

# The role of the industrial Internet of Things (IoT) in modernizing pharmaceutical operations: A review of current trends

## Abstract

This review critically examines the transformative role of the Internet of Things (IoT) in revolutionizing pharmaceutical operations. This article explores how IoT technologies, through real-time monitoring, predictive maintenance, and automated process controls, enhance manufacturing, quality assurance, and supply chain management in an industry characterized by stringent regulatory requirements and complex production processes. This review systematically gathered contemporary literature from reputable databases, such as Google Scholar, IEEE Xplore, and Scopus, employing a rigorous set of inclusion criteria that focused on relevance, publication quality, technological integration, and operational insights. The findings reveal that IoT not only improves operational efficiency and regulatory compliance but also facilitates the adoption of innovations in Industry 4.0, including digital twins, artificial intelligence, and machine learning. Despite these benefits, significant challenges, such as technical integration, cybersecurity risks, and organizational barriers, persist, particularly in developing regions. The review concludes by emphasizing the promising future of IoT in the pharmaceutical sector and highlights the need for targeted investments, workforce development, and supportive regulatory frameworks to fully harness its potential.

## Introduction

### Background

The pharmaceutical industry has long been characterized by stringent regulatory requirements, complex manufacturing processes, and a high need for precision and quality control. In recent years, the Internet Of Things (IoT) has emerged as a transformative technology in this sector, offering opportunities for real-time monitoring, predictive maintenance, and data-driven decision making [1]. These capabilities are paving the way for increased productivity, improved quality, and enhanced regulatory compliance, while simultaneously facilitating the broader adoption of Industry 4.0 principles such as digital twins, Artificial Intelligence (AI), and Machine Learning (ML). The Internet Of Things (IoT) is revolutionizing pharmaceutical operations by integrating smart technologies, real-time monitoring, and data-driven decision-making [2]. The adoption of Industrial Internet

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of Things (IIoT) technologies is significantly reshaping pharmaceutical manufacturing, supply chain management, and quality control by enabling greater efficiency, transparency, and responsiveness [3]. IIoT leverages interconnected industrial devices, machine-to-machine communication, big data, and machine learning to improve various aspects of pharmaceutical operations [3]. This literature review examines the applications, benefits, challenges, and future potential of the IoT in the pharmaceutical industry.

### Objective and aims of the review

The primary objective of this review is to critically examine the transformative role of the Internet Of Things (IoT) in the pharmaceutical industry. Specifically, the review aims to:

**Assess current applications:** Investigate how IoT technologies are integrated into pharmaceutical manufacturing, qual-

ity control, and supply chain management, including real-time monitoring, predictive maintenance, and automated process controls.

**Evaluate benefits:** Highlight the tangible advantages of IoT adoption such as enhanced productivity, improved regulatory compliance, and the generation of actionable data that supports decision-making.

**Identify challenges and limitations:** Analyse the technical, cybersecurity, organizational, and infrastructural barriers that impede the seamless integration of IoT systems, with a particular focus on issues faced by companies in both developed and developing regions.

**Explore future potential:** Discuss how IoT is paving the way for the broader adoption of Industry 4.0 technologies these including digital twins, Artificial Intelligence (AI), and Machine Learning (ML), to further revolutionize pharmaceutical operations.

Ultimately, this review seeks to provide a comprehensive understanding of how IoT is reshaping pharmaceutical processes and to offer insights that can inform future research, strategic planning, and technological innovation within the industry.

## Methodology

### Literature search

The research question was first designed as “How does the adoption of IIoT technology influence the modernization of pharmaceutical manufacturing, supply chain management and quality control.” This was followed by identifying some keywords and their synonyms such as “Industrial Internet of things” (industrial internet, internet of things, industrial automation). “Pharmaceutical manufacturing” (Drug production, medicinal product manufacturing). “Modernization” (Innovation, digital transformation), “Supply chain” (Logistics, Procurement). Other keywords used include “Industry 4.0,” “digital twins,” “predictive maintenance,” “quality control.”

A range of reputable databases and digital libraries (such as Google Scholar, IEEE Xplore and Scopus) were then used to access peer-reviewed articles, conference papers, and authoritative reports. Since the review was on contemporary developments, the literature search targeted recent studies that capture current trends in IoT applications and technological integration.

The Initial screening was based on titles and abstracts and followed by full-text evaluations to ensure that selected studies directly addressed the intersection of IoT and pharmaceutical operations.

### Inclusion criteria

The inclusion criteria were designed to ensure that only the most relevant and high-quality literatures were used in the review. These criteria involved:

**Relevance to pharmaceutical IoT applications:** Only studies directly addressing the application of IoT technologies in pharmaceutical manufacturing, quality control, and supply chain management were considered.

