Cloud Computing, and Big Data Analytics, and their profound impact on various facets of pharmaceutical operations. Through IoT, real-time monitoring and data collection are revolutionizing pharmaceutical manufacturing, leading to improved process control, reduced downtime, and proactive maintenance strategies. AI applications, such as machine learning and predictive analytics, are optimizing research and development, drug discovery, and clinical trials, ultimately delivering substantial time and cost savings. Cloud computing solutions are enhancing data storage and accessibility, further bolstering cost-efficiency across the pharmaceutical landscape. Big Data Analytics, by harnessing vast datasets, are enabling the discovery of valuable insights, thereby improving decision-making, resource allocation, and product quality. The heightened emphasis on quality and safety, reinforced by digitalization, is resulting in more precise quality control, enhanced traceability, and effective compliance management. In conclusion, the digital transformation of the pharmaceutical sector is not merely about saving time and money; it is about enhancing the quality and safety of pharmaceutical products. This comprehensive review underscores the pivotal role of these technological advancements in reshaping the pharmaceutical industry. As we move forward, embracing these digital tools and strategies will be essential for pharmaceutical companies to remain competitive and deliver safer, more efficient, and higher-quality products to meet the evolving needs of healthcare worldwide.

REFERENCES:

1. Crawley, M.J., 2007. *The R Book* John Wiley & Sons. Chichester, UK, 637.
2. Kumar L, Panigrahi C. Communication with doctors: Empowering Pharma field force with modern marketing techniques. *Asian J Manag Res.* 2014;5(2).
3. Reis J, Amorim M, Melão N, Cohen Y, Rodrigues M. Digitalization: A Literature Review and Research Agenda. In: *Lecture Notes on Multidisciplinary Industrial Engineering*. Springer Nature; 2020. pp. 443-456. DOI: 10.1007/978-3-030-43616-2_47.
4. Reinhardt I, Oliveira JC, Ring D. Industry 4.0 and the Future of the Pharmaceutical Industry. *Pharm Eng.* 2021;41:Online Exclusive
5. Hole G, Hole AS, McFalone-Shaw I. Digitalization in the pharmaceutical industry: Key focus areas in the digital implementation process. *International Journal of Pharmaceutics: X.* December 2021; Volume 3: 100095. doi:10.1016/j.ijpx.2021.100095.
6. Ehrhardt M, Behner P. Digitalization in pharma and gaining an edge in operations. *Strategy& (PwC)*; (cited 2016). Available from: <https://www.strategyand.pwc.com/gx/en/insights/2016/digitization-in-pharma.html>
7. Sverdlov O, van Dam J, Hannesdottir K, Thornton-Wells T. Digital therapeutics: An integral component of digital innovation in drug development. *Clin Pharmacol Ther.* 2018;104:72-80.
8. Jamróz, W., Szafraniec, J., Kurek, M., & Jachowicz, R. (2018). 3D Printing in Pharmaceutical and Medical Applications – Recent Achievements and Challenges. In *Pharmaceutical Research* (Vol. 35, Issue 9). Springer New York LLC. <https://doi.org/10.1007/s11095-018-2454-x>
9. Shah, N. . (2023). Artificial Intelligence in Pharma Industry - A Review. *Asian Journal of Pharmaceutics (AJP)*, 17(2). <https://doi.org/10.22377/ajp.v17i2.4840>
10. For drug discovery, biomarker development and advanced r&d landscape overview 2020 AI Startups-240 Corporations-90 R&D Centers-35 Investors-600 www.deep-pharma.tech. (n.d.). www.deep-pharma.tech