**Publication quality:** The review prioritized peer-reviewed journal articles, conference proceedings, and authoritative industry reports to maintain rigorous scholarly standards.

**Technological focus:** Studies that discussed the integration of advanced technologies; such as digital twins, Artificial Intelligence (AI), and Machine Learning (ML), in conjunction with IoT were given particular attention.

**Operational and regulatory insights:** Research that addressed the impact of IoT on operational efficiency, quality assurance, and regulatory compliance within pharmaceutical processes was deemed highly relevant.

**Recent publications:** Recent papers with up-to-date information were given priority.

### Current applications and benefits of IoT in pharmaceutical operations

Pharmaceutical operations are increasingly integrating IoT solutions across various aspects of manufacturing and quality assurance. IoT devices continuously capture critical parameters (temperature, humidity, and pressure) in manufacturing environments, ensuring that production remains within validated ranges [2]. The deployment of smart sensors enables the real-time tracking of raw materials, in-process products, and finished goods, thereby enhancing inventory management and regulatory compliance [2]. In facilities where controlled conditions are critical, IIoT systems monitor cleanrooms and storage areas, thereby reducing the risk of contamination and ensuring adherence to Good Manufacturing Practices (GMP) [4].

The IoT is extensively applied in pharmaceutical manufacturing, quality control, and regulatory compliance. Smart sensors, automated process controls, and cloud-based analytics can improve productivity and efficiency [5]. Furthermore, IIoT enhances traceability and data integrity, facilitating compliance with stringent regulatory standards such as the FDA’s 21 CFR Part 11. These advancements have led to a higher product quality, reduced waste, and cost savings.

The integration of IIoT offers several tangible benefits: automation and real-time data acquisition streamline operations, reducing downtime, and increasing throughput. Continuous monitoring and rapid detection of deviations help to maintain high-quality standards, which are critical for pharmaceutical production. The detailed audit trails generated by IIoT systems support compliance with strict regulatory guidelines and ease the burden of inspections [5]. IIoT systems provide continuous data streams that offer insights into operational performance. This constant feedback loop allows immediate corrective actions when the parameters deviate from the expected norms. For example, sensor data can trigger alarms that prompt operators to check critical equipment before a failure occurs [2].

Using historical data and machine-learning algorithms, IIoT platforms enable predictive maintenance strategies. Rather than relying on scheduled maintenance, manufacturers can anticipate equipment failure and perform maintenance only when necessary. This approach minimizes unexpected downtime and extends the lifespan of high-value assets [6]. With the application of IoT there will be new opportunities for product development and market expansion, contributing to economic progress on a broader scale (Rakholia et al., 2024). The aggregation and analysis of real-time and historical data empowers decision makers to optimize processes and adjust operations dynamically. By leveraging data analytics, companies can identify trends, forecast demand, and improve their overall operational efficiency, leading to better product quality and reduced waste [5].

## Facilitating industry 4.0 adoption: Digital twins, AI, and ML

IIoT is a cornerstone technology for the adoption of Industry 4.0 principles in the pharmaceutical industry. By creating virtual replicas of physical assets and processes, digital twins allow manufacturers to simulate and optimize production lines in a risk-free environment. Digital mirroring can predict system behaviors under various scenarios, leading to smarter and more resilient production strategies [6]. The data generated by IIoT devices provides a rich source for AI and ML applications. These technologies can be used to analyze complex datasets, identify inefficiencies, and optimize the process parameters. The integration of AI-driven insights facilitates continuous improvement and accelerates innovation in pharmaceutical operations [2]. The confluence of these advanced technologies leads to significant improvements in operational agility, enhanced quality control, and a more responsive production environment [1].

### Implications for pharmaceutical supply chain management

The IIoT is transforming supply chain management in the pharmaceutical sector by making it more agile and responsive. Blockchain technology, integrated with IIoT, can ensure the authenticity and accessibility of data across the supply chain, addressing the common issues of inaccurate, incomplete, and inaccessible data [7]. Real-time monitoring of inventory levels allows companies to manage stocks better and reduce the risk of shortages or overproduction. IIoT-enabled tracking ensures that products are stored under optimal conditions, reducing waste and improving shelf-life management [8]. With real-time data on shipment conditions and locations, the IIoT enhances the transparency and efficiency of logistics operations. This leads to more reliable distribution networks that can swiftly adapt to changing market demands and ensure timely delivery to end-users [9,10]. By integrating IIoT into the supply chain, pharmaceutical companies can achieve a patient-centric approach. Enhanced tracking and traceability not only improve product quality but also ensure that patients receive safe and effective medications in a timely manner [10]. The resulting agile and responsive supply chains significantly improve the overall performance of the pharmaceutical value chain, ensuring better patient outcomes and higher satisfaction levels [10].

### Challenges of implementing IIoT in the pharmaceutical industry

The implementation of the Industrial Internet of Things (IIoT) in the pharmaceutical industry, while promising significant operational and regulatory benefits, is fraught with a range of challenges. These obstacles can be broadly categorized into technical, cybersecurity, organizational, financial, and regulatory domains. Addressing these challenges is essential for the successful digital transformation of pharmaceutical operations.

#### Technical and integration barriers

A major hurdle is the integration of IIoT solutions with existing legacy systems. Many pharmaceutical facilities rely on outdated equipment and software that are not readily compatible with modern IIoT platforms. This incompatibility complicates data exchange, process automation, and real-time monitoring [11]. Furthermore, the lack of standardized protocols across devices and systems can lead to interoperability issues, making seamless integration difficult and costly [9].

#### Cybersecurity and data integrity risks

The increased connectivity inherent in IIoT systems ex-

poses pharmaceutical operations to heightened cybersecurity threats. Sensitive data, including proprietary formulations, patient information, and regulatory records, becomes vulnerable to cyberattacks, data breaches, and unauthorized access [12]. Ensuring robust cybersecurity measures, such as encryption, secure authentication, and continuous monitoring, is both technically demanding and resource-intensive. Despite the numerous benefits, the adoption of IIoT in pharmaceutical manufacturing faces several challenges. These include the need for robust cybersecurity measures to protect sensitive data [2,13], the integration of legacy systems with new IIoT technologies, and the lack of skilled personnel to manage and analyse the vast amounts of data generated [9].

#### Organizational and workforce challenges

Successful IIoT adoption requires significant organizational change. Employees must be trained to operate, interpret, and maintain new digital systems. Resistance to change, lack of digital literacy, and insufficient technical expertise can impede implementation [9]. Change management strategies and ongoing workforce development are necessary to foster a culture that embraces digital innovation. For example, studies highlight that workforce upskilling is critical to overcoming resistance in technology adoption [2].

#### Financial and strategic constraints

The initial investment required for IIoT infrastructure including: sensors, connectivity, software, and cybersecurity can be substantial. For many pharmaceutical companies, especially small and medium-sized enterprises, justifying these upfront costs against long-term benefits is challenging [14]. Strategic planning is needed to ensure a clear return on investment and to align IIoT initiatives with broader business objectives.

#### Regulatory and compliance complexities

The pharmaceutical industry is highly regulated, and IIoT implementation must comply with stringent standards for data security, traceability, and quality assurance. Navigating diverse and evolving regulatory requirements across different regions adds complexity, particularly for multinational companies [12]. Inconsistent regulatory frameworks, especially in developing countries, further complicate IIoT adoption [15].

#### Infrastructure and regional disparities

In developing regions, additional barriers include inadequate digital infrastructure, unreliable power supply, and limited internet connectivity. Budgetary constraints and a shortage of skilled professionals further hinder the deployment and maintenance of IIoT systems [15]. These factors contribute to a slower pace of digital transformation compared to developed markets [6].

#### Conclusion

The adoption of the Industrial Internet of Things (IIoT) has revolutionized pharmaceutical operations by enhancing efficiency, improving quality control, and ensuring regulatory compliance. Through real-time monitoring, predictive maintenance, and automated process controls, IIoT technologies are transforming pharmaceutical manufacturing, quality assurance, and supply chain management significantly. Furthermore, the integration of Industry 4.0 principles, including digital twins, Artificial Intelligence (AI), and Machine Learning (ML), is driving the pharmaceutical industry toward smarter, data-driven, and highly automated systems.

Despite its numerous benefits, implementation of IIoT in pharmaceutical operations is challenging. Technical barriers, such as legacy system integration, cybersecurity risks, and infrastructural limitations, pose significant hurdles. Organizational and strategic challenges, including high initial investment costs and the need for workforce upskilling further complicate widespread adoption. In developing nations, financial constraints, skill shortages, and inconsistent regulatory frameworks exacerbate the slow pace of digital transformation. Addressing these challenges requires targeted investments in technology, workforce development, and regulatory harmonization to ensure a seamless transition to IIoT-driven pharmaceutical operations.

The future of IIoT in the pharmaceutical industry is promising. As companies continue to refine their digital strategies, the adoption of smart technologies further enhances productivity, regulatory adherence, and market competitiveness. Governments, industry stakeholders, and regulatory bodies must collaborate to create supportive policies and infrastructure to facilitate the integration of IIoT across different regions. With sustained innovation and strategic implementation, IIoT has the potential to shape a more efficient, transparent, and resilient pharmaceutical ecosystem, ultimately benefiting both industry stakeholders and patients worldwide.

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