11. Thakur A, Mishra AP, Panda B, Rodríguez DCS, Gaurav I, Majhi B. Application of Artificial Intelligence in Pharmaceutical and Biomedical Studies. *Curr Pharm Des.* 2020;26(29):3569-3578. doi: 10.2174/1381612826666200515131245. PMID: 32410553
12. <https://www.starmind.ai/resources/how-using-ai-in-clinical-trials-accelerates-drug-development#:~:text=By%20finding%20patterns%20in%20data,populations%2C%20treatment%20regimens%20and%20dosages.>
13. Prashant, & Vipula, N. (2020). Artificial Intelligence (AI), Internet of Things (IoT) and Machine Learning (ML) in Healthcare-A Way Forward. In *International Journal of Creative Research Thoughts* (Vol. 8, Issue 7). www.ijcrt.org
14. <https://www.fda.gov/media/165743/download#:~:text=AI%20methods%20can%20also%20be%20used%20to%20monitor%20product%20quality,a%20product's%20given%20quality%20attribute.>
15. Thakur A, Mishra AP, Panda B, Rodríguez DCS, Gaurav I, Majhi B. Application of Artificial Intelligence in Pharmaceutical and Biomedical Studies. *Curr Pharm Des.* 2020;26(29):3569-3578. doi: 10.2174/1381612826666200515131245. PMID: 32410553.
16. <https://thesneffels.com/application-of-internet-of-things-iot-in-pharma-industry/>
17. Miraz MH, Ali M, Excell PS, Picking R. A Review on Internet of Things (IoT), Internet of Everything (IoE) and Internet of Nano Things (IoNT). <https://ieeexplore.ieee.org/document/7317398>
18. Singh M, Sachan S, Singh A, Singh KK. Internet of Things in pharma industry: Possibilities and challenges. In: *Emergence of Pharmaceutical Industry Growth with Industrial IoT Approach.* Elsevier; 2019. p. 195-216. Available from: <https://doi.org/10.1016/B978-0-12-819593-2.00007-8>
19. Sharma A, Kaur J, Singh I. Internet of Things (IoT) in Pharmaceutical Manufacturing, Warehousing, and Supply Chain Management. *SN Computer Science.* 2020;1. DOI: 10.1007/s42979-020-00248-2.
20. Prashant, Vipula N. Artificial Intelligence (AI), Internet of Things (IoT), and Machine Learning (ML) in Healthcare - A Way Forward. *International Journal of Creative Research Thoughts.* 2020;8(7). Available at: www.ijcrt.org
21. Thoben K-D, Wiesner S, Wuest T. "Industrie 4.0" and Smart Manufacturing-A Review of Research Issues and Application Examples.
22. Li W, Kara S. Methodology for monitoring manufacturing environment by using wireless sensor network (WSN) and the internet of things (IoT). *Proced CIRP.* 2017;61:323-8. <https://doi.org/10.1016/j.procir.2016.11.182>
23. R. Beica, Enabling information age through advanced packaging technologies and electronic materials, in: 2018 Pan Pacific Microelectronics Symposium (Pan Pacific), IEEE, 2018, pp. 1-5.
24. <https://www.ibm.com/analytics/big-dataanalytics#:~:text=Big%20data%20analytics%20is%20the,sizes%20from%20terabytes%20to%20zettabytes>
25. Birje, M. N., Challagidad, P. S., Goudar, R. H., & Tapale, M. T. (2017). Cloud computing review: concepts, technology, challenges and security. In *Int. J. Cloud Computing* (Vol. 6, Issue 1).
26. 5 Top Cloud Computing Startups impacting Pharma | StartUs Insights (startus-insights.com)
27. *Staedter, T. (n.d.). Cloud Computing in a Regulated Pharma Environment Issues and Concerns about Data Security and Safety. Page no 2*
28. Bhattamisra SK, Banerjee P, Gupta P, Mayuren J, Patra S, Candasamy M. Artificial Intelligence in Pharmaceutical and Healthcare Research. *Big Data Cogn Comput.* 2023;7:10. doi:10.3390/bdcc7010010.
29. Raghupathi W, Raghupathi V. Big Data Analytics in Healthcare: Promise and Potential. *Health Inf Sci Syst.* 2014;2(1):3. doi:10.1186/2047-2501-2-3.
30. Shailaja, P., & Nikhila Pallavi, D. (2022). A Review on "Role of Big Data Analytics in Health Care Sector and Pharmaceutical Industry." In *International Journal for Research Trends and Innovation (www.ijrti.org)* (Vol. 7). www.ijrti.org
31. Lamberti, M. J., Wilkinson, M., Donzanti, B. A., Wohlhieter, G. E., Parikh, S., Wilkins, R. G., & Getz, K. (2019). *A Study on the Application and Use of Artificial Intelligence to Support Drug Development. Clinical Therapeutics.* doi:10.1016/j.clinthera.2019.05.0
32. Shivraj Popat Jadhav, Komal Nikam, Anand Gandhi, Kishor Salunkhe, Narendra Shinde.. Applications of computer science in Pharmacy: An overview. *Natl J Physiol Pharm Pharmacol.* (2012), (cited September 03, 2023); 2(1): 1-9.